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Impact of the Nutri-Score front-of-pack nutrition label on purchasing intentions of individuals with chronic diseases: results of a randomized trial

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3 **Impact of the Nutri-Score front-of-pack nutrition label on purchasing intentions of**
4 **individuals with chronic diseases: results of a randomized trial**
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3 22 **ABSTRACT**
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5 23 **Objective** : The effect of front-of-pack nutrition labels such as the Nutri-Score on food
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7 24 purchases has never been assessed among individuals suffering from nutrition-related chronic
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9 25 diseases specifically, while dietary modifications are generally part of their care. This study
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11 26 aimed to investigate the effect of the Nutri-Score on the nutritional quality of purchasing
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13 27 intentions among adults suffering from a cardiometabolic disease, compared to no label and the
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15 28 Reference Intakes (RIs), a label already implemented by some food manufacturers in France.
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19 29 **Setting**: Secondary prevention – mainland France
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21 30 **Participants** : 2,431 eligible participants were randomly assigned and 1,180 participants
22
23 31 (65.5% women, mean age 65.0±7.1 years) completed the shopping task and were included in
24
25 32 the analyses.
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28 33 **Intervention**: A three-arm randomized controlled trial using an experimental online
29
30 34 supermarket was conducted in 2017. Participants with cardiometabolic diseases were invited to
31
32 35 simulate food purchases with the Nutri-Score, or with the RIs or no label.
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35 36 **Primary and secondary outcome measures** : The primary outcome was the nutritional quality
36
37 37 of the shopping cart, estimated using the French-modified Food Standard Agency Nutrient
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39 38 Profiling System (FSAm-NPS), and secondary outcomes included the nutrient content of
40
41 39 purchases.
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44 40 **Results**: The mean (SD) FSAm-NPS score was significantly lower in the Nutri-Score arm
45
46 41 (1.29(3.61) points), reflecting a higher overall nutritional quality of purchases, compared to the
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48 42 RIs (1.86(3.23) points) and no label (1.92(2.90) points) arms (p-value=0.01). Moreover, the
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50 43 Nutri-Score led to significantly lower content in calories and saturated fatty acids compared to
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52 44 the two other arms.
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3 45 **Conclusions:** The Nutri-Score appears to encourage healthier food choices among individuals
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5 46 suffering from cardiometabolic chronic diseases, for which an improvement of the dietary
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7 47 quality is often part of the treatment.
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10 48 **Trial registration :** NCT02769455
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15 50 **Article summary**

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17 51 Strengths and limitations of this study

- 18
19 52 • Inclusion of a rarely explored population in a randomized controlled trial pertaining to
20
21 53 the effectiveness of front-of-package labelling on food choices
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24 54 • This controlled experimental environment allowed assessing the effect of the Nutri-
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26 55 Score in standardized conditions and optimizing internal validity of the study.
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29 56 • Limitation pertaining to a high rate of participants who did not complete the shopping
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31 57 task.
32
33 58 • The trial investigated purchasing intentions rather than actual food purchases.
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37
38 60 **Keywords:** Front-of-pack nutrition label; cardiometabolic diseases; Food purchases;
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40 61 Nutritional quality; Experimental online supermarket
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62 INTRODUCTION

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64 Non-Communicable Diseases (NCDs), such as obesity, type 2 diabetes, cardiovascular diseases
65 and cancer have become a major burden for the current health systems.[1] For these diseases,
66 dietary factors have been recognized to be one of the major leading risk factors in developed
67 countries, resulting in 11 million deaths worldwide in 2017, and represent modifiable
68 determinants through primary prevention.[2] In France, cardiovascular diseases remain the
69 second leading cause of deaths by NCDs, accounting for 30% approximately of mortality.[3]
70 Regarding obesity, the prevalence was estimated at 17% within the French adult population in
71 2015,[4] and the prevalence of type 2 diabetes was around 5% in 2016.[5]

72
73 Hence, in the context of secondary or tertiary prevention, many treatment guidelines highlight
74 the importance to modify dietary habits to improve the nutritional status of individuals and thus
75 control these nutrition-related NCDs.[1] For example, controlling for Saturated Fatty Acids
76 (SFA), sugars and salt intakes and increasing fruits and vegetables, pulses, and fibres
77 consumption are encouraged in the management of several NCDs or risk factors such as obesity,
78 arterial hypertension and diabetes.[1] Nutritional labelling has been suggested to be an
79 interesting tool in helping individuals suffering from NCDs achieve balanced nutritional
80 intakes.[6] However, it has been shown that nutritional information on the back of packages
81 were poorly understood and used during food choices.[7] While few studies have suggested
82 that individuals suffering from nutrition-related NCDs would pay more attention to nutritional
83 information and check for specific nutrients,[8,9] another study has observed no difference of
84 nutritional information use between patients and individuals with no chronic condition.[6]

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3 86 In the last decade, Front-of-Pack nutrition Labels (FoPLs) have been identified to improve the
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5 87 nutritional quality of food choices at the point-of-purchase in the general population,[10–19]
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8 88 and to encourage reformulation and innovation of food products.[20,21] In France, the
9
10 89 summary FoPL Nutri-Score has been adopted in October 2017 (and then in several European
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12 90 countries) to indicate the nutritional quality of products in supermarkets.[22] By the end of
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14 91 2019, the brands which adopted the Nutri-Score represented approximately 25% of the volume
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16 92 of pre-packed foods sales with more than 300 manufacturers engaged.[23] The Nutri-Score has
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18 93 been demonstrated to be well perceived, understood and to have a positive effect on food
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20 94 purchases in the general French population[14,18,24–27] and students.[28] However, as the
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22 95 measure is implemented on a voluntary basis, it coexists on the French market with the
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24 96 Reference Intakes label (RIs),[29] used by multiple food manufacturers since 2006 in Europe,
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26 97 and the absence of any front-of-pack labelling.
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33 99 To our knowledge, no study has specifically investigated the effect of FoPLs, including the
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35 100 Nutri-Score, on food purchases of patients suffering from nutrition-related NCDs only. Thus,
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37 101 the study aimed to determine the effect of the Nutri-Score on purchasing intentions of
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39 102 individuals suffering from nutrition-related cardiometabolic chronic diseases, compared to the
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41 103 current French labelling situations, i.e. the RIs or no FoPL, as a secondary or primary prevention
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43 104 tool.
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111 **METHODS**

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113 **Trial design and participants**

114 A three-arm parallel group randomized trial was conducted in 2017 targeting individuals
115 suffering from cardiometabolic NCDs. The study was approved by the Institutional Review
116 Bard of the INSERM (IRB n°IRB0000388 FWA00005831), the National Commission for Data
117 Protection and Liberties (CNIL n° 909216) and the *Comité consultatif sur le traitement de*
118 *l'information en matière de recherche dans le domaine de la santé*, and registered at
119 <https://clinicaltrials.gov/ct2/show/NCT02769455>. Electronic consent was obtained from each
120 participant. A methodology similar to a trial targeting students was used.[28]

121

122 Participants were recruited from the NutriNet-Santé cohort by a targeted emailing campaign in
123 2016, using the following criteria: age, BMI, and the declaration of one of the diseases included
124 in the present study. Briefly, the NutriNet-Santé is an ongoing web-based prospective
125 observational cohort study launched in France in May 2009, including adult volunteers
126 recruited by multi-media campaigns.[30] Each individual who agreed to participate was asked
127 to fulfil an inclusion questionnaire and provide information on gender, age, occupation,
128 educational level, household composition, and weekly budget for grocery shopping. They were
129 also asked to self-estimate their nutrition knowledge level on a 4-point scale (between “I am
130 very knowledgeable about nutrition” and “I do not know anything about nutrition”), and to
131 provide information on their grocery shopping frequency in general and online (“Always”,
132 “Often”, “Sometimes” and “Never”). Finally, they were invited to declare if they had been
133 diagnosed or were currently under medical supervision for at least one of the following
134 nutrition-related chronic diseases: obesity, type 2 diabetes, dyslipidaemia, arterial hypertension,

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3 135 cardiovascular disease. Thus, individuals involved in grocery shopping, over 50 years old, and
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5 136 with at least one of the chronic diseases from the list above, were eligible to participate.
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9 10 138 **Patient and public involvement**

11
12 139 The research question underlying the study was driven by considerations regarding tools to
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14 140 improve patients' empowerment concerning their diets. Patients were not directly involved in
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17 141 the development of the protocol or in recruitment of participants. Dissemination of the research
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19 142 results will be done through the NutriNet-Santé cohort platform, with an abstract in the French
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21 143 language, allowing for all participants to be informed.
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24 144 25 26 145 **Randomization and blinding**

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28 146 Eligible participants were randomly allocated to one of the three arms using a random block
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30 147 method with permuted blocks of size 3, 6, 9 and 12, without stratification. The randomization
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33 148 list was only available to the independent statistician who generated the randomization
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35 149 sequence and the computer programmer who uploaded the list on the secured platform. Given
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37 150 the nature of the intervention, participants could not be blinded of the intervention; however,
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39 151 they were only informed about the main objectives of the experimental online supermarket,
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42 152 aiming to investigate determinants of purchasing behaviour. No information was given on the
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44 153 FoPLs or the explicit purpose of the trial.
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47 154 48 49 155 **Intervention and procedure**

50 51 156 Experimental arm

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53 157 The experimental arm consisted on the Nutri-Score applied on the front of package of all pre-
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56 158 packed foods included in the online supermarket. The Nutri-Score is a summary FoPL
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58 159 characterizing the overall nutritional quality of foods. The label is based on the Food Standards
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3 160 Agency Nutrient Profiling System, modified by the High Council of Public Health to better
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5 161 discriminate foods from specific categories (cheese, fats and beverages) consistently with
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7 162 nutritional recommendations (FSAm-NPS).[18] The FSAm-NPS is calculated for 100g (or
8
9 163 100mL) of food, and allocates from 0 to 10 points for each nutrient which should be limited
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11 164 (energy (kJ), SFA (g), sugars (g), and sodium (mg)) and from 0 to 5 points to each favourable
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13 165 nutrient which should be encouraged (proteins (g), fibres (g), and the content in fruits,
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15 166 vegetables, legumes and nuts (%)). A discrete score is finally obtained by subtracting the
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17 167 favourable points from the unfavourable points, ranging therefore between -15, for food
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19 168 products with higher nutritional quality, to +40 points for food products with lower nutritional
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21 169 quality. Then, the Nutri-Score is represented by a 5-colour scale with a corresponding letter,
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23 170 from dark green (A) indicating the highest nutritional quality to dark orange (E) for products
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25 171 with the lowest nutritional quality.
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33 173 Control arms

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35 174 Two control arms were also included: (1) the RIs FoPL was affixed on all pre-packed food
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37 175 items, and (2) no front-of-pack nutritional labelling at all. The RIs is a nutrient-specific
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39 176 monochromatic label endorsed by some manufacturers, indicating the kilocalories and the
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41 177 amount of fat, SFA, sugars and sodium in gram per serving, and their contribution in
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43 178 percentages to the guideline-based daily intakes.[29] In the no label arm, no nutrition label was
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45 179 applied on the front of food packages on the experimental online supermarket.
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52 181 The experimental online supermarket was composed of three sections. First, the upper section
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54 182 included the logo of the supermarket, a search bar, an access to the shopping cart, and the tabs
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56 183 for the different food categories. Second, a central section displaying advertisements and
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58 184 showing shoppers in a supermarket aisle was included. The rotating banner ad on the left side
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3 185 of the central section included one specific ad and four ads on non-dietary information such as
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5 186 information on national campaigns of health promotion. In the two arms with a FoPL, the
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7 187 specific ad drew awareness on the label with additional information on its computation and use.
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9 188 In the no label arm, additional information was provided on the proper conservation of fresh
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11 189 food products. On the central section, the participant could also view the different products
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13 190 depending on the food categories, and access the information (name, brand, price, nutritional
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15 191 information, etc) by clicking on the product. For the two label arms, the nutritional label was
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17 192 affixed on the front of the package and next to the product on a larger scale to improve its
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19 193 readability. Third, the lower section included links to the various food categories, links for
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21 194 information and links towards account information. An example of a food item included in the
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23 195 experimental online supermarket with its three versions depending on the trial arm is shown in
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25 196 Figure 1 and a picture of the experimental online supermarket is presented in Figure S1 [28].
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33 198 Procedure

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35 199 For this specific purpose, an experimental online supermarket was developed, similar to
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37 200 previous trials.[18,28] Eligible participants were invited to simulate a shopping task as if they
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39 201 were in their usual supermarket, but without any payment required and no instruction on the
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41 202 amount, the duration or the number of participants they were asked to shop for. The
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43 203 experimental online supermarket resembled existing grocery shopping websites with a virtual
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45 204 shopping cart, a virtual payment procedure, a search tab and promotional banners. As in real
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47 205 shopping websites, participants could choose products categorized in multiple food groups and
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49 206 subgroups, using a hierarchical structure and names of the categories similar to existing online
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51 207 supermarkets. The food offer was a representative sample of the products commonly sold on
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53 208 French online supermarkets and included 751 foods and beverages (pre-packed products
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55 209 carrying a FoPL on the Nutri-Score and RIs arms, and raw products without any label in the
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3 210 three arms according to the European regulation), divided into twenty food categories. For all
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5 211 products, name, brand, price (per unit and per kg or litter), a picture of the product (with or
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7 212 without a FoPL, depending on the arm) and the nutritional composition as well as the list of
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9 213 ingredients were provided. For each food item, at least two different products were proposed,
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11 214 including a national brand and a retailer's brand. The number of brands proposed balanced the
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13 215 nutritional variability observed for a given type of food.
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16 216 **Outcomes**

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19 217 The primary outcome was the overall nutritional quality of the shopping cart, assessed by the
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21 218 mean of the FSAm-NPS score across all the items in the cart, computed for 100g. A lower
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23 219 overall FSAm-NPS score of the shopping cart reflects a higher nutritional quality of the entire
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25 220 selection of products within the cart.
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28 221 Secondary outcomes were, by order of importance, the content of the shopping cart in energy,
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30 222 SFA, sugars, sodium, fibres, fruits and vegetables, and proteins, for 100g of the shopping cart.
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34 224 **Statistical analyses**

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37 225 The final sample size was calculated for an effect size of 0.2 (for the main outcome, FSAm-
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39 226 NPS score), a power of 90% and a p-value of 0.02 considering the three-arm design, resulting
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41 227 in 1,956 individuals, i.e. 652 participants per arm. To reach this final sample size while
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43 228 considering non-respondents, 2,431 individuals were initially randomized and the number of
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45 229 individuals validating their shopping cart was monitored.
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51 231 Per protocol analyses were carried out, given that only one measure was collected for the
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53 232 outcome. All participants meeting the inclusion criteria and who completed the shopping task
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55 233 were included in the analyses. The primary outcome was compared between the three trial arms
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57 234 using one-way ANOVA (p-value \leq 0.05 significant). Pairwise comparisons among FoPLs were
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3 235 performed using Tukey tests to consider multiple comparisons ($p\text{-value} \leq 0.05$ significant).
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5 236 Then, secondary outcome variables were also compared between the three arms using a
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7 237 hierarchical gatekeeping strategy[28] with the following order: 1. Energy, 2. SFA, 3. Sugars, 4.
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9 238 Sodium, 5. Fibres, 6. Fruits and vegetables, 7. Proteins. When the comparison across the three
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11 239 arms for a component was not significant, the comparison of following secondary outcomes
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13 240 was stopped. The gatekeeping strategy order was determined using the relative importance of
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15 241 the various nutrients to health (with the most unfavourable elements first) and the results of
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17 242 previous studies assessing FoPL effects on the nutritional quality of food purchases.[18]
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19 243 Analyses were performed considering the FSAm-NPS score of all products from the
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21 244 experimental supermarket, including also raw items that were not labelled in any trial arm (i.e.
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23 245 fruits, vegetables, meat and poultry). Multiple sensitivity analyses were then performed. First,
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25 246 sensitivity analyses were computed (1) including only labelled food products (i.e. pre-packed
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27 247 foods and beverages), (2) excluding participants whose spending amount was below the 5th
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29 248 percentile or over the 95th percentile of the distribution of the cost of the shopping carts in the
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31 249 sample, and (3) using multiple imputations on missing outcomes (25 imputed sets) to consider
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33 250 the non-response rate. Missing primary and secondary outcomes of non-respondents were
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35 251 imputed using the individual characteristics of the individuals, including sociodemographic and
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37 252 nutrition-related lifestyle data collected in the inclusion questionnaire. The total quantities of
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39 253 calories, SFA, sugars, sodium, fibres, and proteins in the shopping carts were also calculated
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41 254 and compared across the three arms using ANOVA. The composition of the shopping cart
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43 255 across the different food categories was calculated in percentage of the total number of products
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45 256 in the cart (mean and standard error). The contributions of each food group to the nutrient
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47 257 amounts in the shopping carts were then calculated and expressed a mean percentage and
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49 258 standard error. Finally, the distribution of the products across the different Nutri-Score classes
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3 259 was also compared between the three arms, taking into account all food products including raw
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5 260 foods that were non-labelled.
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10 262 All tests of significance were two-sided, and analyses were carried out with the SAS software
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12 263 (version 9.4; SAS Institute, Inc.).
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18 19 266 **RESULTS**

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23 268 Among 3,728 individuals with chronic diseases assessed for eligibility, 1,297 did not meet
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25 269 inclusion criteria, resulting in 2,431 participants randomly assigned to one of the three arms
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27 270 (Figure 2). Among them, 1,180 individuals with a nutrition-related chronic disease fully
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29 271 completed the shopping task and were finally included in the analyses. The other subjects who
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31 272 did not complete their shopping cart were excluded from the analyses, as their purchasing
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33 273 behaviour may not be representative of their habits. Overall, participants of the trial included
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35 274 65.5% of women, 27.8% of subjects with primary educational level, and their mean age was
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37 275 65.0±7.1 years (Table 1). Regarding purchasing behaviour, 61.2% declared doing always their
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39 276 grocery shopping and 29.7% reported having purchased foods online at least once. Among
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41 277 them, 16.2% reported purchasing online at least one time per week. 57.2% of the included
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43 278 participants declared having an intermediate self-estimated nutrition knowledge level, and
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45 279 51.4% often reading the nutrition facts. The two main chronic diseases represented in the trial
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47 280 were arterial hypertension (65.7%) and dyslipidaemia (33.9%), then followed by cardiovascular
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49 281 diseases (15.2%), type 2 diabetes (14.7%), and obesity (13.8%). Approximately 30% of
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51 282 participants reported having more than one of the diseases included in the trial. Individual
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53 283 characteristics of participants were globally similar between the three arms. The mean cost of
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3 284 the shopping cart was 75.0±51.5 euros overall, 80.0±57.8 euros in the Nutri-Score arm,
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5 285 73.9±48.3 euros in the RIs arm and 71.2±47.3 euros in the no label arm. The mean weight of
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7 286 the shopping carts was 16.6±14.3 kg in the Nutri-Score arm with 22.9±21.9 products on
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9 287 average, 24.2±14.7 kg in the Reference Intakes arm with 33.6±22.0 products on average, and
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11 288 22.7±14.2 kg in the no label arm with 31.1±21.3 products on average
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17 290 According to the flow diagram, approximately 50% of participants did not complete the virtual
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19 291 shopping task. Individual characteristics between respondents and non-respondents were
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21 292 compared and results are displayed in Table S1. Even if non-respondents had some small
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23 293 disparities on their sociodemographic and lifestyle characteristics compared to respondents, this
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25 294 potential bias was similar in the three arms. Indeed, the interaction term between each individual
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27 295 characteristic and the arm to model the probability of no response was not statistically
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29 296 significant ($p\text{-value} \geq 0.1$).
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Table 1 Individual characteristics of included participants, NutriNet-Santé cohort (N=1,180)

	Nutri-Score	Reference Intakes	No label	Total
Total (n)	394	392	394	1180
Gender, n(%)				
Men	131 (33.3)	124 (31.6)	152 (38.6)	407 (34.5)
Women	263 (66.7)	268 (68.4)	242 (61.4)	773 (65.5)
Age, years	64.8 ± 6.9	64.8 ± 7.3	65.4 ± 7.1	65.0 ± 7.1
Educational level, n(%)				
Primary	122 (31.0)	102 (26.0)	104 (26.4)	328 (27.8)
Secondary	53 (13.4)	51 (13.0)	74 (18.8)	178 (15.1)
University, undergraduate degree	103 (26.1)	122 (31.2)	99 (25.1)	324 (27.4)
University, postgraduate degree	98 (24.9)	102 (26.0)	103 (26.1)	303 (25.7)
Other	18 (4.6)	15 (3.8)	14 (3.6)	47 (4.0)
Grocery shopping frequency, n(%)				
Always	231 (58.63)	252 (64.3)	239 (60.6)	722 (61.2)
Often	122 (30.96)	107 (27.3)	113 (28.7)	342 (29.0)
Sometimes	41 (10.41)	33 (8.4)	42 (10.7)	116 (9.8)
Online grocery shopping, yes n(%)	119 (30.2)	129 (32.9)	103 (26.1)	351 (29.7)
Online grocery shopping frequency, n(%)				
At least one time per week	16 (13.4)	20 (15.5)	21 (20.4)	57 (16.2)
One or two times per month	22 (18.5)	26 (20.1)	15 (14.5)	63 (18.0)
One time every two or three months	29 (24.4)	33 (25.6)	17 (16.5)	79 (22.5)
One or two times per year	23 (19.3)	21 (16.3)	29 (28.2)	73 (20.8)
Less than one time per year	29 (24.4)	29 (22.5)	21 (20.4)	79 (22.5)
Weekly budget for grocery shopping (€), n(%)				
< 30€	13 (3.3)	17 (4.3)	16 (4.1)	46 (3.9)
30 – 50€	76 (19.3)	74 (18.9)	63 (16.0)	213 (18.0)
50 – 100€	151 (38.3)	168 (42.9)	160 (40.6)	479 (40.6)
> 100€	151 (38.3)	130 (33.1)	147 (37.3)	428 (36.3)
Missing	3 (0.8)	3 (0.8)	8 (2.0)	14 (1.2)
Perceived nutritional knowledge, n(%)				
High	38 (9.6)	38 (9.7)	22 (5.6)	98 (8.3)
Intermediate	222 (56.4)	220 (56.1)	233 (59.1)	675 (57.2)
Low	125 (31.7)	125 (31.9)	124 (31.5)	374 (31.7)
No	9 (2.3)	7 (1.8)	9 (2.3)	25 (2.1)
Missing data	0	2 (0.5)	6 (1.5)	8 (0.7)
Nutrition facts reading frequency, n(%)				
Always	63 (16.0)	55 (14.0)	54 (13.7)	172 (14.6)
Often	202 (51.3)	199 (50.8)	206 (52.3)	607 (51.4)

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Sometimes	117 (29.7)	122 (31.1)	119 (30.2)	358 (30.3)
Never	12 (3.0)	14 (3.6)	9 (2.3)	35 (3.0)
Missing data	0	2 (0.5)	6 (1.5)	8 (0.7)
Chronic disease diagnosed, n(%)				
Arterial hypertension	265 (67.3)	256 (65.3)	254 (64.5)	775 (65.7)
Diabetes mellitus	51 (12.9)	55 (14.0)	67 (17.0)	173 (14.7)
Cardiovascular disease	65 (16.5)	48 (12.2)	66 (16.8)	179 (15.2)
Dyslipidemia	141 (35.8)	127 (32.4)	132 (33.5)	400 (33.9)
Obesity	43 (10.9)	58 (14.8)	62 (15.7)	163 (13.8)
Total cost of the shopping cart (€)	80.0 ± 57.8	73.9 ± 48.3	71.2 ± 47.3	75.0 ± 51.5
Number of products in the shopping cart	22.9 ± 21.9	33.6 ± 22.0	31.1 ± 21.3	29.2 ± 22.2
Weight of the shopping cart (kg)	16.6 ± 14.3	24.2 ± 14.7	22.7 ± 14.2	21.2 ± 14.8

Values are mean ± standard deviation or n (%) as appropriate.

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3 315 **Outcomes**
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5 316 The FSAm-NPS score was lower in the Nutri-Score arm (1.29 ± 3.61 points), reflecting a higher
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7 overall nutritional quality of the shopping carts, followed by the RIs arm (1.86 ± 3.23 points)
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9 and no label (1.92 ± 2.9 points) (Table 2). The difference of FSAm-NPS scores were statistically
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11 significant between the Nutri-Score and the RIs groups (mean difference= $-0.57[-1.11;-0.02]$;
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13 p-value= 0.04), and between the Nutri-Score and no label ($-0.63[-1.17;-0.08]$; p-value= 0.02).
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15 No significant difference was observed between the RIs and no label ($-0.06[-0.61;0.48]$; p-
16 321
17 value= 1.0). Furthermore, the Nutri-Score label led to a significantly lower content of the
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19 shopping carts in calories and SFA, compared to the RIs and no label (p-values ≤ 0.0001 for
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21 comparisons of calories between the Nutri-Score and both RIs and no label; p-values= 0.01 for
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23 comparisons of SFA between the Nutri-Score and both RIs and no label). The differences
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25 between the RIs and no label arms were not significant. The differences of sugars content
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27 between the three arms were not significant; then comparisons of subsequent secondary
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29 outcomes were stopped.
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Table 2 Overall nutritional quality, energy and nutrient content for 100g of the shopping cart

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=394	N=392	N=394		Difference ^a	P ^b	Difference ^a	P ^b	Difference ^a	P ^b
Overall nutritional quality (FSAm-NPS score/100g)	1.29 (3.61)	1.86 (3.23)	1.92 (2.9)	0.01	-0.63 (-1.17;-0.08)	0.02	-0.57 (-1.11;-0.02)	0.04	-0.06 (-0.61;0.48)	1.0
Calories (kcal/100g)	153.53 (76.96)	184.06 (64.38)	175.38 (64.22)	<0.0001	-21.85 (-33.35;-10.35)	<0.0001	-30.53 (-42.05;-19.02)	<0.0001	8.68 (-2.83;20.20)	0.2
Saturated fatty acids (g/100g)	3.24 (3.13)	3.78 (2.13)	3.77 (2.36)	0.004	-0.53 (-0.96;-0.10)	0.01	-0.53 (-0.96;-0.10)	0.01	0.01 (-0.42;0.44)	1.0
Sugars (g/100g)	5.92 (3.58)	5.89 (3.25)	5.65 (3.81)	0.5	0.27 (-0.32;0.87)	0.5	0.03 (-0.56;0.63)	1.0	0.24 (-0.35;0.84)	0.6
Sodium (mg/100g)	189.83 (200.21)	195.51 (104.13)	212.73 (158.16)							
Fibers (g/100g)	1.37 (0.99)	1.89 (1.17)	1.65 (0.97)							
Fruits and vegetables (%)	34.12 (22.87)	29.51 (16.03)	28.90 (14.81)							
Proteins (g/100g)	7.36 (3.43)	7.29 (2.20)	7.58 (3.33)							

^a Mean difference (95% Confidence Interval)^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

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3 330 When analyses considered pre-packed products only, the overall difference of shopping carts'
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5 331 FSAm-NPS score between the three arms was no longer significant suggesting inter-food group
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7 332 substitutions (Table S2). However, results for the secondary outcomes remained consistent with
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9 333 the main analyses. In sensitivity analyses excluding outliers on the spending amount, similar
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11 334 results were observed for primary and secondary outcomes (Table S3). Results of the sensitivity
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13 335 analyses using multiple imputations are presented in Table S4 for analyses considering all food
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15 336 products and Table S5 for analyses considering only labelled food items. Results using multiple
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17 337 imputations were consistent with the main analyses; however, the amplitude of differences
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19 338 between arms was lower and comparisons were no longer significant, except for calories for
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21 339 which the Nutri-Score also led to lower contents compared to the two other arms (Tables S4
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23 340 and S5). The participants in the Nutri-Score arm purchased less calories, SFA, sugars, sodium,
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25 341 fibres, and proteins compared to the two other arms (Table S6).

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29 343 Table S7 describes the shopping carts composition in terms of the mean number of products
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31 344 per food category in each of the three arms. In the Nutri-Score arm, participants tended to
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33 345 purchase more products from the fruits (especially fresh fruit), meat and water categories
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35 346 (compared to the RIs), and fewer products from vegetables, dairy products, cheeses, sweets and
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37 347 starchy foods such as pasta, rice, rush potatoes and semolina. The average percentages of raw
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39 348 products (i.e. not labelled in the label arms) purchased by participants were 32.9%±18.4% in
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41 349 the no label arm, 33.2%±18.2% in the RIs arm, and 42.0%±28.1% in the Nutri-Score arm. The
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43 350 percentage contributions of food groups to nutrient intakes in the overall shopping carts are
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45 351 presented in Table S8 (only for nutrients where a difference between arms was observed in the
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47 352 main analyses). Thus, the lower calorie and SFA contents of the shopping carts in the Nutri-
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49 353 Score arm compared to the RIs arms could be explained by fewer products purchased in the
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51 354 dairy products, cheese, but also sweets and starchy foods. Finally, the proportion of healthier
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3 355 food products in the shopping carts classified as A was significantly higher in the Nutri-Score
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5 356 arm compared to the two other arms (difference = 5.63 [2.02;9.24], p-value=0.0008 compared
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7 357 to no label; difference = 4.85 [1.24;8.47], p-value=0.005 compared to the RIs), which can be
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9 358 partly explained by the higher proportion of raw fruits and meats in the shopping carts of
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11 359 participants from the Nutri-Score group – corresponding to products with higher nutritional
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13 360 quality (Table S9). On the contrary, the proportion of unhealthier products classified as D or E
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15 361 was significantly lower in the Nutri-Score arm compared to the two other arms or the RIs only.
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17 362 No significant difference was observed between the RIs and no label.
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26 365 **DISCUSSION**

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30 367 Results of the present study showed that the Nutri-Score label significantly led to an
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32 368 improvement of the overall nutritional quality of food purchases in individuals with
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34 369 cardiometabolic chronic disease. Moreover, the Nutri-Score led to lower contents of the
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36 370 shopping carts in energy and SFA compared to the two other arms. Similar trends were observed
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38 371 with multiple imputations; nevertheless, differences were no longer statistically significant. No
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40 372 significant difference was observed between the RIs and no label. Moreover, in both FoPLs
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42 373 arms, and particularly in the Nutri-Score arm, substitutions between food groups were observed,
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44 374 with more raw products purchased – corresponding mainly to fruits and butcher's meats from
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46 375 higher nutritional quality. It appeared that the participants exposed to the Nutri-Score purchased
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48 376 less products and from higher overall nutritional quality (i.e. lower FSAm-NPS score).
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56 378 The present findings are consistent with studies which observed a positive effect of interpretive
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58 379 FoPLs and especially the Nutri-Score on the nutritional quality of intentional or real food
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3 380 purchases, while the RIs demonstrated a limited or non-significant effect in the general
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5 381 population[14,18] or students.[28] This could be partly explained by the features of the
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7 382 schemes. Indeed, the summary indicator of the Nutri-Score, combining colours and text, would
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10 383 be easier to read and understand.[16,18,19,31–37] On the contrary, the RIs with its nutrient-
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12 384 specific and monochromatic format, has been shown to be more complicated to identify and
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14 385 understand in the general population,[18,36,37] creating notably potential decisional conflicts
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17 386 and prioritization of nutrients.[38] Nevertheless, to our knowledge, this is the first study to
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19 387 assess the effect of FoPLs on purchasing intentions among individuals suffering from nutrition-
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21 388 related NCDs. Only one study investigated the effect of the Traffic Lights nutrient-specific label
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24 389 and the three-stars summary label on food purchases in vending machine among patients in an
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26 390 Australian hospital and observed a positive effect of the labels to identify healthier products.
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28 391 However, the experiment was performed in a specific context and no focus was made on
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30 392 patients suffering specifically from nutrition-related NCDs.[12]

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35 394 Interestingly, while previous studies among patients with hypertension, hypercholesterolemia,
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37 395 type 2 diabetes or hyperlipidaemia found that they were more likely to read information on salt
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40 396 and SFA respectively,[39] and have lower intakes in energy and SFA,[9] in the present study,
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42 397 the RIs did not help consumers to select products with significantly less SFA compared to no
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44 398 label. On the contrary, the Nutri-Score which does not provide numerical data but rather
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47 399 summarized information, led to significantly lower contents of the shopping carts in SFA
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49 400 compared to no label and the RIs. These results on the Nutri-Score effect are particularly
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51 401 important, given that a decrease of the intakes in energy, SFA and salt with an increase of fruits
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53 402 and vegetables consumption are recommended among patients suffering from nutrition-related
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56 403 NCDs.[1] Moreover, despite these recommendations, it has been observed in a study within the
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58 404 NutriNet-Santé cohort that adults with a cardiometabolic disease tended to have unhealthier
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3 405 dietary habits overall (e.g. lower intakes of fruits, higher intakes of meat, processed meat and
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5 406 added fats) compared to healthy controls,[40] which supports the interest of public health
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7 407 measures encouraging healthier food choices among these individuals.
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12 409 When analyses were restricted to labelled items only, no significant difference of the overall
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14 410 nutritional quality between the Nutri-Score and the other arms was found. These results reflect
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16 411 that the use of the Nutri-Score may encourage also substitutions between food categories.
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18 412 Indeed, participants who were exposed to the Nutri-Score tended to purchase more non-labelled
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20 413 raw products, in particular fruits, meat and poultry, characterized by healthier nutritional
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28 416 The present study provides insights regarding the effect of the Nutri-Score on purchasing
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30 417 intentions of individuals with nutrition-related NCDs compared to the current labelling situation
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32 418 in France and other European countries. First, strength of the study pertained in the inclusion
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34 419 of a specific population rarely explored in the nutritional labelling field, and its randomized
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36 420 controlled design, which resulted in comparable groups allowing accurate estimations of the
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38 421 labels' effect. Furthermore, the experiment was conducted on an experimental online
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40 422 supermarket, closed to real online grocery shopping conditions, with a range of different
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42 423 products with distinct nutritional profiles, brands and the use of real packaging. This controlled
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44 424 experimental environment allowed assessing the effect of the Nutri-Score in standardized
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46 425 conditions and optimizing internal validity of the study. Nevertheless, some limitations should
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48 426 be acknowledged. First, a high rate of participants did not complete the shopping task. Hence,
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50 427 respondents may have different individual characteristics, leading however to a potential non-
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52 428 differential bias which could limit the generalizability of the results. In addition, the reduced
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54 429 sample size could have led to a decreased statistical power preventing us from detecting some
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3 430 potential small differences. Moreover, it is important to notice that analyses with multiple
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5 431 imputations led to similar trends but with non-significant differences given the increase of
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7 432 variance in the sample. Second, the trial involved voluntary participants, who may have greater
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9 433 interest and knowledge in nutrition than the French population of patients. Thus, participants in
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11 434 the no label arm might have made healthier food choices than the general population and the
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13 435 effects of FoPLs in comparison could have been underestimated. Third, despite the diversity of
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15 436 the food offer proposed, the number of products was somewhat limited, and some participants
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17 437 may not have found their usual product and chose foods they would not buy in real shopping
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19 438 situation. In addition, the representativity of the experimental food offer was not carefully
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21 439 assessed. These elements would limit the external validity of the study and the generalisability of
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23 440 the results to a real online supermarket. Moreover, compared to the French average, the higher
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25 441 proportion of subjects who declared doing often their grocery shopping online, may have led to
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27 442 a sample with sociodemographic differences compared to the French population of patients.
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29 443 Fourth, the trial investigated purchasing intentions rather than actual food purchases that may
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31 444 have led the participants to take the experiment less seriously or to spend more money than they
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33 445 would actually do. Complementary studies should be conducted in real-life settings to provide
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35 446 additional elements on the Nutri-Score effectiveness. Nevertheless, virtual purchasing
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37 447 behaviours of individuals have been suggested to be good predictors of real behaviours.[41]
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39 448 Finally, the study included cases of self-reported cardiometabolic chronic conditions with no
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41 449 validation required. Therefore, we were not able to ascertain whether the participants were
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43 450 following specific diets or nutritional recommendations during the period of the trial, which
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45 451 could have modified their purchasing behaviours. The present study focused on the Nutri-Score
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47 452 effect as a secondary or tertiary prevention tool of NCDs, and complement previous studies
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49 453 which have been conducted on the general population including individual without any chronic
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51 454 conditions, or on specific subgroups such as students. Furthermore, it could have been
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3 455 interesting to also include individuals having someone in the household with a chronic
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5 456 condition.
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10 458 These results support that the Nutri-Score may improve the nutritional quality of food choices
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12 459 of consumers suffering from nutrition-related chronic diseases. This is particularly important
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14 460 given that an improvement of the dietary habits and the nutritional status of these individuals is
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16 461 a major element in the secondary prevention and the management of these non-communicable
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18 462 diseases. These findings are complementary to studies having observed a favourable effect of
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20 463 the Nutri-Score or its underlying nutrient profiling system on chronic diseases risk, in a context
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22 464 of primary prevention, through an improvement of food purchases and nutrient intakes.[18,42]
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474 **Competing interests**

475 All authors declare no competing interests.

477 **Author contributorship**

478 ME, CJ and IB wrote the statistical analysis plan, analysed the data, and drafted and revised the
479 paper. SP, PD, MT, PG, LF, RP, PR, SH and EKG analysed the data and critically revised the
480 paper for important intellectual content. SH and CJ designed data collection tools, implemented
481 the study, monitored data collection for the whole study, and critically revised the draft paper
482 for important intellectual content. All authors, external and internal, had full access to all of the
483 data (including statistical reports and tables) in the study and can take responsibility for the
484 integrity of the data and the accuracy of the data analysis. All authors have read and approved
485 the final manuscript.

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6
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12 495 **Ethics approval and consent to participate**

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14 496 The study was approved by the Institutional Review Board of INSERM (IRB Inserm
15
16 497 n°IRB0000388 FWA00005831) and the National Commission for Data Protection and
17
18 498 Liberties (CNIL n° 909216), and registered at:
19
20 499 <https://clinicaltrials.gov/ct2/show/NCT02769455>. Electronic consent was obtained from each
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22 500 participant of the trial.
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28 502 **Data sharing**

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30 503 All data supporting the findings of this study are included in the present article or the
31
32 504 supplemental material. No additional data available.
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3 **Figure 1** An example of a food product in the Nutri-Score (1), Reference Intakes (2), and no
4 label (3) arms
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10 **Figure 2** Flow diagram of the randomized controlled trial
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13 * Subjects who validated their online shopping cart and did not encounter technical issues
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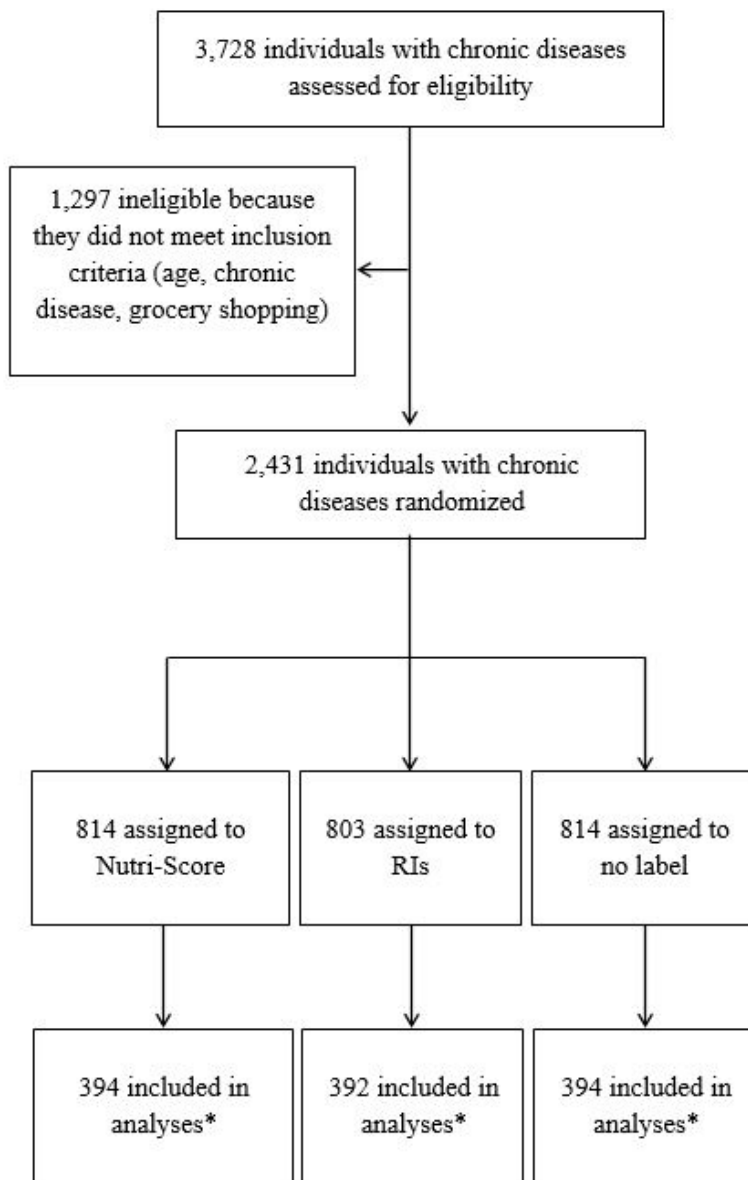


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Table S1 Individual characteristics of respondents and non-respondents in the randomized controlled trial by randomization group, France, 2017

	Nutri-Score		Reference Intakes		No label		<i>P</i> ^a
	Respondents	Non-respondents	Respondents	Non-respondents	Respondents	Non-respondents	
Total (n)	394	420	392	411	394	420	
Sex, n(%)							0.5
Men	131 (33.2)	158 (37.6)	124 (31.6)	143 (34.8)	152 (38.6)	157 (37.4)	
Women	263 (66.8)	262 (62.4)	268 (68.4)	268 (65.2)	242 (61.4)	263 (62.6)	
Age, years	64.8 ± 6.9	65.8 ± 7.5	64.8 ± 7.3	66.5 ± 7.1	65.4 ± 7.1	66.2 ± 7.2	0.5
Educational level							0.2
Primary	122 (31)	131 (31.2)	102 (26)	140 (34.1)	104 (26.4)	131 (31.2)	
Secondary	53 (13.5)	83 (19.8)	51 (13)	77 (18.7)	74 (18.8)	71 (16.9)	
University, undergraduate degree	103 (26.1)	94 (22.4)	122 (31.1)	98 (23.8)	99 (25.1)	103 (24.5)	
University, postgraduate degree	98 (24.9)	93 (22.1)	102 (26)	77 (18.7)	103 (26.1)	102 (24.3)	
Other	18 (4.6)	19 (4.5)	15 (3.8)	19 (4.6)	14 (3.6)	13 (3.1)	
Grocery shopping frequency, n(%)							0.6
Always	231 (58.6)	235 (56)	252 (64.3)	229 (55.7)	239 (60.7)	245 (58.3)	
Often	122 (31)	134 (31.9)	107 (27.3)	128 (31.1)	113 (28.7)	127 (30.2)	
Sometimes	41 (10.4)	51 (12.1)	33 (8.4)	54 (13.1)	42 (10.7)	48 (11.4)	
Online grocery shopping, yes n(%)	119 (30.2)	96 (22.9)	129 (32.9)	102 (24.8)	103 (26.1)	109 (26)	0.2
Online grocery shopping frequency, n(%)							0.4
At least one time per week	16 (13.4)	8 (8.3)	20 (15.5)	14 (13.7)	21 (20.4)	13 (11.9)	
One or two times per month	22 (18.5)	25 (26)	26 (20.2)	20 (19.6)	15 (14.6)	25 (22.9)	
One time every two or three months	29 (24.4)	15 (15.6)	33 (25.6)	23 (22.5)	17 (16.5)	22 (20.2)	
One or two times per year	23 (19.3)	23 (24)	21 (16.3)	29 (28.4)	29 (28.2)	32 (29.4)	
Less than one time per year	29 (24.4)	25 (26)	29 (22.5)	16 (15.7)	21 (20.4)	17 (15.6)	
Weekly budget for grocery shopping (€)							0.2
≤30€	13 (3.3)	20 (4.8)	17 (4.3)	10 (2.4)	16 (4.1)	6 (1.4)	
30 – 50€	76 (19.3)	65 (15.5)	74 (18.9)	78 (19)	63 (16)	65 (15.5)	
50 – 100€	151 (38.3)	159 (37.9)	168 (42.9)	158 (38.4)	160 (40.6)	164 (39)	
≥100€	151 (38.3)	154 (36.7)	130 (33.2)	140 (34.1)	147 (37.3)	167 (39.8)	
Missing	3 (0.8)	22 (5.2)	3 (0.8)	25 (6.1)	8 (2)	18 (4.3)	
Perceived nutritional knowledge, n(%)							0.1
High	38 (9.6)	33 (7.9)	38 (9.7)	26 (6.3)	22 (5.6)	44 (10.5)	
Intermediate	222 (56.3)	226 (53.8)	220 (56.1)	231 (56.2)	233 (59.1)	221 (52.6)	
Low	125 (31.7)	135 (32.1)	125 (31.9)	125 (30.4)	124 (31.5)	132 (31.4)	
No	9 (2.3)	9 (2.1)	7 (1.8)	7 (1.7)	9 (2.3)	6 (1.4)	
Missing data	0	17 (4)	2 (0.5)	22 (5.4)	6 (1.5)	17 (4)	
Nutrition facts reading frequency, n(%)							0.3
Always	63 (16)	68 (16.2)	55 (14)	58 (14.1)	54 (13.7)	71 (16.9)	
Often	202 (51.3)	190 (45.2)	199 (50.8)	210 (51.1)	206 (52.3)	177 (42.1)	
Sometimes	117 (29.7)	127 (30.2)	122 (31.1)	106 (25.8)	119 (30.2)	142 (33.8)	
Never	12 (3)	18 (4.3)	14 (3.6)	15 (3.6)	9 (2.3)	13 (3.1)	
Missing data	0	17 (4)	2 (0.5)	22 (5.4)	6 (1.5)	17 (4)	

Values are mean ± standard deviation or n (%) as appropriate.

^a A multivariable logistic regression was conducted to model the probability of non-response depending on the individual sociodemographic and lifestyle characteristics and the arm of randomization. The *P* corresponds to the p-value of the interaction term between the individual characteristic and the trial arm. The comparison of the educational level and weekly budget for grocery shopping variables between respondents and non-respondents were not performed given that information was missing for non-respondents.

Table S2 Overall nutritional quality, energy and nutrient content for 100g of the shopping cart among labelled products only

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=369	N=390	N=392		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	4.35 (3.5)	4.27 (3.43)	4.49 (3.41)	0.7	-0.13 (-0.72;0.45)	0.9	0.08 (-0.51;0.67)	0.9	-0.21 (-0.79;0.36)	0.7
Calories (kcal/100g)	188.42 (111.64)	237.94 (80.74)	226.59 (85.24)	<0.0001	-38.16 (-54.02;-22.3)	<0.0001	-49.52 (-65.39;-33.64)	<0.0001	11.35 (-4.28;26.99)	0.2
Saturated fatty acids (g/100g)	4.60 (4.48)	5.34 (2.97)	5.43 (3.28)	0.003	-0.83 (-1.45;-0.22)	0.004	-0.74 (-1.36;-0.13)	0.01	-0.09 (-0.70;0.52)	0.9
Sugars (g/100)	5.80 (5.16)	6.45 (4.23)	6.43 (6.00)	0.1	-0.63 (-1.51;0.25)	0.2	-0.66 (-1.54;0.23)	0.2	0.03 (-0.84;0.9)	1.0
Sodium (mg/100g)	267.67 (284.89)	252.19 (130.25)	267.10 (200.7)							
Fiber (g/100g)	1.45 (1.56)	2.27 (1.74)	1.95 (1.54)							
Fruits and vegetables (%)	17.98 (20.94)	17.48 (13.99)	16.95 (12.61)							
Proteins (g/100g)	6.35 (4.31)	7.89 (2.87)	7.99 (3.92)							

^a Mean difference (95% Confidence Interval)^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.**Table S3** Sensitivity analyses: overall nutritional quality, energy and nutrient content for 100g of the shopping cart excluding outliers on the spending amount

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=351	N=354	N=357		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	0.99 (3.30)	1.69 (2.84)	1.8 (2.58)	0.0004	-0.81 (-1.32;-0.29)	0.0007	-0.69 (-1.21;-0.17)	0.005	-0.12 (-0.63;0.40)	0.9
Calories (kcal/100g)	152.06 (74.84)	180.89 (58.10)	173.53 (57.8)	<0.0001	-21.47 (-32.77;-10.17)	<0.0001	-28.83 (-40.15;-17.51)	<0.0001	7.36 (-3.91;18.63)	0.3
Saturated fatty acids (g/100g)	3.19 (2.73)	3.76 (2.02)	3.78 (2.03)	0.0005	-0.59 (-0.99;-0.18)	0.002	-0.58 (-0.98;-0.17)	0.002	-0.01 (-0.41;0.39)	1.0
Sugars (g/100)	5.9 (3.31)	5.79 (2.93)	5.61 (3.10)	0.5	0.29 (-0.26;0.84)	0.4	0.11 (-0.44;0.66)	0.9	0.18 (-0.36;0.73)	0.7
Sodium (mg/100g)	171.75 (144.16)	193.37 (96.17)	205.5 (143.31)							
Fiber (g/100g)	1.41 (1.01)	1.91 (1.17)	1.67 (0.96)							
Fruits and vegetables (%)	35.29 (22.57)	30.66 (14.69)	30.11 (13.93)							
Proteins (g/100g)	7.30 (3.25)	7.25 (2.03)	7.53 (2.92)							

^a Mean difference (95% Confidence Interval)^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). Participants whose spending amount was below the 5th or over the 95th percentile of the distribution of the cost of the shopping carts in the sample were excluded. FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

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Table S4 Sensitivity analyses using multiple imputations: overall nutritional quality, energy and nutrient content for 100g of the shopping cart

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=814	N=803	N=814		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	1.51 (1.87)	1.78 (1.87)	1.84 (2.04)	0.1	-0.33 (-0.69;0.03)	0.07	-0.27 (-0.63;0.08)	0.1	-0.06 (-0.43;0.32)	0.8
Calories (kcal/100g)	162.95 (41.32)	177.21 (39.24)	173.24 (44.67)	0.0009	-10.28 (-18.26;2.31)	0.01	-14.26 (-21.87;6.65)	0.0003	3.98 (-4.09;12.05)	0.3
Saturated fatty acids (g/100g)	3.43 (1.62)	3.68 (1.41)	3.70 (1.64)	0.1	-0.27 (-0.56;0.02)	0.07	-0.25 (-0.54;0.04)	0.1	-0.02 (-0.32;0.28)	0.9
Sugars (g/100g)	5.86 (2.11)	5.86 (2.02)	5.74 (2.22)	0.6	0.12 (-0.32;0.55)	0.6	-0.01 (-0.46;0.45)	1.0	0.12 (-0.30;0.54)	0.6
Sodium (mg/100g)	194.73 (102.46)	196.38 (97.05)	205.54 (113.03)							
Fiber (g/100g)	1.51 (0.62)	1.76 (0.64)	1.64 (0.68)							
Fruits and vegetables (%)	32.25 (10.94)	30.12 (10.35)	29.78 (11.19)							
Proteins (g/100g)	7.41 (1.73)	7.35 (1.86)	7.48 (1.97)							

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

Table S5 Sensitivity analyses using multiple imputations: overall nutritional quality, energy and nutrient content for 100g of the shopping cart among labelled products only

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=789	N=801	N=812		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	3.51 (11.8)	3.52 (11.82)	3.61 (11.53)	0.6	-0.10 (-0.57;0.36)	0.7	-0.01 (-0.46;0.43)	1.0	-0.09 (-0.53;0.35)	0.7
Calories (kcal/100g)	176.66 (343.52)	201.81 (344.94)	195.53 (330.17)	0.001	-18.87 (-31.27;-6.5)	0.003	-25.15 (-38.22;-12.09)	0.0002	-6.29 (-5.17;17.74)	0.3
Saturated fatty acids (g/100g)	3.97 (14.84)	4.34 (15.04)	4.37 (14.67)	0.2	-0.41 (-0.88;0.06)	0.09	-0.38 (-0.88;0.12)	0.1	-0.03 (-0.47;0.41)	0.9
Sugars (g/100g)	4.64 (19.27)	4.99 (19.48)	4.96 (19.33)	0.5	-0.32 (-0.97;0.33)	0.3	-0.35 (-0.97;0.28)	0.3	0.02 (-0.63;0.68)	0.9
Sodium (mg/100g)	220.7 (688.19)	216.53 (675.15)	221.69 (672.91)							
Fiber (g/100g)	1.43 (5.42)	1.83 (5.44)	1.68 (5.27)							
Fruits and vegetables (%)	16.76 (50.37)	16.55 (50.69)	16.43 (49.19)							
Proteins (g/100g)	6.12 (14.32)	6.86 (13.06)	6.89 (12.84)							

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

Table S6 Total quantities of calories and nutrients in the shopping carts purchased in the three arms of the trial

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	Mean (SD)	Mean (SD)	Mean (SD)		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Calories (kcal)	2229.74(2336.45)	3395.80(2232.5)	3173.73(2235.09)	<0.0001	-943.99(-1323.29;-564.7)	<0.0001	-1166.06(-1545.84;-786.29)	<0.0001	222.07(-157.71;601.85)	0.4
Saturated fatty acids (g)	35.88(40.21)	53.08(37.21)	52.60(38.35)	<0.0001	-16.72(-23.18;-10.27)	<0.0001	-17.20(-23.66;-10.73)	<0.0001	0.47(-5.99;6.94)	1.0
Sugars (g)	78.09(71.76)	116.70(90.74)	103.08(79.66)	<0.0001	-24.99(-38.54;-11.43)	<0.0001	-38.60(-52.17;-25.03)	<0.0001	13.61(0.04;27.19)	0.05
Sodium (mg)	1914.81(2121.69)	2875.46(2298.01)	2803.92(2232.81)	<0.0001	-889.11(-1260.04;-518.19)	<0.0001	-960.66(-1332.06;-589.26)	<0.0001	71.54(-299.86;442.95)	0.9
Fiber (g)	17.13(17.45)	29.81(21.11)	26.17(20.05)	<0.0001	-9.04(-12.32;-5.76)	<0.0001	-12.68(-15.96;-9.4)	<0.0001	3.64(0.36;6.92)	0.03
Proteins (g)	98.66(92.33)	145.51(93.35)	142.44(94.72)	<0.0001	-43.78(-59.41;-28.15)	<0.0001	-46.85(-62.5;-31.2)	<0.0001	3.07(-12.58;18.72)	0.9

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). SD: Standard Deviation

Table S7 Percentage of the number of products in the shopping cart from the different food categories

Food groups	Nutri-Score	Reference Intakes	No label
Fruits, vegetables, legumes, grains and starches			
Fresh fruits	17,69(22,1)	7,14(6,76)	7,07(6,68)
Processed fruits	1,96(8,99)	0,73(1,72)	0,82(2,05)
Fresh vegetables	6,13(10,74)	10,76(9,87)	9,73(8,82)
Processed vegetables	2,79(5,09)	4,22(5,14)	3,43(4,69)
Legumes and potatoes	1,50(3,45)	3,08(4,64)	2,49(5,28)
Seeds and dried fruits	0,81(2,44)	0,83(1,82)	1,08(3,14)
Dairy products	10,25(11,77)	12,46(10,36)	13,33(14,06)
Cheeses	2,96(5,01)	4,84(7,39)	5,17(6,15)
Meat, fish and processed foods			
Pre-packed meat	0,11(0,68)	0,20(0,99)	0,21(0,83)
Meat	12,52(14,99)	6,02(6,04)	6,94(10,14)
Processed meats	4,64(11,25)	3,35(4,93)	3,5(5,25)
Fresh fish	2,66(6,6)	2,71(5,94)	2,44(3,51)
Processed fish	0,51(1,84)	0,68(1,89)	0,79(3)
Sea delicatessen and canned fish	1,85(3,88)	2,58(3,83)	3,67(10,21)
Sweet products			
Biscuits	1,09(2,95)	2,40(8,16)	1,17(2,26)
Sweets	3,17(5,26)	5,24(5,39)	4,88(6,35)
Breakfast cereals	0,18(0,86)	0,32(1,27)	0,26(1,11)
Breads, rusks and pastries	1,78(4,90)	2,53(4,19)	3,56(9,43)
Ice creams	0,58(1,84)	0,73(2,09)	0,71(2,39)
Salty products			
Prepared dishes	1,26(3,39)	2,06(6,4)	1,75(3,68)
Pasta, rice, mashed potatoes and semolina	2,21(4,07)	4,68(9,44)	3,47(5,85)
Savoury aperitif products	0,44(1,40)	1,05(2,85)	0,66(1,79)
Salads	0,35(1,34)	0,40(1,53)	0,18(0,95)
Soups	0,49(2,21)	1,12(6,57)	1,08(7,57)
Sauces and condiments	3,75(9,23)	3,86(4,47)	4,26(6,07)
Oils and fats	4,43(9,22)	4,06(4,02)	3,92(4,04)
Beverages			
Waters	8,95(14,68)	5,96(8,85)	8,71(16,74)
Fruit juices	2,36(6,58)	1,52(5,77)	1,07(2,55)
Sweetened drinks and sodas	2,58(5,50)	4,48(6,51)	3,64(4,38)

Values correspond to mean (Standard deviation).

Table S8 Percent contributions of food groups to nutrient intakes of the overall shopping cart

Food groups	Calories			Saturated Fatty Acids		
	Nutri-Score	Reference Intakes	No label	Nutri-Score	Reference Intakes	No label
Fruits, vegetables, legumes, grains and starches						
Fresh fruits	12,03(21,1)	2,76(4,93)	2,53(2,98)	5,64(21,07)	0,43(5,11)	0,12(0,29)
Processed fruits	1,46(8,67)	0,31(0,91)	0,34(0,88)	0,92(8,48)	0,06(0,49)	0,05(0,15)
Fresh vegetables	1,93(6,41)	2,48(3,77)	2,06(2,48)	0,82(7,1)	0,30(1,19)	0,15(0,24)
Processed vegetables	0,92(2,29)	1,38(2,42)	1,18(3,18)	0,48(4,45)	0,43(1,60)	0,36(1,19)
Legumes and potatoes	2,47(5,55)	5,15(8,23)	4,10(7,97)	0,39(2,42)	0,63(3,61)	0,78(5,35)
Seeds and dried fruits	2,19(5,88)	2,33(5,16)	2,97(6,77)	1,49(4,68)	1,60(4,44)	1,87(6,25)
Oils and fats	7,61(11,16)	8,01(8,74)	9,57(13,59)	10,79(16,63)	12,86(15,25)	14,02(18,27)
Beverages	5,38(9,19)	8,32(11,10)	9,81(10,39)	11,87(18,7)	19,59(21,72)	22,38(21,8)
Meat, fish and processed foods						
Pre-packed meat	0,08(0,52)	0,20(1,20)	0,23(0,98)	0,1(0,81)	0,37(3,46)	0,37(1,85)
Meat	18,07(24,94)	6,51(8,20)	7,63(12,95)	22,31(34,83)	6,99(12,52)	6,25(12,70)
Processed meats	4,77(11,74)	3,68(7,20)	3,84(5,55)	5,66(15,52)	4,29(9,25)	4,65(9,43)
Fresh fish	2,17(7,01)	2,2(6,38)	1,62(2,62)	1,69(8,35)	1,46(7,16)	0,67(1,69)
Processed fish	0,38(1,58)	0,58(2,17)	0,63(2,16)	0,22(1,05)	0,45(3,01)	0,46(2,49)
Sea delicatessen and canned fish	1,92(5,13)	2,64(4,66)	3,51(10,18)	1,43(5,13)	1,85(4,58)	2,41(9,00)
Sweet products						
Biscuits	2,41(5,96)	4,77(11,63)	3,05(6,08)	2,23(6,55)	4,9(13,55)	2,75(6,73)
Sweets	5,54(10,11)	8,64(9,86)	8,42(10,7)	7,24(14,58)	11,47(16,33)	10,06(14,67)
Breakfast cereals	0,33(1,55)	0,66(2,51)	0,58(2,45)	0,10(0,54)	0,25(1,34)	0,15(0,77)
Breads, rusks and pastries	3,16(7,95)	4,28(6,62)	5,76(11,22)	0,94(3,49)	0,94(2,46)	2,09(10,59)
Ice creams	0,50(1,58)	0,7(2,44)	0,65(2,83)	0,89(3,63)	1,10(4,07)	0,82(3,77)
Salty products						
Prepared dishes	1,44(3,66)	2,24(6,88)	2,22(4,84)	1,25(3,46)	2,07(7,24)	2,06(7,47)
Pasta, rice, mashed potatoes and semolina	4,05(7,18)	8,37(13,13)	6,57(9,03)	0,86(3,79)	2,33(10,33)	1,10(3,15)
Savoury aperitif products	0,97(3,09)	2,30(5,50)	1,6(4,26)	0,43(1,82)	1,16(3,53)	0,76(2,21)
Salads	0,21(0,83)	0,25(1,06)	0,12(0,67)	0,08(0,34)	0,12(0,62)	0,04(0,22)
Soups	0,16(1,29)	0,57(5,53)	0,67(7,40)	0,15(1,35)	0,52(5,39)	0,61(7,41)
Sauces and condiments	2,72(8,87)	1,94(3,23)	2,20(5,24)	1,90(8,97)	0,96(2,07)	1,14(4,45)
Oils and fats	14,60(18,45)	16,48(14,66)	16,68(15,00)	19,52(25,10)	21,53(20,74)	22,84(21,77)
Beverages						
Waters	0(0,03)	0(0,03)	0(0,03)	0(0,05)	0(0,10)	0,01(0,11)
Fruit juices	1,26(4,70)	0,63(5,25)	0,36(1,03)	0(0)	0(0)	0(0)
Sweetened drinks and sodas	1,29(5,36)	1,62(4,61)	1,12(3,61)	0,62(3,36)	1,36(5,99)	1,04(4,14)

The relatively high contributions of calories and saturated fatty acids for fruits and vegetables in the Nutri-Score arm could be partly explained by participants having only fruits or vegetables in their shopping carts, thus increasing the overall contribution at the sample level, even though they are low in calories and saturated fatty acids.

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Table S9 Distribution of the products across the five Nutri-Score classes

Nutri-Score	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	Mean proportion	Mean proportion	Mean proportion		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
A	58.16±25.02	53.3±20.26	52.53±20.07	0.0004	5.63(2.02;9.24)	0.0008	4.85(1.24;8.47)	0.005	0.78(-2.86;4.41)	0.9
B	10.55±10.43	13.87±10.09	15.55±14.14	<0.0001	-5.01(-6.93;-3.08)	<0.0001	-3.33(-5.26;-1.4)	0.0002	-1.68(-3.62;0.26)	0.1
C	15.60±19.08	12.14±10.82	11.52±11.2	<0.0001	4.08(1.73;6.43)	0.0001	3.46(1.10;5.81)	0.002	0.62(-1.74;2.99)	0.8
D	12.30±12.92	16.05±11.51	15.98±12.02	<0.0001	-3.68(-5.69;-1.68)	<0.0001	-3.75(-5.76;-1.74)	<0.0001	0.06(-1.95;2.08)	1.0
E	3.40±5.69	4.63±8.57	4.42±5.42	0.02	-1.02(-2.12;0.08)	0.07	-1.23(-2.34;-0.13)	0.02	0.21(-0.90;1.33)	0.9

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). All products were taken into account, including also raw foods that were non-labelled.

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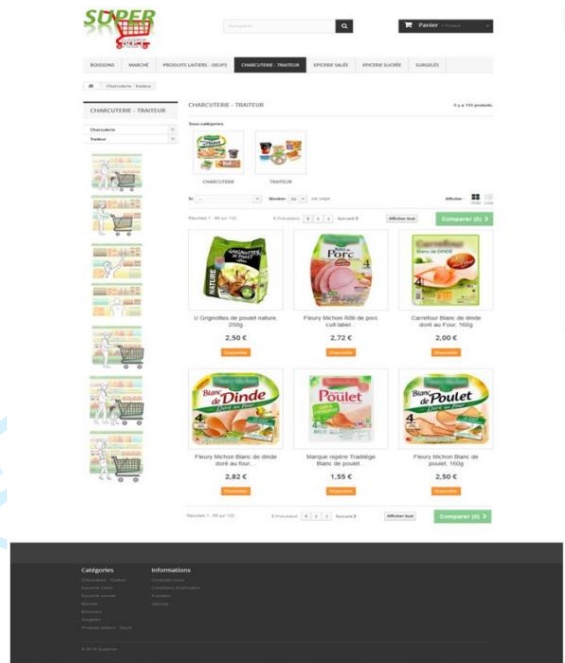


Figure S1 Screenshot of the experimental online supermarket



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5-6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4-5
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-17
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Impact of the Nutri-Score front-of-pack nutrition label on purchasing intentions of individuals with chronic diseases: results of a randomized trial

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3 **Impact of the Nutri-Score front-of-pack nutrition label on purchasing intentions of**
4 **individuals with chronic diseases: results of a randomized trial**
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3 21 **ABSTRACT**
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5 22 **Objective** : To our knowledge, the effect of front-of-pack nutrition labels such as the Nutri-
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7 23 Score on food purchases has never been assessed among individuals suffering from nutrition-
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9 24 related chronic diseases specifically, while dietary modifications are generally part of their care.
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11 25 This study aimed to investigate the effect of the Nutri-Score on the nutritional quality of
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13 26 purchasing intentions among adults suffering from a cardiometabolic disease, compared to no
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15 27 label and the Reference Intakes (RIs), a label already implemented by some food manufacturers
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17 28 in France.

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21 29 **Setting**: Secondary prevention – mainland France

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24 30 **Participants** : 2,431 eligible participants were randomly assigned and 1,180 participants
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26 31 (65.5% women, mean age 65.0±7.1 years) completed the shopping task and were included in
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28 32 the analyses.

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31 33 **Intervention**: A three-arm randomized controlled trial using an experimental online
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33 34 supermarket was conducted in 2017. Participants with cardiometabolic diseases were invited to
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35 35 simulate food purchases with the Nutri-Score, the RIs or no label.

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37 36 **Primary and secondary outcome measures** : The primary outcome was the nutritional quality
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39 37 of the shopping cart, estimated using the French-modified Food Standard Agency Nutrient
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41 38 Profiling System (FSAm-NPS), and secondary outcomes included the nutrient content of
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43 39 purchases.

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46 40 **Results**: The mean (SD) FSAm-NPS score was significantly lower in the Nutri-Score arm
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48 41 (1.29(3.61) points), reflecting a higher overall nutritional quality of purchasing intentions,
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50 42 compared to the RIs (1.86(3.23) points) and no label (1.92(2.90) points) arms (p-value=0.01).
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52 43 Moreover, the Nutri-Score led to significantly lower content in calories and saturated fatty acids
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54 44 compared to the two other arms. These differences resulted from participants avoiding some
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3 45 packaged products (sweets, dairy and starches) and purchasing larger amounts of fresh fruit and
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5 46 meat.

7 47 **Conclusions:** The Nutri-Score exhibited a significant higher nutritional quality of purchasing
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9 48 intentions, encouraging healthier food choices among individuals suffering from
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11 49 cardiometabolic chronic diseases.

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14 50 **Trial registration :** NCT02769455
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19 52 **Article summary**

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21 53 Strengths and limitations of this study

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24 54 • Inclusion of a rarely explored population in a randomized controlled trial pertaining to
25
26 55 the effectiveness of front-of-package labelling on food choices
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28 56 • This controlled experimental environment allowed assessing the effect of the Nutri-
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30 57 Score in standardized conditions and optimizing internal validity of the study.
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32 58 • Limitation pertaining to a high rate of participants who did not complete the shopping
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34 59 task.
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36 60 • The trial investigated purchasing intentions rather than actual food purchases.
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42 62 **Keywords:** Front-of-pack nutrition label; cardiometabolic diseases; Food purchases;
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44 63 Nutritional quality; Experimental online supermarket
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64 INTRODUCTION

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66 Non-Communicable Diseases (NCDs), such as obesity, type 2 diabetes, cardiovascular diseases
67 and cancer have become a major burden for the current health systems.[1] For these diseases,
68 dietary factors have been recognized to be one of the major leading risk factors in developed
69 countries, resulting in 11 million deaths worldwide in 2017, and represent modifiable
70 determinants through primary prevention.[2] In France, cardiovascular diseases remain the
71 second leading cause of deaths by NCDs, accounting for 30% approximately of mortality.[3]
72 Regarding obesity, the prevalence was estimated at 17% within the French adult population in
73 2015,[4] and the prevalence of type 2 diabetes was around 5% in 2016.[5]

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75 Hence, in the context of secondary or tertiary prevention, many treatment guidelines highlight
76 the importance to modify dietary habits to improve the nutritional status of individuals and thus
77 control these nutrition-related NCDs.[1] For example, controlling for saturated fatty acids
78 (SFA), sugars and salt intakes and increasing fruits and vegetables, pulses, and fibres
79 consumption are encouraged in the management of several NCDs or risk factors such as obesity,
80 arterial hypertension and diabetes.[1] Nutritional labelling has been suggested to be an
81 interesting tool in helping individuals suffering from NCDs achieve balanced nutritional
82 intakes.[6] However, it has been shown that nutritional information on the back of packages
83 were poorly understood and used during food choices.[7] While few studies have suggested
84 that individuals suffering from nutrition-related NCDs would pay more attention to nutritional
85 information and check for specific nutrients,[8,9] another study has observed no difference of
86 nutritional information use between patients and individuals with no chronic condition.[6]

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3 88 In the last decade, Front-of-Pack nutrition Labels (FoPLs) have been identified to improve the
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5 89 nutritional quality of food choices at the point-of-purchase in the general population,[10–19]
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8 90 and to encourage reformulation and innovation of food products.[20,21] In France, the
9
10 91 summary FoPL Nutri-Score has been adopted in October 2017 (and then in several European
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12 92 countries) to indicate the nutritional quality of products in supermarkets.[22] By the end of
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14 93 2019, the brands which adopted the Nutri-Score represented approximately 25% of the volume
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16 94 of pre-packed foods sales with more than 300 manufacturers engaged.[23] The Nutri-Score has
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18 95 been demonstrated to be well perceived, understood and to have a positive effect on food
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20 96 purchases in the general French population[14,18,24–27] and students.[28] However, as the
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22 97 measure is implemented on a voluntary basis, it coexists on the French market with the
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24 98 Reference Intakes label (RIs),[29] used by multiple food manufacturers since 2006 in Europe,
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26 99 and the absence of any front-of-pack labelling.
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33 101 To our knowledge, no study has specifically investigated the effect of FoPLs, including the
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35 102 Nutri-Score, on food purchasing intentions of patients suffering from nutrition-related NCDs
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37 103 only. Thus, the study aimed to determine the effect of the Nutri-Score on purchasing intentions
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39 104 of individuals suffering from nutrition-related cardiometabolic chronic diseases, compared to
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41 105 the current French labelling situations, i.e. the RIs or no FoPL, as a secondary or primary
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43 106 prevention tool.
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113 **METHODS**

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115 **Trial design and participants**

116 A three-arm parallel group randomized trial was conducted in 2017 targeting individuals
117 suffering from cardiometabolic NCDs. The study was approved by the Institutional Review
118 Bard of the INSERM (IRB n°IRB0000388 FWA00005831), the National Commission for Data
119 Protection and Liberties (CNIL n° 909216) and the *Comité consultatif sur le traitement de*
120 *l'information en matière de recherche dans le domaine de la santé*, and registered at
121 <https://clinicaltrials.gov/ct2/show/NCT02769455>. Electronic consent was obtained from each
122 participant. A methodology similar to a trial targeting students was used.[28]

123

124 Participants were recruited from the NutriNet-Santé cohort by a targeted emailing campaign in
125 2016, using the following criteria: age, BMI, and the declaration of one of the diseases included
126 in the present study. Briefly, the NutriNet-Santé is an ongoing web-based prospective
127 observational cohort study launched in France in May 2009, including adult volunteers
128 recruited by multi-media campaigns.[30] Each individual who agreed to participate was asked
129 to fulfil an inclusion questionnaire and provide information on gender, age, occupation,
130 educational level, household composition, and weekly budget for grocery shopping. They were
131 also asked to self-estimate their nutrition knowledge level on a 4-point scale (between “I am
132 very knowledgeable about nutrition” and “I do not know anything about nutrition”), and to
133 provide information on their grocery shopping frequency in general and online (“Always”,
134 “Often”, “Sometimes” and “Never”). Finally, they were invited to declare if they had been
135 diagnosed or were currently under medical supervision for at least one of the following
136 nutrition-related chronic diseases: obesity, type 2 diabetes, dyslipidaemia, arterial hypertension,

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3 137 cardiovascular disease. Thus, individuals involved in grocery shopping, over 50 years old, and
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5 138 with at least one of the chronic diseases from the list above, were eligible to participate.
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10 140 **Patient and public involvement**

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12 141 The research question underlying the study was driven by considerations regarding tools to
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14 142 improve patients' empowerment concerning their diets. Patients were not directly involved in
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16 143 the development of the protocol or in recruitment of participants. Dissemination of the research
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18 144 results will be done through the NutriNet-Santé cohort platform, with an abstract in the French
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20 145 language, allowing for all participants to be informed.
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26 147 **Randomization and blinding**

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28 148 Eligible participants were randomly allocated to one of the three arms using a random block
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30 149 method with permuted blocks of size 3, 6, 9 and 12, without stratification. The randomization
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32 150 list was only available to the independent statistician who generated the randomization
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34 151 sequence and the computer programmer who uploaded the list on the secured platform. Given
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36 152 the nature of the intervention, participants could not be blinded of the intervention; however,
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38 153 they were only informed about the main objectives of the experimental online supermarket,
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40 154 aiming to investigate determinants of purchasing behaviour. No information was given on the
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42 155 FoPLs or the explicit purpose of the trial.
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49 157 **Intervention and procedure**

51 158 **Experimental arm**

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53 159 The experimental arm consisted on the Nutri-Score applied on the front of package of all pre-
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55 160 packed foods included in the online supermarket. The Nutri-Score is a summary FoPL
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57 161 characterizing the overall nutritional quality of foods. The label is based on the Food Standards
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3 162 Agency Nutrient Profiling System, modified by the High Council of Public Health to better
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5 163 discriminate foods from specific categories (cheese, fats and beverages) consistently with
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7 164 nutritional recommendations (FSAm-NPS).[18] The FSAm-NPS is calculated for 100g (or
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9 165 100mL) of food, and allocates from 0 to 10 points for each nutrient which should be limited
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11 166 (energy (kJ), SFA (g), sugars (g), and sodium (mg)) and from 0 to 5 points to each favourable
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13 167 nutrient which should be encouraged (proteins (g), fibres (g), and the content in fruits,
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15 168 vegetables, legumes and nuts (%)). A discrete score is finally obtained by subtracting the
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17 169 favourable points from the unfavourable points, ranging therefore between a minimum of -15,
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19 170 for food products with higher nutritional quality, to a maximum of +40 points for food products
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21 171 with lower nutritional quality. Hence, the lower the FSAm-NPS score, the healthier the
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23 172 products. Then, the Nutri-Score is represented by a 5-colour scale with a corresponding letter,
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25 173 from dark green (A) indicating the highest nutritional quality to dark orange (E) for products
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27 174 with the lowest nutritional quality.
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35 176 Control arms

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37 177 Two control arms were also included: (1) the RIs FoPL was affixed on all pre-packed food
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39 178 items, and (2) no front-of-pack nutritional labelling at all. The RIs is a nutrient-specific
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41 179 monochromatic label endorsed by some manufacturers, indicating the kilocalories and the
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43 180 amount of fat, SFA, sugars and sodium in gram per serving, and their contribution in
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45 181 percentages to the guideline-based daily intakes.[29] In the no label arm, no nutrition label was
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47 182 applied on the front of food packages on the experimental online supermarket.
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54 184 The experimental online supermarket was composed of three sections. First, the upper section
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56 185 included the logo of the supermarket, a search bar, an access to the shopping cart, and the tabs
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58 186 for the different food categories. Second, a central section displaying advertisements and
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3 187 showing shoppers in a supermarket aisle was included. The rotating banner ad on the left side
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5 188 of the central section included one specific ad and four ads on non-dietary information such as
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7 189 information on national campaigns of health promotion. In the two arms with a FoPL, the
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9 190 specific ad drew awareness on the label with additional information on its computation and use.
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11 191 In the no label arm, additional information was provided on the proper conservation of fresh
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13 192 food products. On the central section, the participant could also view the different products
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15 193 depending on the food categories, and access the information (name, brand, price, nutritional
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17 194 information, etc) by clicking on the product. For the two label arms, the nutritional label was
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19 195 affixed on the front of the package and next to the product on a larger scale to improve its
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21 196 readability. Third, the lower section included links to the various food categories, links for
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23 197 information and links towards account information. An example of a food item included in the
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25 198 experimental online supermarket with its three versions depending on the trial arm is shown in
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27 199 Figure 1 and a picture of the experimental online supermarket is presented in Figure S1 [28].
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201 Procedure

202 For this specific purpose, an experimental online supermarket was developed, similar to
203 previous trials.[18,28] Eligible participants were invited to simulate a shopping task as if they
204 were in their usual supermarket, but without any payment required and no instruction on the
205 amount, the duration or the number of participants they were asked to shop for. The
206 experimental online supermarket resembled existing grocery shopping websites with a virtual
207 shopping cart, a virtual payment procedure, a search tab and promotional banners. As in real
208 shopping websites, participants could choose products categorized in multiple food groups and
209 subgroups, using a hierarchical structure and names of the categories similar to existing online
210 supermarkets. The food offer was a representative sample of the products commonly sold on
211 French online supermarkets and included 751 foods and beverages (pre-packed products

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3 212 carrying a FoPL on the Nutri-Score and RIs arms, and raw products without any label in the
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5 213 three arms according to the European regulation), divided into twenty food categories. For all
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7 214 products, name, brand, price (per unit and per kg or litter), a picture of the product (with or
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9 215 without a FoPL, depending on the arm) and the nutritional composition as well as the list of
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11 216 ingredients were provided. For each food item, at least two different products were proposed,
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13 217 including a national brand and a retailer's brand. The number of brands proposed balanced the
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15 218 nutritional variability observed for a given type of food.

19 219 **Outcomes**

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21 220 The primary outcome was the overall nutritional quality of the shopping cart, assessed by the
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23 221 mean of the FSAm-NPS score across all the items in the cart, computed for 100g. A lower
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25 222 overall FSAm-NPS score of the shopping cart reflects a higher nutritional quality of the entire
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27 223 selection of products within the cart. Minimal theoretical value is -15, maximal theoretical value
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29 224 is +40.

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31 225 Secondary outcomes were, by order of importance, the content of the shopping cart in energy,
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33 226 SFA, sugars, sodium, fibres, fruits and vegetables, and proteins, for 100g of the shopping cart.

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38 228 **Statistical analyses**

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41 229 The final sample size was calculated for an effect size of 0.2 (for the main outcome, FSAm-
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43 230 NPS score, calculated by minimization of estimates from previous studies showing a 0.62 point
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45 231 difference between Nutri-Score and control arm, with an SD of 2.55 of the average FSAm-NPS
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47 232 of the shopping cart [26]), a power of 90% and a p-value of 0.02 considering the three-arm
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49 233 design, resulting in 1,956 individuals, i.e. 652 participants per arm. To reach this final sample
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51 234 size while considering non-respondents, 2,431 individuals were initially randomized and the
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53 235 number of individuals validating their shopping cart was monitored.

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3 237 Per protocol analyses were carried out, given that only one measure was collected for the
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5 238 outcome. All participants meeting the inclusion criteria and who completed the shopping task
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8 239 were included in the analyses. The primary outcome was compared between the three trial arms
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10 240 using one-way ANOVA ($p\text{-value}\leq 0.05$ significant). Pairwise comparisons among FoPLs were
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12 241 performed using Tukey tests to consider multiple comparisons ($p\text{-value}\leq 0.05$ significant).
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14 242 Then, secondary outcome variables were also compared between the three arms using a
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16 243 hierarchical gatekeeping strategy[28] with the following order: 1. Energy, 2. SFA, 3. Sugars, 4.
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18 244 Sodium, 5. Fibres, 6. Fruits and vegetables, 7. Proteins. When the comparison across the three
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20 245 arms for a component was not significant, the comparison of following secondary outcomes
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22 246 was stopped. The gatekeeping strategy order was determined using the relative importance of
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24 247 the various nutrients to health (with the most unfavourable elements first) and the results of
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26 248 previous studies assessing FoPL effects on the nutritional quality of food purchases.[18]
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28 249 Analyses were performed considering the FSAm-NPS score of all products from the
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30 250 experimental supermarket, including also raw items that were not labelled in any trial arm (i.e.
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32 251 fruits, vegetables, meat and poultry). Multiple sensitivity analyses were then performed. First,
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34 252 sensitivity analyses were computed (1) including only labelled food products (i.e. pre-packed
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36 253 foods and beverages), (2) excluding participants whose spending amount was below the 5th
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38 254 percentile or over the 95th percentile of the distribution of the cost of the shopping carts in the
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40 255 sample, and (3) using multiple imputations on missing outcomes (25 imputed sets) to consider
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42 256 the non-response rate and thus provide intention-to-treat estimates. Missing primary and
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44 257 secondary outcomes of non-respondents were imputed using the individual characteristics of
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46 258 the individuals, including sociodemographic and nutrition-related lifestyle data collected in the
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48 259 inclusion questionnaire. The total quantities of calories, SFA, sugars, sodium, fibres, and
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50 260 proteins in the shopping carts were also calculated and compared across the three arms using
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52 261 ANOVA. The composition of the shopping cart across the different food categories was
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3 262 calculated in percentage of the total number of products in the cart (mean and standard error).
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5 263 The contributions of each food group to the nutrient amounts in the shopping carts were then
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7 264 calculated and expressed a mean percentage and standard error. Finally, the distribution of the
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10 265 products across the different Nutri-Score classes was also compared between the three arms,
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12 266 taking into account all food products including raw foods that were non-labelled.
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17 268 All tests of significance were two-sided, and analyses were carried out with the SAS software
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19 269 (version 9.4; SAS Institute, Inc.).
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25 272 **RESULTS**

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30 274 Among 3,728 individuals with chronic diseases assessed for eligibility, 1,297 did not meet
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32 275 inclusion criteria, resulting in 2,431 participants randomly assigned to one of the three arms
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34 276 (Figure 2). Among them, 1,180 individuals with a nutrition-related chronic disease fully
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36 277 completed the shopping task and were finally included in the analyses. The other subjects who
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38 278 did not complete their shopping cart were excluded from the analyses, as their purchasing
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40 279 behaviour may not be representative of their habits. Overall, participants of the trial included
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42 280 65.5% of women, 27.8% of subjects with primary educational level, and their mean age was
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44 281 65.0±7.1 years (Table 1). Regarding purchasing behaviour, 61.2% declared doing always their
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46 282 grocery shopping and 29.7% reported having purchased foods online at least once. Among
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48 283 them, 16.2% reported purchasing online at least one time per week. 57.2% of the included
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50 284 participants declared having an intermediate self-estimated nutrition knowledge level, and
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52 285 51.4% often reading the nutrition facts. The two main chronic diseases represented in the trial
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54 286 were arterial hypertension (65.7%) and dyslipidaemia (33.9%), then followed by cardiovascular
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3 287 diseases (15.2%), type 2 diabetes (14.7%), and obesity (13.8%). Approximately 30% of
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5 288 participants reported having more than one of the diseases included in the trial. Individual
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7 289 characteristics of participants were globally similar between the three arms. The mean cost of
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9 the shopping cart was 75.0±51.5 euros overall, 80.0±57.8 euros in the Nutri-Score arm,
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11 73.9±48.3 euros in the RIs arm and 71.2±47.3 euros in the no label arm. The mean weight of
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13 the shopping carts was 16.6±14.3 kg in the Nutri-Score arm with 22.9±21.9 products on
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15 average, 24.2±14.7 kg in the Reference Intakes arm with 33.6±22.0 products on average, and
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17 22.7±14.2 kg in the no label arm with 31.1±21.3 products on average.
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23 296 According to the flow diagram, approximately 50% of participants did not complete the virtual
24 297 shopping task. Individual characteristics between respondents and non-respondents were
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26 298 compared for intention-to-treat analyses and results are displayed in Table S1. Even if non-
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28 299 respondents had some small disparities on their sociodemographic and lifestyle characteristics
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30 compared to respondents, this potential bias was similar in the three arms. Indeed, the
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32 interaction term between each individual characteristic and the arm to model the probability of
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34 no response was not statistically significant (p-value≥0.1).
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Table 1 Individual characteristics of included participants, NutriNet-Santé cohort (n=1,180)

	Nutri-Score	Reference Intakes	No label	Total
Total (n)	394	392	394	1180
Gender, n(%)				
Men	131 (33.3)	124 (31.6)	152 (38.6)	407 (34.5)
Women	263 (66.7)	268 (68.4)	242 (61.4)	773 (65.5)
Age, years	64.8 ± 6.9	64.8 ± 7.3	65.4 ± 7.1	65.0 ± 7.1
Educational level, n(%)				
Primary	122 (31.0)	102 (26.0)	104 (26.4)	328 (27.8)
Secondary	53 (13.4)	51 (13.0)	74 (18.8)	178 (15.1)
University, undergraduate degree	103 (26.1)	122 (31.2)	99 (25.1)	324 (27.4)
University, postgraduate degree	98 (24.9)	102 (26.0)	103 (26.1)	303 (25.7)
Other	18 (4.6)	15 (3.8)	14 (3.6)	47 (4.0)
Grocery shopping frequency, n(%)				
Always	231 (58.63)	252 (64.3)	239 (60.6)	722 (61.2)
Often	122 (30.96)	107 (27.3)	113 (28.7)	342 (29.0)
Sometimes	41 (10.41)	33 (8.4)	42 (10.7)	116 (9.8)
Online grocery shopping, yes n(%)	119 (30.2)	129 (32.9)	103 (26.1)	351 (29.7)
Online grocery shopping frequency, n(%)				
At least one time per week	16 (13.4)	20 (15.5)	21 (20.4)	57 (16.2)
One or two times per month	22 (18.5)	26 (20.1)	15 (14.5)	63 (18.0)
One time every two or three months	29 (24.4)	33 (25.6)	17 (16.5)	79 (22.5)
One or two times per year	23 (19.3)	21 (16.3)	29 (28.2)	73 (20.8)
Less than one time per year	29 (24.4)	29 (22.5)	21 (20.4)	79 (22.5)
Weekly budget for grocery shopping (€), n(%)				
< 30€	13 (3.3)	17 (4.3)	16 (4.1)	46 (3.9)
30 – 50€	76 (19.3)	74 (18.9)	63 (16.0)	213 (18.0)
50 – 100€	151 (38.3)	168 (42.9)	160 (40.6)	479 (40.6)
> 100€	151 (38.3)	130 (33.1)	147 (37.3)	428 (36.3)
Missing	3 (0.8)	3 (0.8)	8 (2.0)	14 (1.2)
Perceived nutritional knowledge, n(%)				
High	38 (9.6)	38 (9.7)	22 (5.6)	98 (8.3)
Intermediate	222 (56.4)	220 (56.1)	233 (59.1)	675 (57.2)
Low	125 (31.7)	125 (31.9)	124 (31.5)	374 (31.7)
No	9 (2.3)	7 (1.8)	9 (2.3)	25 (2.1)
Missing data	0	2 (0.5)	6 (1.5)	8 (0.7)
Nutrition facts reading frequency, n(%)				
Always	63 (16.0)	55 (14.0)	54 (13.7)	172 (14.6)
Often	202 (51.3)	199 (50.8)	206 (52.3)	607 (51.4)
Sometimes	117 (29.7)	122 (31.1)	119 (30.2)	358 (30.3)
Never	12 (3.0)	14 (3.6)	9 (2.3)	35 (3.0)
Missing data	0	2 (0.5)	6 (1.5)	8 (0.7)
Chronic disease diagnosed, n(%)				
Arterial hypertension	265 (67.3)	256 (65.3)	254 (64.5)	775 (65.7)
Diabetes mellitus	51 (12.9)	55 (14.0)	67 (17.0)	173 (14.7)
Cardiovascular disease	65 (16.5)	48 (12.2)	66 (16.8)	179 (15.2)
Dyslipidemia	141 (35.8)	127 (32.4)	132 (33.5)	400 (33.9)
Obesity	43 (10.9)	58 (14.8)	62 (15.7)	163 (13.8)
Total cost of the shopping cart (€)	80.0 ± 57.8	73.9 ± 48.3	71.2 ± 47.3	75.0 ± 51.5

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3	Number of products in the shopping cart	22.9 ± 21.9	33.6 ± 22.0	31.1 ± 21.3	29.2 ± 22.2
4	Weight of the shopping cart (kg)	16.6 ± 14.3	24.2 ± 14.7	22.7 ± 14.2	21.2 ± 14.8

5 Values are mean ± standard deviation or n (%) as appropriate.

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For peer review only

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3 313 **Outcomes**
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5 314 The FSAm-NPS score was lower in the Nutri-Score arm (1.29 ± 3.61 points), reflecting a higher
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7 overall nutritional quality of the shopping carts, followed by the RIs arm (1.86 ± 3.23 points)
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9 and no label (1.92 ± 2.9 points) (Table 2). The difference of FSAm-NPS scores were statistically
10 316
11 significant between the Nutri-Score and the RIs groups (mean difference= $-0.57[-1.11;-0.02]$;
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13 p-value= 0.04), and between the Nutri-Score and no label ($-0.63[-1.17;-0.08]$; p-value= 0.02).
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15 No significant difference was observed between the RIs and no label ($-0.06[-0.61;0.48]$; p-
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17 value= 1.0). Furthermore, the Nutri-Score label led to a significantly lower content of the
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19 shopping carts in calories and SFA, compared to the RIs and no label (p-values ≤ 0.0001 for
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21 comparisons of calories between the Nutri-Score and both RIs and no label; p-values= 0.01 for
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23 comparisons of SFA between the Nutri-Score and both RIs and no label). The differences
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25 between the RIs and no label arms were not significant. The differences of sugars content
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27 between the three arms were not significant; then comparisons of subsequent secondary
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29 outcomes were stopped.
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Table 2 Overall nutritional quality, energy and nutrient content for 100g of the shopping cart

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	n=394	n=392	n=394		Difference ^a	P ^b	Difference ^a	P ^b	Difference ^a	P ^b
Overall nutritional quality (FSAm-NPS score/100g)	1.29 ±3.61	1.86 ± 3.23	1.92 ±2.9	0.01	-0.63 (-1.17;-0.08)	0.02	-0.57 (-1.11;-0.02)	0.04	-0.06 (-0.61;0.48)	1.0
Calories (kcal/100g)	153.53 ±76.96	184.06 ±64.38	175.38 ±64.22	<0.0001	-21.85 (-33.35;-10.35)	<0.0001	-30.53 (-42.05;-19.02)	<0.0001	8.68 (-2.83;20.20)	0.2
Saturated fatty acids (g/100g)	3.24 ±3.13	3.78 ±2.13	3.77 ±2.36	0.004	-0.53 (-0.96;-0.10)	0.01	-0.53 (-0.96;-0.10)	0.01	0.01 (-0.42;0.44)	1.0
Sugars (g/100g)	5.92 ±3.58	5.89 ±3.25	5.65 ±3.81	0.5	0.27 (-0.32;0.87)	0.5	0.03 (-0.56;0.63)	1.0	0.24 (-0.35;0.84)	0.6
Sodium (mg/100g)	189.83 ±200.21	195.51 ±104.13	212.73 ±158.16							
Fibers (g/100g)	1.37 ± 0.99	1.89 ±1.17	1.65 ±0.97							
Fruits and vegetables (%)	34.12 ± 22.87	29.51 ±16.03	28.90 ±14.81							
Proteins (g/100g)	7.36 ± 3.43	7.29 ±2.20	7.58 ±3.33							

^a Mean difference (95% Confidence Interval)^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

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3 328 When analyses considered pre-packed products only, the overall difference of shopping carts'
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5 329 FSAm-NPS score between the three arms was no longer significant suggesting inter-food group
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7 330 substitutions (Table S2). However, results for the secondary outcomes remained consistent with
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9 331 the main analyses. In sensitivity analyses excluding outliers on the spending amount, similar
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11 332 results were observed for primary and secondary outcomes (Table S3). Results of the sensitivity
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13 333 analyses using multiple imputations and providing intention-to-treat estimates are presented in
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15 334 Table S4 for analyses considering all food products and Table S5 for analyses considering only
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17 335 labelled food items. Results using multiple imputations were consistent with the main analyses;
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19 336 however, the amplitude of differences between arms was lower and comparisons were no longer
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21 337 significant, except for calories for which the Nutri-Score also led to lower contents compared
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23 338 to the two other arms (Tables S4 and S5). The participants in the Nutri-Score arm purchased less
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25 339 calories, SFA, sugars, sodium, fibres, and proteins compared to the two other arms (Table S6).
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29 341 Table S7 describes the shopping carts composition in terms of the mean number of products
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31 342 per food category in each of the three arms. In the Nutri-Score arm, participants tended to
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33 343 purchase more products from the fruits (especially fresh fruit), meat and water categories
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35 344 (compared to the RIs), and fewer products from vegetables, dairy products, cheeses, sweets and
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37 345 starchy foods such as pasta, rice, rush potatoes and semolina. The average percentages of raw
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39 346 products (i.e. not labelled in the label arms) purchased by participants were 32.9%±18.4% in
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41 347 the no label arm, 33.2%±18.2% in the RIs arm, and 42.0%±28.1% in the Nutri-Score arm. The
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43 348 percentage contributions of food groups to nutrient intakes in the overall shopping carts are
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45 349 presented in Table S8 (only for nutrients where a difference between arm was observed in the
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47 350 main analyses). Thus, the lower calorie and SFA contents of the shopping carts in the Nutri-
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49 351 Score arm compared to the RIs arms could be explained by fewer products purchased in the
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51 352 dairy products, cheese, but also sweets and starchy foods. Finally, the proportion of healthier
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3 353 food products in the shopping carts classified as A was significantly higher in the Nutri-Score
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5 354 arm compared to the two other arms (difference = 5.63 [2.02;9.24], p-value=0.0008 compared
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7 355 to no label; difference = 4.85 [1.24;8.47], p-value=0.005 compared to the RIs), which can be
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9 356 partly explained by the higher proportion of raw fruits and meats in the shopping carts of
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11 357 participants from the Nutri-Score group – corresponding to products with higher nutritional
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13 358 quality (Table S9). On the contrary, the proportion of unhealthier products classified as D or E
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15 359 was significantly lower in the Nutri-Score arm compared to the two other arms or the RIs only.
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17 360 No significant difference was observed between the RIs and no label.
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26 363 **DISCUSSION**

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30 365 Results of the present study showed that the Nutri-Score label significantly led to an
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32 366 improvement of the overall nutritional quality of food purchasing intentions in individuals with
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34 367 cardiometabolic chronic disease. Moreover, the Nutri-Score led to lower contents of the
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36 368 shopping carts in energy and SFA compared to the two other arms. Similar trends were observed
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38 369 with multiple imputations; nevertheless, differences were no longer statistically significant. No
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40 370 significant difference was observed between the RIs and no label. Moreover, in both FoPLs
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42 371 arms, and particularly in the Nutri-Score arm, substitutions between food groups were observed,
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44 372 with more raw products purchased – corresponding mainly to fruits and butcher's meats from
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46 373 higher nutritional quality. It appeared that the participants exposed to the Nutri-Score purchased
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48 374 less products and from higher overall nutritional quality (i.e. lower FSAm-NPS score).
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56 376 The present findings are consistent with studies which observed a positive effect of interpretive
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58 377 FoPLs and especially the Nutri-Score on the nutritional quality of intentional or real food
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3 378 purchases, while the RIs demonstrated a limited or non-significant effect in the general
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5 379 population [14,18] or students.[28] This could be partly explained by the features of the
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7 380 schemes. Indeed, the summary indicator of the Nutri-Score, combining colours and text, would
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9 381 be easier to read and understand.[16,18,19,31–37] On the contrary, the RIs with its nutrient-
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11 382 specific and monochromatic format, has been shown to be more complicated to identify and
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13 383 understand in the general population,[18,36,37] creating notably potential decisional conflicts
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15 384 and prioritization of nutrients.[38] Nevertheless, to our knowledge, this is the first study to
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17 385 assess the effect of FoPLs on purchasing intentions among individuals suffering from nutrition-
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19 386 related NCDs. Only one study investigated the effect of the Traffic Lights nutrient-specific label
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21 387 and the three-stars summary label on food purchases in vending machine among patients in an
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23 388 Australian hospital and observed a positive effect of the labels to identify healthier products.
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25 389 However, the experiment was performed in a specific context and no focus was made on
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27 390 patients suffering specifically from nutrition-related NCDs.[12]
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35 392 Interestingly, while previous studies among patients with hypertension, hypercholesterolemia,
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37 393 type 2 diabetes or hyperlipidaemia found that they were more likely to read information on salt
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39 394 and SFA respectively,[39] and have lower intakes in energy and SFA,[9] in the present study,
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41 395 the RIs did not help consumers to select products with significantly less SFA compared to no
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43 396 label. On the contrary, the Nutri-Score which does not provide numerical data but rather
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45 397 summarized information, led to significantly lower contents of the shopping carts in SFA
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47 398 compared to no label and the RIs. These results on the Nutri-Score effect are particularly
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49 399 important, given that a decrease of the intakes in energy, SFA and salt with an increase of fruits
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51 400 and vegetables consumption are recommended among patients suffering from nutrition-related
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53 401 NCDs.[1] Moreover, despite these recommendations, it has been observed in a study within the
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55 402 NutriNet-Santé cohort that adults with a cardiometabolic disease tended to have unhealthier
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3 403 dietary habits overall (e.g. lower intakes of fruits, higher intakes of meat, processed meat and
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5 404 added fats) compared to healthy controls,[40] which supports the interest of public health
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7 405 measures encouraging healthier food choices among these individuals.
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12 407 When analyses were restricted to labelled items only, no significant difference of the overall
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14 408 nutritional quality between the Nutri-Score and the other arms was found. These results reflect
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16 409 that the use of the Nutri-Score may encourage also substitutions between food categories.
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18 410 Indeed, participants who were exposed to the Nutri-Score tended to purchase more non-labelled
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20 411 raw products, in particular fruits, meat and poultry, characterized by healthier nutritional
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22 412 quality. This substitution between food categories has been observed in other populations under
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24 413 the same or similar experimental conditions [28,41,42]. Some hypotheses could explain these
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26 414 results. In general, the impact of front-of-pack labelling has been found to vary according the
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28 415 food category [43], partly in relation to consumer motivation [44]. More specifically, the Nutri-
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30 416 Score provides an explicit comparative scale of the nutritional quality of pre-packed foods and
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32 417 may have raised awareness as to the lower nutritional value of some pre-packed products. By
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34 418 comparison, this may have heightened the perceived healthiness fruit or meat products, even in
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36 419 the absence of any labelling. As to beverages, water being the only beverage receiving a 'A'
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38 420 Nutri-Score, its promotion is particularly straightforward in the system. Another hypothesis
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40 421 relates to the overall awareness to the importance of food choices that the presence of the Nutri-
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42 422 Score may have spurred, acting as a global reminder of previously received nutritional
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44 423 education in patients. In doing so, the Nutri-Score scheme may cue concerns/motivations about
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46 424 eating healthier products overall[45]. Finally, the choice to purchase more fresh fruits, meats,
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48 425 and water (perceived as A-grade products) may also suggest compensatory behaviours designed
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50 426 to offset choosing some less healthy products. It may also be worth noting that in choosing
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52 427 more fresh fruits, meats, and water, (rather than increasing the purchase of vegetables),
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3 428 consumers may also seek to balance the perceived healthiness of their choices with perceived
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5 429 taste/palatability. These speculations as to the motivations and goals underlying specific food
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8 430 choices patterns following the introduction of a front-of-pack labelling scheme should be
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10 431 further explored in future studies, to devise efficient strategies to reinforce the observed trends.
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14 433 The present study provides insights regarding the effect of the Nutri-Score on purchasing
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16 434 intentions of individuals with nutrition-related NCDs compared to the current labelling situation
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19 435 in France and other European countries. First, strength of the study pertained in the inclusion
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21 436 of a specific population rarely explored in the nutritional labelling field, and its randomized
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24 437 controlled design, which resulted in comparable groups allowing accurate estimations of the
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26 438 labels' effect. Furthermore, the experiment was conducted on an experimental online
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29 439 supermarket, closed to real online grocery shopping conditions, with a range of different
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31 440 products with distinct nutritional profiles, brands and the use of real packaging. This controlled
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33 441 experimental environment allowed assessing the effect of the Nutri-Score in standardized
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35 442 conditions and optimizing internal validity of the study. Finally, we provided intention-to-treat
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38 443 analyses of the participants (Table S1) and intention-to-treat estimates through multiple
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40 444 imputation methods. Nevertheless, some limitations should be acknowledged. First, a high rate
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42 445 of participants did not complete the shopping task. Hence, respondents may have different
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45 446 individual characteristics, leading however to a potential non-differential bias which could limit
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47 447 the generalizability of the results. In addition, the reduced sample size could have led to a
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49 448 decreased statistical power preventing us from detecting some potential small differences.
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51 449 Moreover, it is important to notice that analyses with multiple imputations led to similar trends
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54 450 but with non-significant differences given the wide variance in the sample. Second, the trial
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56 451 involved voluntary participants, who may have greater interest and knowledge in nutrition than
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58 452 the French population of patients. Thus, participants in the no label arm might have made
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3 453 healthier food choices than the general population and the effects of FoPLs in comparison could
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5 454 have been underestimated. Third, despite the diversity of the food offer proposed, the number
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7 455 of products was somewhat limited, and some participants may not have found their usual
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9 456 product and chose foods they would not buy in real shopping situation. In addition, the
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11 457 representativity of the experimental food offer was not carefully assessed. These elements
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13 458 would limit the extern validity of the study and the generalisability of the results to a real online
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15 459 supermarket. Moreover, compared to the French average, the higher proportion of subjects who
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17 460 declared doing often their grocery shopping online, may have led to a sample with
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19 461 sociodemographic differences compared to the French population of patients. Fourth, the trial
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21 462 investigated purchasing intentions rather than actual food purchases that may have led the
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23 463 participants to take the experiment less seriously or to spend more money than they would
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25 464 actually do. Complementary studies should be conducted in real-life settings to provide
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27 465 additional elements on the Nutri-Score effectiveness. Nevertheless, virtual purchasing
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29 466 behaviours of individuals have been suggested to be good predictors of real behaviours.[46]
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31 467 Finally, the study included cases of self-reported cardiometabolic chronic conditions with no
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33 468 validation required. Therefore, we were not able to ascertain whether the participants were
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35 469 following specific diets or nutritional recommendations during the period of the trial, which
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37 470 could have modified their purchasing behaviours. The present study focused on the Nutri-Score
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39 471 effect as a secondary or tertiary prevention tool of NCDs, and complement previous studies
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41 472 which have been conducted on the general population including individual without any chronic
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43 473 conditions, or on specific subgroups such as students. Furthermore, it could have been
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45 474 interesting to also include individuals having someone in the household with a chronic
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47 475 condition.
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3 477 These results support that the Nutri-Score may improve the nutritional quality of food choices
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5 478 of consumers suffering from nutrition-related chronic diseases. This is particularly important
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7 479 given that an improvement of the dietary habits and the nutritional status of these individuals is
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9 480 a major element in the secondary prevention and the management of these non-communicable
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11 481 diseases. These findings are complementary to studies having observed a favourable effect of
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13 482 the Nutri-Score or its underlying nutrient profiling system on chronic diseases risk, in a context
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15 483 of primary prevention, through an improvement of food purchases and nutrient intakes.[18,47]
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493 **Competing interests**

494 All authors declare no competing interests.

496 **Author contributorship**

497 ME, CJ and IB wrote the statistical analysis plan, analysed the data, and drafted and revised the
498 paper. SP, PD, MT, PG, LF, RP, PR, SH and EKG analysed the data and critically revised the
499 paper for important intellectual content. SH and CJ designed data collection tools, implemented
500 the study, monitored data collection for the whole study, and critically revised the draft paper
501 for important intellectual content. All authors, external and internal, had full access to all of the
502 data (including statistical reports and tables) in the study and can take responsibility for the
503 integrity of the data and the accuracy of the data analysis. All authors have read and approved
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4
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6
7
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9

10 513

11 12 514 **Competing interests**

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15 515 The authors do not report any conflicts of interest
16

17 516

18 19 517 **Ethics approval and consent to participate**

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21 518 The study was approved by the Institutional Review Board of INSERM (IRB Inserm
22
23 519 n°IRB0000388 FWA00005831) and the National Commission for Data Protection and
24
25 520 Liberties (CNIL n° 909216), and registered at:

26
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28 521 <https://clinicaltrials.gov/ct2/show/NCT02769455>. Electronic consent was obtained from each
29
30 522 participant of the trial.
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33 34 35 524 **Data sharing**

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37 525 All data supporting the findings of this study are included in the present article or the
38
39 526 supplemental material. No additional data available.
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3 **Figure 1** An example of a food product in the Nutri-Score (1), Reference Intakes (2), and no
4 label (3) arms. Images developed by the co-authors.
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10 **Figure 2** Flow diagram of the randomized controlled trial
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13 * Subjects who validated their online shopping cart and did not encounter technical issues
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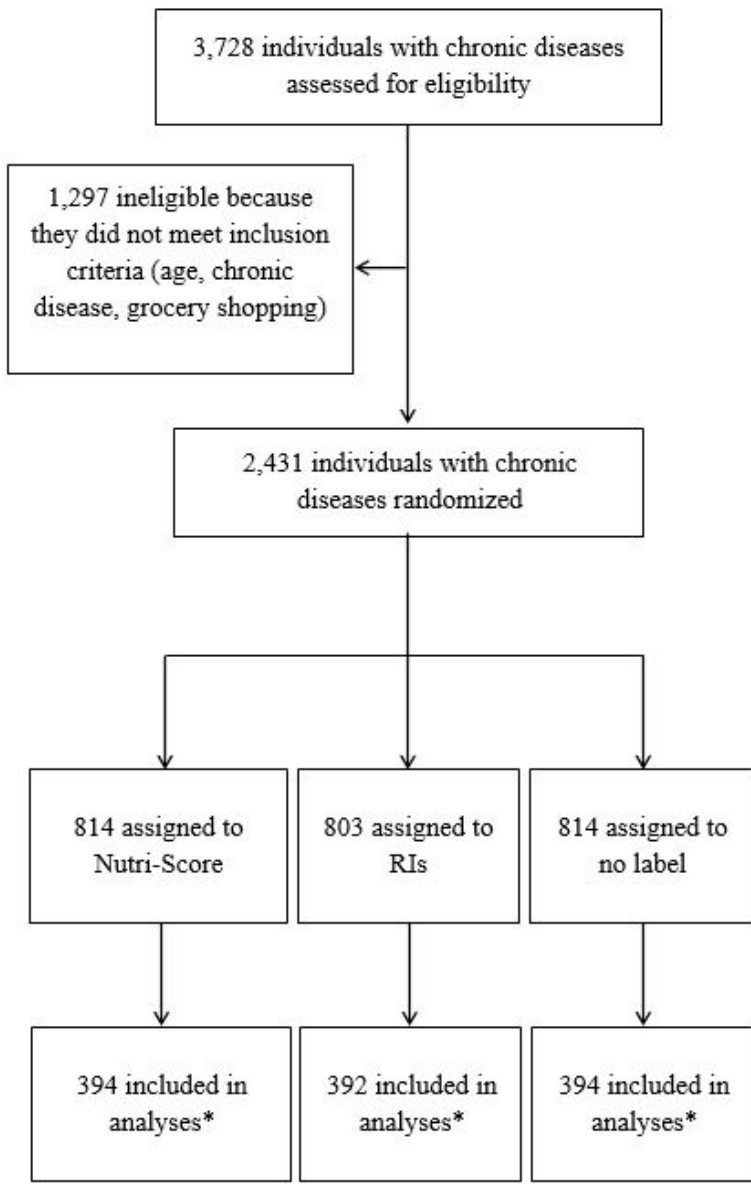
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An example of a food product in the Nutri-Score (1), Reference Intakes (2), and no label (3) arms. Images developed by the co-authors.

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Flow diagram of the randomized controlled trial

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Table S1 Individual characteristics of respondents and non-respondents in the randomized controlled trial by randomization group, France, 2017

	Nutri-Score		Reference Intakes		No label		<i>P</i> ^a
	Respondents	Non-respondents	Respondents	Non-respondents	Respondents	Non-respondents	
Total (n)	394	420	392	411	394	420	
Sex, n(%)							0.5
Men	131 (33.2)	158 (37.6)	124 (31.6)	143 (34.8)	152 (38.6)	157 (37.4)	
Women	263 (66.8)	262 (62.4)	268 (68.4)	268 (65.2)	242 (61.4)	263 (62.6)	
Age, years	64.8 ± 6.9	65.8 ± 7.5	64.8 ± 7.3	66.5 ± 7.1	65.4 ± 7.1	66.2 ± 7.2	0.5
Educational level							0.2
Primary	122 (31)	131 (31.2)	102 (26)	140 (34.1)	104 (26.4)	131 (31.2)	
Secondary	53 (13.5)	83 (19.8)	51 (13)	77 (18.7)	74 (18.8)	71 (16.9)	
University, undergraduate degree	103 (26.1)	94 (22.4)	122 (31.1)	98 (23.8)	99 (25.1)	103 (24.5)	
University, postgraduate degree	98 (24.9)	93 (22.1)	102 (26)	77 (18.7)	103 (26.1)	102 (24.3)	
Other	18 (4.6)	19 (4.5)	15 (3.8)	19 (4.6)	14 (3.6)	13 (3.1)	
Grocery shopping frequency, n(%)							0.6
Always	231 (58.6)	235 (56)	252 (64.3)	229 (55.7)	239 (60.7)	245 (58.3)	
Often	122 (31)	134 (31.9)	107 (27.3)	128 (31.1)	113 (28.7)	127 (30.2)	
Sometimes	41 (10.4)	51 (12.1)	33 (8.4)	54 (13.1)	42 (10.7)	48 (11.4)	
Online grocery shopping, yes n(%)	119 (30.2)	96 (22.9)	129 (32.9)	102 (24.8)	103 (26.1)	109 (26)	0.2
Online grocery shopping frequency, n(%)							0.4
At least one time per week	16 (13.4)	8 (8.3)	20 (15.5)	14 (13.7)	21 (20.4)	13 (11.9)	
One or two times per month	22 (18.5)	25 (26)	26 (20.2)	20 (19.6)	15 (14.6)	25 (22.9)	
One time every two or three months	29 (24.4)	15 (15.6)	33 (25.6)	23 (22.5)	17 (16.5)	22 (20.2)	
One or two times per year	23 (19.3)	23 (24)	21 (16.3)	29 (28.4)	29 (28.2)	32 (29.4)	
Less than one time per year	29 (24.4)	25 (26)	29 (22.5)	16 (15.7)	21 (20.4)	17 (15.6)	
Weekly budget for grocery shopping (€)							0.2
≤30€	13 (3.3)	20 (4.8)	17 (4.3)	10 (2.4)	16 (4.1)	6 (1.4)	
30 – 50€	76 (19.3)	65 (15.5)	74 (18.9)	78 (19)	63 (16)	65 (15.5)	
50 – 100€	151 (38.3)	159 (37.9)	168 (42.9)	158 (38.4)	160 (40.6)	164 (39)	
≥100€	151 (38.3)	154 (36.7)	130 (33.2)	140 (34.1)	147 (37.3)	167 (39.8)	
Missing	3 (0.8)	22 (5.2)	3 (0.8)	25 (6.1)	8 (2)	18 (4.3)	
Perceived nutritional knowledge, n(%)							0.1
High	38 (9.6)	33 (7.9)	38 (9.7)	26 (6.3)	22 (5.6)	44 (10.5)	
Intermediate	222 (56.3)	226 (53.8)	220 (56.1)	231 (56.2)	233 (59.1)	221 (52.6)	
Low	125 (31.7)	135 (32.1)	125 (31.9)	125 (30.4)	124 (31.5)	132 (31.4)	
No	9 (2.3)	9 (2.1)	7 (1.8)	7 (1.7)	9 (2.3)	6 (1.4)	
Missing data	0	17 (4)	2 (0.5)	22 (5.4)	6 (1.5)	17 (4)	
Nutrition facts reading frequency, n(%)							0.3
Always	63 (16)	68 (16.2)	55 (14)	58 (14.1)	54 (13.7)	71 (16.9)	
Often	202 (51.3)	190 (45.2)	199 (50.8)	210 (51.1)	206 (52.3)	177 (42.1)	
Sometimes	117 (29.7)	127 (30.2)	122 (31.1)	106 (25.8)	119 (30.2)	142 (33.8)	
Never	12 (3)	18 (4.3)	14 (3.6)	15 (3.6)	9 (2.3)	13 (3.1)	
Missing data	0	17 (4)	2 (0.5)	22 (5.4)	6 (1.5)	17 (4)	

Values are mean ± standard deviation or n (%) as appropriate.

^a A multivariable logistic regression was conducted to model the probability of non-response depending on the individual sociodemographic and lifestyle characteristics and the arm of randomization. The *P* corresponds to the p-value of the interaction term between the individual characteristic and the trial arm. The comparison of the educational level and weekly budget for grocery shopping variables between respondents and non-respondents were not performed given that information was missing for non-respondents.

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Table S2 Overall nutritional quality, energy and nutrient content for 100g of the shopping cart among labelled products only

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=369	N=390	N=392		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	4.35 (3.5)	4.27 (3.43)	4.49 (3.41)	0.7	-0.13 (-0.72;0.45)	0.9	0.08 (-0.51;0.67)	0.9	-0.21 (-0.79;0.36)	0.7
Calories (kcal/100g)	188.42 (111.64)	237.94 (80.74)	226.59 (85.24)	<0.0001	-38.16 (-54.02;-22.3)	<0.0001	-49.52 (-65.39;-33.64)	<0.0001	11.35 (-4.28;26.99)	0.2
Saturated fatty acids (g/100g)	4.60 (4.48)	5.34 (2.97)	5.43 (3.28)	0.003	-0.83 (-1.45;-0.22)	0.004	-0.74 (-1.36;-0.13)	0.01	-0.09 (-0.70;0.52)	0.9
Sugars (g/100g)	5.80 (5.16)	6.45 (4.23)	6.43 (6.00)	0.1	-0.63 (-1.51;0.25)	0.2	-0.66 (-1.54;0.23)	0.2	0.03 (-0.84;0.9)	1.0
Sodium (mg/100g)	267.67 (284.89)	252.19 (130.25)	267.10 (200.7)							
Fiber (g/100g)	1.45 (1.56)	2.27 (1.74)	1.95 (1.54)							
Fruits and vegetables (%)	17.98 (20.94)	17.48 (13.99)	16.95 (12.61)							
Proteins (g/100g)	6.35 (4.31)	7.89 (2.87)	7.99 (3.92)							

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

Table S3 Sensitivity analyses: overall nutritional quality, energy and nutrient content for 100g of the shopping cart excluding outliers on the spending amount

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=351	N=354	N=357		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	0.99 (3.30)	1.69 (2.84)	1.8 (2.58)	0.0004	-0.81 (-1.32;-0.29)	0.0007	-0.69 (-1.21;-0.17)	0.005	-0.12 (-0.63;0.40)	0.9
Calories (kcal/100g)	152.06 (74.84)	180.89 (58.10)	173.53 (57.8)	<0.0001	-21.47 (-32.77;-10.17)	<0.0001	-28.83 (-40.15;-17.51)	<0.0001	7.36 (-3.91;18.63)	0.3
Saturated fatty acids (g/100g)	3.19 (2.73)	3.76 (2.02)	3.78 (2.03)	0.0005	-0.59 (-0.99;-0.18)	0.002	-0.58 (-0.98;-0.17)	0.002	-0.01 (-0.41;0.39)	1.0
Sugars (g/100g)	5.9 (3.31)	5.79 (2.93)	5.61 (3.10)	0.5	0.29 (-0.26;0.84)	0.4	0.11 (-0.44;0.66)	0.9	0.18 (-0.36;0.73)	0.7
Sodium (mg/100g)	171.75 (144.16)	193.37 (96.17)	205.5 (143.31)							
Fiber (g/100g)	1.41 (1.01)	1.91 (1.17)	1.67 (0.96)							
Fruits and vegetables (%)	35.29 (22.57)	30.66 (14.69)	30.11 (13.93)							
Proteins (g/100g)	7.30 (3.25)	7.25 (2.03)	7.53 (2.92)							

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). Participants whose spending amount was below the 5th or over the 95th percentile of the distribution of the cost of the shopping carts in the sample were excluded. FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

Table S4 Sensitivity analyses using multiple imputations: overall nutritional quality, energy and nutrient content for 100g of the shopping cart

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=814	N=803	N=814		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	1.51 (1.87)	1.78 (1.87)	1.84 (2.04)	0.1	-0.33 (-0.69;0.03)	0.07	-0.27 (-0.63;0.08)	0.1	-0.06 (-0.43;0.32)	0.8
Calories (kcal/100g)	162.95 (41.32)	177.21 (39.24)	173.24 (44.67)	0.0009	-10.28 (-18.26;2.31)	0.01	-14.26 (-21.87;6.65)	0.0003	3.98 (-4.09;12.05)	0.3
Saturated fatty acids (g/100g)	3.43 (1.62)	3.68 (1.41)	3.70 (1.64)	0.1	-0.27 (-0.56;0.02)	0.07	-0.25 (-0.54;0.04)	0.1	-0.02 (-0.32;0.28)	0.9
Sugars (g/100g)	5.86 (2.11)	5.86 (2.02)	5.74 (2.22)	0.6	0.12 (-0.32;0.55)	0.6	-0.01 (-0.46;0.45)	1.0	0.12 (-0.30;0.54)	0.6
Sodium (mg/100g)	194.73 (102.46)	196.38 (97.05)	205.54 (113.03)							
Fiber (g/100g)	1.51 (0.62)	1.76 (0.64)	1.64 (0.68)							
Fruits and vegetables (%)	32.25 (10.94)	30.12 (10.35)	29.78 (11.19)							
Proteins (g/100g)	7.41 (1.73)	7.35 (1.86)	7.48 (1.97)							

^a Mean difference (95% Confidence Interval)^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.**Table S5** Sensitivity analyses using multiple imputations: overall nutritional quality, energy and nutrient content for 100g of the shopping cart among labelled products only

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	N=789	N=801	N=812		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Overall nutritional quality (FSAm-NPS score/100g)	3.51 (11.8)	3.52 (11.82)	3.61 (11.53)	0.6	-0.10 (-0.57;0.36)	0.7	-0.01 (-0.46;0.43)	1.0	-0.09 (-0.53;0.35)	0.7
Calories (kcal/100g)	176.66 (343.52)	201.81 (344.94)	195.53 (330.17)	0.001	-18.87 (-31.27;-6.5)	0.003	-25.15 (-38.22;-12.09)	0.0002	-6.29 (-5.17;17.74)	0.3
Saturated fatty acids (g/100g)	3.97 (14.84)	4.34 (15.04)	4.37 (14.67)	0.2	-0.41 (-0.88;0.06)	0.09	-0.38 (-0.88;0.12)	0.1	-0.03 (-0.47;0.41)	0.9
Sugars (g/100g)	4.64 (19.27)	4.99 (19.48)	4.96 (19.33)	0.5	-0.32 (-0.97;0.33)	0.3	-0.35 (-0.97;0.28)	0.3	0.02 (-0.63;0.68)	0.9
Sodium (mg/100g)	220.7 (688.19)	216.53 (675.15)	221.69 (672.91)							
Fiber (g/100g)	1.43 (5.42)	1.83 (5.44)	1.68 (5.27)							
Fruits and vegetables (%)	16.76 (50.37)	16.55 (50.69)	16.43 (49.19)							
Proteins (g/100g)	6.12 (14.32)	6.86 (13.06)	6.89 (12.84)							

^a Mean difference (95% Confidence Interval)^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). FSAm-NPS: modified Food Standards Agency Nutrient Profiling System.

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Table S6 Total quantities of calories and nutrients in the shopping carts purchased in the three arms of the trial

	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	Mean (SD)	Mean (SD)	Mean (SD)		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
Calories (kcal)	2229.74(2336.45)	3395.80(2232.5)	3173.73(2235.09)	<0.0001	-943.99(-1323.29;-564.7)	<0.0001	-1166.06(-1545.84;-786.29)	<0.0001	222.07(-157.71;601.85)	0.4
Saturated fatty acids (g)	35.88(40.21)	53.08(37.21)	52.60(38.35)	<0.0001	-16.72(-23.18;-10.27)	<0.0001	-17.20(-23.66;-10.73)	<0.0001	0.47(-5.99;6.94)	1.0
Sugars (g)	78.09(71.76)	116.70(90.74)	103.08(79.66)	<0.0001	-24.99(-38.54;-11.43)	<0.0001	-38.60(-52.17;-25.03)	<0.0001	13.61(0.04;27.19)	0.05
Sodium (mg)	1914.81(2121.69)	2875.46(2298.01)	2803.92(2232.81)	<0.0001	-889.11(-1260.04;-518.19)	<0.0001	-960.66(-1332.06;-589.26)	<0.0001	71.54(-299.86;442.95)	0.9
Fiber (g)	17.13(17.45)	29.81(21.11)	26.17(20.05)	<0.0001	-9.04(-12.32;-5.76)	<0.0001	-12.68(-15.96;-9.4)	<0.0001	3.64(0.36;6.92)	0.03
Proteins (g)	98.66(92.33)	145.51(93.35)	142.44(94.72)	<0.0001	-43.78(-59.41;-28.15)	<0.0001	-46.85(-62.5;-31.2)	<0.0001	3.07(-12.58;18.72)	0.9

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). SD: Standard Deviation

Table S7 Percentage of the number of products in the shopping cart from the different food categories

Food groups	Nutri-Score	Reference Intakes	No label
Fruits, vegetables, legumes, grains and starchs			
Fresh fruits	17,69(22,1)	7,14(6,76)	7,07(6,68)
Processed fruits	1,96(8,99)	0,73(1,72)	0,82(2,05)
Fresh vegetables	6,13(10,74)	10,76(9,87)	9,73(8,82)
Processed vegetables	2,79(5,09)	4,22(5,14)	3,43(4,69)
Legumes and potatoes	1,50(3,45)	3,08(4,64)	2,49(5,28)
Seeds and dried fruits	0,81(2,44)	0,83(1,82)	1,08(3,14)
Dairy products	10,25(11,77)	12,46(10,36)	13,33(14,06)
Cheeses	2,96(5,01)	4,84(7,39)	5,17(6,15)
Meat, fish and processed foods			
Pre-packed meat	0,11(0,68)	0,20(0,99)	0,21(0,83)
Meat	12,52(14,99)	6,02(6,04)	6,94(10,14)
Processed meats	4,64(11,25)	3,35(4,93)	3,5(5,25)
Fresh fish	2,66(6,6)	2,71(5,94)	2,44(3,51)
Processed fish	0,51(1,84)	0,68(1,89)	0,79(3)
Sea delicatessen and canned fish	1,85(3,88)	2,58(3,83)	3,67(10,21)
Sweet products			
Biscuits	1,09(2,95)	2,40(8,16)	1,17(2,26)
Sweets	3,17(5,26)	5,24(5,39)	4,88(6,35)
Breakfast cereals	0,18(0,86)	0,32(1,27)	0,26(1,11)
Breads, rusks and pastries	1,78(4,90)	2,53(4,19)	3,56(9,43)
Ice creams	0,58(1,84)	0,73(2,09)	0,71(2,39)
Salty products			
Prepared dishes	1,26(3,39)	2,06(6,4)	1,75(3,68)
Pasta, rice, mashed potatoes and semolina	2,21(4,07)	4,68(9,44)	3,47(5,85)
Savoury aperitif products	0,44(1,40)	1,05(2,85)	0,66(1,79)
Salads	0,35(1,34)	0,40(1,53)	0,18(0,95)
Soups	0,49(2,21)	1,12(6,57)	1,08(7,57)
Sauces and condiments	3,75(9,23)	3,86(4,47)	4,26(6,07)
Oils and fats	4,43(9,22)	4,06(4,02)	3,92(4,04)
Beverages			
Waters	8,95(14,68)	5,96(8,85)	8,71(16,74)
Fruit juices	2,36(6,58)	1,52(5,77)	1,07(2,55)
Sweetened drinks and sodas	2,58(5,50)	4,48(6,51)	3,64(4,38)

Values correspond to mean (Standard deviation).

Table S8 Percent contributions of food groups to nutrient intakes of the overall shopping cart

Food groups	Calories			Saturated Fatty Acids		
	Nutri-Score	Reference Intakes	No label	Nutri-Score	Reference Intakes	No label
Fruits, vegetables, legumes, grains and starchs						
Fresh fruits	12,03(21,1)	2,76(4,93)	2,53(2,98)	5,64(21,07)	0,43(5,11)	0,12(0,29)
Processed fruits	1,46(8,67)	0,31(0,91)	0,34(0,88)	0,92(8,48)	0,06(0,49)	0,05(0,15)
Fresh vegetables	1,93(6,41)	2,48(3,77)	2,06(2,48)	0,82(7,1)	0,30(1,19)	0,15(0,24)
Processed vegetables	0,92(2,29)	1,38(2,42)	1,18(3,18)	0,48(4,45)	0,43(1,60)	0,36(1,19)
Legumes and potatoes	2,47(5,55)	5,15(8,23)	4,10(7,97)	0,39(2,42)	0,63(3,61)	0,78(5,35)
Seeds and dried fruits	2,19(5,88)	2,33(5,16)	2,97(6,77)	1,49(4,68)	1,60(4,44)	1,87(6,25)
Oils and fats	7,61(11,16)	8,01(8,74)	9,57(13,59)	10,79(16,63)	12,86(15,25)	14,02(18,27)
Beverages	5,38(9,19)	8,32(11,10)	9,81(10,39)	11,87(18,7)	19,59(21,72)	22,38(21,8)
Meat, fish and processed foods						
Pre-packed meat	0,08(0,52)	0,20(1,20)	0,23(0,98)	0,1(0,81)	0,37(3,46)	0,37(1,85)
Meat	18,07(24,94)	6,51(8,20)	7,63(12,95)	22,31(34,83)	6,99(12,52)	6,25(12,70)
Processed meats	4,77(11,74)	3,68(7,20)	3,84(5,55)	5,66(15,52)	4,29(9,25)	4,65(9,43)
Fresh fish	2,17(7,01)	2,2(6,38)	1,62(2,62)	1,69(8,35)	1,46(7,16)	0,67(1,69)
Processed fish	0,38(1,58)	0,58(2,17)	0,63(2,16)	0,22(1,05)	0,45(3,01)	0,46(2,49)
Sea delicatessen and canned fish	1,92(5,13)	2,64(4,66)	3,51(10,18)	1,43(5,13)	1,85(4,58)	2,41(9,00)
Sweet products						
Biscuits	2,41(5,96)	4,77(11,63)	3,05(6,08)	2,23(6,55)	4,9(13,55)	2,75(6,73)
Sweets	5,54(10,11)	8,64(9,86)	8,42(10,7)	7,24(14,58)	11,47(16,33)	10,06(14,67)
Breakfast cereals	0,33(1,55)	0,66(2,51)	0,58(2,45)	0,10(0,54)	0,25(1,34)	0,15(0,77)
Breads, rusks and pastries	3,16(7,95)	4,28(6,62)	5,76(11,22)	0,94(3,49)	0,94(2,46)	2,09(10,59)
Ice creams	0,50(1,58)	0,7(2,44)	0,65(2,83)	0,89(3,63)	1,10(4,07)	0,82(3,77)
Salty products						
Prepared dishes	1,44(3,66)	2,24(6,88)	2,22(4,84)	1,25(3,46)	2,07(7,24)	2,06(7,47)
Pasta, rice, mashed potatoes and semolina	4,05(7,18)	8,37(13,13)	6,57(9,03)	0,86(3,79)	2,33(10,33)	1,10(3,15)
Savoury aperitif products	0,97(3,09)	2,30(5,50)	1,6(4,26)	0,43(1,82)	1,16(3,53)	0,76(2,21)
Salads	0,21(0,83)	0,25(1,06)	0,12(0,67)	0,08(0,34)	0,12(0,62)	0,04(0,22)
Soups	0,16(1,29)	0,57(5,53)	0,67(7,40)	0,15(1,35)	0,52(5,39)	0,61(7,41)
Sauces and condiments	2,72(8,87)	1,94(3,23)	2,20(5,24)	1,90(8,97)	0,96(2,07)	1,14(4,45)
Oils and fats	14,60(18,45)	16,48(14,66)	16,68(15,00)	19,52(25,10)	21,53(20,74)	22,84(21,77)
Beverages						
Waters	0(0,03)	0(0,03)	0(0,03)	0(0,05)	0(0,10)	0,01(0,11)
Fruit juices	1,26(4,70)	0,63(5,25)	0,36(1,03)	0(0)	0(0)	0(0)
Sweetened drinks and sodas	1,29(5,36)	1,62(4,61)	1,12(3,61)	0,62(3,36)	1,36(5,99)	1,04(4,14)

The relatively high contributions of calories and saturated fatty acids for fruits and vegetables in the Nutri-Score arm could be partly explained by participants having only fruits or vegetables in their shopping carts, thus increasing the overall contribution at the sample level, even though they are low in calories and saturated fatty acids.

Table S9 Distribution of the products across the five Nutri-Score classes

Nutri-Score	Nutri-Score	Reference Intakes	No label	P-value	Nutri-Score vs no label		Nutri-Score vs Reference Intakes		Reference Intakes vs no label	
	Mean proportion	Mean proportion	Mean proportion		Difference ^a	P-value ^b	Difference ^a	P-value ^b	Difference ^a	P-value ^b
A	58.16±25.02	53.3±20.26	52.53±20.07	0.0004	5.63(2.02;9.24)	0.0008	4.85(1.24;8.47)	0.005	0.78(-2.86;4.41)	0.9
B	10.55±10.43	13.87±10.09	15.55±14.14	<0.0001	-5.01(-6.93;-3.08)	<0.0001	-3.33(-5.26;-1.4)	0.0002	-1.68(-3.62;0.26)	0.1
C	15.60±19.08	12.14±10.82	11.52±11.2	<0.0001	4.08(1.73;6.43)	0.0001	3.46(1.10;5.81)	0.002	0.62(-1.74;2.99)	0.8
D	12.30±12.92	16.05±11.51	15.98±12.02	<0.0001	-3.68(-5.69;-1.68)	<0.0001	-3.75(-5.76;-1.74)	<0.0001	0.06(-1.95;2.08)	1.0
E	3.40±5.69	4.63±8.57	4.42±5.42	0.02	-1.02(-2.12;0.08)	0.07	-1.23(-2.34;-0.13)	0.02	0.21(-0.90;1.33)	0.9

^a Mean difference (95% Confidence Interval)

^b P-value using Tukey's multiple comparisons tests. Boldface indicates statistical significance (p-value≤0.05). All products were taken into account, including also raw foods that were non-labelled.

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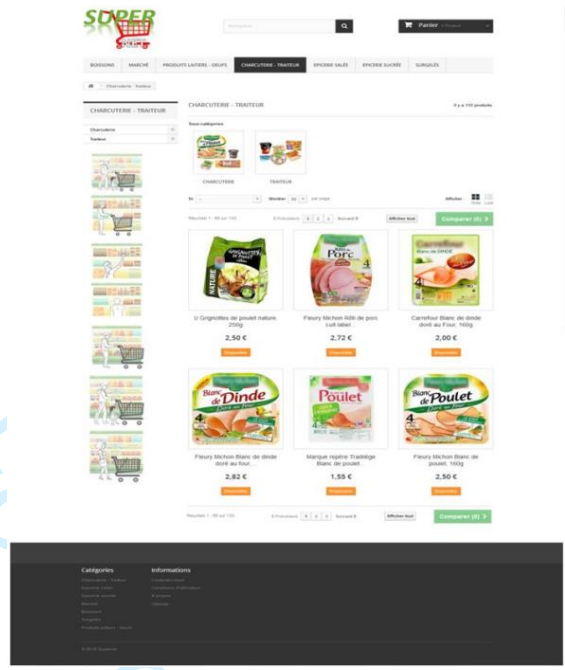


Figure S1 Screenshot of the experimental online supermarket



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5-6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

1		assessing outcomes) and how	
2		11b If relevant, description of the similarity of interventions	NA
3	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	8-9
4		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
5			
6	Results		
7	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	9
8	diagram is strongly	were analysed for the primary outcome	
9	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	Figure 2
10	Recruitment	14a Dates defining the periods of recruitment and follow-up	4-5
11		14b Why the trial ended or was stopped	NA
12	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 1
13	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	Figure 2
14		by original assigned groups	
15	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	12
16	estimation	precision (such as 95% confidence interval)	
17		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
18	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	14
19		pre-specified from exploratory	
20	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
21			
22	Discussion		
23	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17
24	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	17
25	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-17
26			
27	Other information		
28	Registration	23 Registration number and name of trial registry	5
29	Protocol	24 Where the full trial protocol can be accessed, if available	NA
30	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	19

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37 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also
38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.
39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
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