# Effects of front-of-pack nutrition labels on food purchases: a randomised controlled trial

Submission date	Recruitment status	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
07/11/2017	No longer recruiting			
Registration date	Overall study status	Statistical analysis plan		
13/11/2017	Completed	Results		
Last Edited	Condition category	Individual participant data		
01/04/2019	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>		

#### Plain English summary of protocol

Background and study aims

Unhealthy eating is a key risk factor in chronic non-communicable diseases such as cardiovascular disorders (like heart attacks and strokes) and diabetes (uncontrolled blood sugar, which have sharply risen and account for 60% of deaths worldwide. Public health authorities are eager to start prevention programmes promoting foods of better nutritional quality. One such policy is the recent European regulation on the provision of nutrition information to consumers, introduced in December 2016, stating that "the energy value and the amount of nutrients [...] may be given by other forms of expression and/or presented using graphical forms or symbols in addition to words or numbers". This information, provided on a voluntary basis, must be placed on the "front of pack" (FOP) of the food product. The aim of this study to measure and compare the effects of four front-of-pack (FOP) nutritional labelling systems on the nutritional quality of supermarket food purchases.

Who can participate?

Shoppers at the supermarkets during the study.

## What does the study involve?

Participants are informed of the study in each tested supermarket through specific leaflets, shelf stoppers, and displays, which are controlled for similar amount of information. 1.75 million stickers are affixed to the front of the packages of 1,298 products in four categories (fresh prepared foods, pastries, breads, and canned prepared foods). Two of the tested systems provided nutrient-level information: Nutri-Repère displayed energy level per portion as well as total fat, saturated fat, sugars and salt in grams, as a percentage of Guideline Daily Amounts (GDA), and as a blue bar chart, while Nutri-Couleurs provided the same information minus the bar chart but with the green-yellow-red color coding of the British Traffic Lights system for each nutrient. The other two systems provided a synthetic evaluation based on the amount of positive and negative nutrients: SENS (Simplified Nutritional Labelling System) displayed one of four labels with recommended consumption frequency or quantity, colored from green to purple, while Nutri-Score showed the location of a cursor on a ruler with five color-coded grades, from A (green) to E (red). Retailers provided detailed purchase data of the loyalty card holders shopping in the 60 stores one year before and during the intervention period. The main outcome was the nutritional quality of the purchases measured using the nutrient profiling scoring

system developed for the British Food Standard Agency (FSA). This was measured for all shoppers and for low-price shoppers.

What are the possible benefits and risks of participating? There are no direct benefits or risks with participating.

Where is the study run from?

This study is being run by Toulouse School of Economics (France) and takes place in French supermarkets from three national chains in France.

When is the study starting and how long is it expected to run for? February 2016 to December 2016

Who is funding the study?

- 1. Fonds Français pour l'Alimentation et la Santé (French Fund for Food and Health) (France)
- 2. French National Health-Insurance Fund for Salaried Workers (France)

Who is the main contact?

1. Professor Pierre Dubois (Scientific) pierre.dubois@tse-fr.eu

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## Contact information

#### Type(s)

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

#### Scientific Title

Impact of analytic and synthetic front-of-pack graphical nutrition labels on the nutritional quality of supermarket food purchases: Evidence from a french randomized control experiment

## Study objectives

Do front-of-pack (FOP) nutritional labeling systems differently affect the nutritional quality of supermarket food purchases?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

No ethical approval was required. The study was authorized by ministerial decree 2016-980 of 19 /07/2016 signed by French Prime Minister.

## Study design

A five-arm, real-life randomized control trial (RCT) with baseline (10 weeks) and intervention (10 weeks)

## Primary study design

Interventional

## Secondary study design

Cluster randomised trial

## Study setting(s)

Other

## Study type(s)

#### Prevention

#### Participant information sheet

See additional files (in French)

## Health condition(s) or problem(s) studied

Nutrition labelling

#### Interventions

The intervention assesses the effects of four validated front of package FOP nutritional labelling systems using the food purchase of 191,000 loyalty card holders in 1,298 products in four categories (fresh prepared foods, pastries, breads, and canned prepared foods).

Four labelling system are tested. Two of the tested systems provided nutrient-level information: Nutri-Repère displayed energy level per portion as well as total fat, saturated fat, sugars and salt in grams, as a percentage of Guideline Daily Amounts (GDA), and as a blue bar chart; Nutri-Couleurs the French equivalent of the British Traffic Lights system. The other two systems provided a synthetic evaluation based on the amount of positive and negative nutrients: SENS (Simplified Nutritional Labelling System) displayed one of four labels with recommended consumption frequency or quantity, colored from green to purple, while Nutri-Score showed the location of a cursor on a ruler with five color-coded grades, from A (green) to E (red).

From September 26th to December 4th 2016, the FOP labels are put on actual food products, with each system being simultaneously tested in 10 randomly selected supermarkets - four Carrefour, three Simply Market, and three Casino stores - for 10 weeks. In addition, twenty control supermarkets, with no added FOP labelling, are randomly chosen: eight Carrefour, six Simply Market, and six Casino stores. The supermarkets were selected from four French regions: Île de France (Grande Couronne), Hauts de France (Nord Pas de Calais and Picardie), Haute Normandie, Rhône-Alpes (Ain, Loire, Rhône). The random sampling of the 60 supermarkets is carried out to include at least 40% of the stores in underprivileged areas, to ensure we would have enough underprivileged consumers in our sample.

Consumers are informed of the intervention in each tested supermarket through specific leaflets, shelf stoppers, and displays, which are controlled for similar amount of information.

Retailers provided detailed purchase data of the loyalty card holders shopping in the 60 stores one year before (baseline period) and during the intervention period.

The effects of graphical FOP nutritional labeling on the nutritional quality of purchases are estimated using two statistical methods: first difference and difference in differences. The effects are estimated for all labeled products in the data set and by product category.

#### Intervention Type

Behavioural

#### Primary outcome measure

Nutritional quality of food purchases is measured by the quantity-weighted average of the FSA score of the labeled foods purchased by each loyalty card holder over ten weeks in 2016, September 26th and December 4th and the ten equivalent weeks in 2015, between September 28th and December 6th (baseline).

#### Secondary outcome measures

Nutritional quality of food purchases for low-price shopper is measured by the quantity-weighted average of the FSA score of the labeled foods purchased by each loyalty card holder that belongs the 40% of shoppers paying the lowest average price over ten weeks in 2016, September 26th and December 4th and the ten equivalent weeks in 2015, between September 28th and December 6th (baseline).

#### Overall study start date

23/02/2016

#### Completion date

04/12/2016

# Eligibility

#### Key inclusion criteria

All loyalty cardholders who made at least one shopping trip in one of the 60 supermarkets during the trial period, as well as the same data for the ten equivalent weeks in 2015, between September 28th and December 6th were included in the trial.

#### Participant type(s)

Other

#### Age group

Adult

#### Sex

Both

## Target number of participants

191,790 loyalty cardholders were selected; 26,213 (26,975; 37,875; 32,817; 67,910) individuals shopping in Nutri-Couleurs (Nutri-Repère; Nutri-Score; SENS; control) stores.

## Key exclusion criteria

All Loyalty cardholders who never made a shopping trip in one of the 60 supermarkets.

#### Date of first enrolment

26/09/2016

#### Date of final enrolment

01/10/2016

## Locations

#### Countries of recruitment

France

## Study participating centre

## Carrefour market stores (Carrefour)

102 avenue de Paris (Rue Alexandra David-Néel) 91300 Massy Massy France 91300

## Study participating centre Simply market Store (Auchan)

Villeneuve d'Ascq France 59650

## Study participating centre

Casino

Saint-Etienne France 42008

# Sponsor information

#### Organisation

French Ministry for Solidarity and Health

#### Sponsor details

14 Avenue Duquesne Paris France 75350

#### Sponsor type

Government

# Funder(s)

#### Funder type

Charity

#### Funder Name

Fonds Français pour l'Alimentation et la Santé (French Fund for Food and Health)

#### **Funder Name**

French National Health-Insurance Fund for Salaried Workers

## **Results and Publications**

#### Publication and dissemination plan

Plans to publish in the American Journal of Clinical Nutrition. Protocol: http://solidarites-sante.gouv.fr/IMG/pdf/rapport\_du\_comite\_scientifique\_11\_avril\_2016.pdf
Main steps of the intervention: http://solidarites-sante.gouv.fr/archives/article/l-evaluation-enconditions-reelles-d-achat-des-systemes-d-information-317290

## Intention to publish date

17/01/2018

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Daniel Nairaud (d.nairaud@alimentation-sante.org). The data are the ownership of the Fond Français pour Alimentation et la Santé (the French Fund for Food and Health, FFAS), and they are available on scientific project submission.

#### IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		13/11/2017	01/04/2019	No	Yes
Participant information sheet		13/11/2017	01/04/2019	No	Yes
Participant information sheet		13/11/2017	01/04/2019	No	Yes
Participant information sheet		13/11/2017	01/04/2019	No	Yes