ISRCTN12389597 https://doi.org/10.1186/ISRCTN12389597

Evaluation and comparison of the effectiveness of front-of-package labeling systems for pre-packaged and ultra-processed foods and non-alcoholic beverages in El Salvador

Submission date
06/07/2023

Recruitment status
No longer recruiting

Registration date
17/07/2023

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The study has been designed to understand how people perceive labels of food products. The objective of the study is to evaluate and compare the efficacy of front-of-package nutritional labelling systems in changing the choice of consumers in El Salvador.

Who can participate?
Adults aged 18 years old or older, that reside in El Salvador, and have no visual impairment.

What does the study involve? Participants will be shown a series of images of packaged food products and will be asked to answer a series of simple questions:
- Which product would you buy?
- Which is the product least harmful to health?
- Is the content of any of the following nutrients in this product higher than recommended for a healthy diet? Sugar; Sodium; Total fat/fat; Saturated fat; Trans fat; None of the nutrients.
The survey will take approximately 15 minutes.

What are the possible benefits and risks of participating?
Participants will receive no direct benefit, but their participation may help us understand how people use food product labels when making decisions, which may result in benefits to the entire population. Participation does not imply any risk to participants.

Where is the study run from?
World Health Organization Regional Office for the Americas (USA)

When is the study starting and how long is it expected to run for?
August 2021 to February 2022

Who is funding the study?
1. The Pan American Health Organization (USA)
2. Resolve to Save Lives (Global)

Who is the main contact?
Alexandra Gálvez, alebeagal0112@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Fabio Da Silva Gomes

ORCID ID
https://orcid.org/0000-0003-4997-4642

Contact details
525 23rd St NW
Washington DC
United States of America
20037
+1 2029743695
gomesfabio@paho.org

Additional identifiers

Protocol serial number
PAHOERC.0380.02-SLV

Study information

Scientific Title
Effects of front-of-package nutrition labelling systems on objective understanding and purchase intention of food and non-alcoholic drink products in El Salvador: randomized controlled trial

Study objectives
The front-of-package nutritional labeling systems tested have:
1. A different efficacy in improving consumers' ability to correctly identify products with excessive amounts of sugars, fats, and sodium
2. A different efficacy in improving consumers' ability to correctly identify the product option that is the least harmful to health
3. A different efficacy in improving cosumers' purchase intention reducing the choice for products with an excessive content of nutrients associated with noncommunicable diseases (i.e. sugars, fats, sodium)

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 01/02/2022, Pan American Health Organization Ethical Review Committee (PAHOERC) (525 23rd St NW, Washington DC, 20037, United States of America; +1 2029743548; pahoerc@paho.org), ref: PAHOERC.0380.02

2. Approved 13/01/2022, Comité Institucional de Ética - Instituto de Nutrición de Centro América y Panamá (INCAP) (Calzada Roosevelt 6-25 zona 11, Guatemala, -, Guatemala; +502 2315-7900; e-mail@incap.int), ref: CIE-REV 111/2021

Primary study design
Interventional

Study design
Single center single blinded parallel randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Improvement on consumers' ability to correctly identify products with excessive amounts of sugars, fats, and sodium, to correctly identify the product option that is the least harmful to health, and to choose to purchase the least harmful choices or none of them options if they are all harmful.

Interventions
Allocation is random at equal rate (1/4) to four study groups (three experimental and the control group). The randomisation of the experimental conditions and groups was completed adopting a Williams design to ensure the order of categories of products and the order of products within categories was random and balanced for all groups. This randomisation produced five random and balanced sequences of categories of products and products within categories used for each of the four groups, resulting in 20 possible combinations of groups and sequences (4×5), equally balanced and order within each group. Participants in each group are exposed to either one of the experimental conditions or allocated to the control group.

Participants in the experimental groups are shown two-dimensional (2D) images of 15 different mock-up products presented at random and balanced orders between and within categories of products. The mock-up products do not correspond to real commercial products available in the Salvadorian market but have similar characteristics in terms of package and graphic design and nutritional composition. Four sets of mock-ups are used. Each set includes three (3) products from each of five (5) product categories of ultra-processed products commonly consumed (3×5=15 mock-up products). The product categories are breakfast cereal extrudates, flavoured milks, cookies, packaged white breads, and yoghurts. The same 15 mock-up products are used in each group; the only difference across groups is the front-of-package (FOP) labelling scheme they feature. Mock-ups shown to participants feature solely one of the following FOPL schemes tested, according to the group they are allocated to: black octagonal warning labels (OWL group), traffic-light labelling (TFL group), guideline daily amounts (GDA group), or no FOP label (control group).

Intervention Type
Other

Primary outcome(s)
Measured by responses of participants to the stimuli in different experimental/control groups, and responses obtained from respondents by the interviewers by means of the application of a structured questionnaire after they were shown two-dimensional images of mock-up products:
1. The participant's decision to buy products
2. The correct identification of sugars, sodium and/or saturated fats found to be in excess in the products

Key secondary outcome(s)
Sociodemographic variables, including gender, age and education level by a structured questionnaire after seeing the mock-up products

Completion date
14/02/2022

Eligibility

Key inclusion criteria
Adults residing in El Salvador aged 18 years old or older

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
200 Years

Sex
All

Total final enrolment
1216

Key exclusion criteria
1. Visually impaired people
2. Persons unable to give informed consent
3. People who deny being part of this study

Date of first enrolment
01/02/2022

Date of final enrolment

14/02/2022

Locations

Countries of recruitment
El Salvador

Study participating centre
Centro para la Defensa del Consumidor
11 Avenida Norte
No. 525 Bis
Centro de Gobierno
San Salvador
El Salvador
-

Sponsor information

Organisation
World Health Organization Regional Office for the Americas

ROR
https://ror.org/008kev776

Funder(s)

Funder type
Government

Funder Name
Pan American Health Organization

Alternative Name(s)
Organización Panamericana de la Salud, PAHO

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location

United States of America

Funder Name
Resolve to Save Lives

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/06/2025	27/06/2025	Yes	No