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Evaluation and comparison of the effectiveness of front-of-package labeling systems for pre-packaged and ultra-processed foods and non-alcoholic beverages in Cartago and San José, Costa Rica

Submission date	Recruitment status	[ ] Prospectively registered
06/07/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/07/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/07/2023	Other	[ ] Record updated in last year

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 Costa Rica.

Who can participate?
Adult supermarket shoppers aged 18 years or older, residing in Costa Rica, 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?
April 2021 to January 2022

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PAHOERC.0380.02-CRI

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 Costa Rica: 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 08/12/2021, Comité Ético Científico - Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud (INCIENSA) (Apartado 4-2250, Tres Ríos, -, Costa Rica; +506 2279-9911; sec_cec@inciensa.sa.cr), ref: IC-2021-02

2. approved 22/12/2021, 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

Study design
Single blinded parallel randomized controlled trial

Primary study design
Interventional

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 an equal rate (1/5) to five study groups (four experimental and the control group). The randomisation of the experimental conditions and groups was completed by 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 four random and balanced sequences of categories of products and products within categories used for each of the five groups, resulting in 20 possible combinations of groups and sequences (5×4), 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 12 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 Costa Rican 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 four (4) product categories of ultra-processed products commonly consumed (3×4=12 mock-up products). The product categories are breakfast cereal extrudates, chocolate

milks, crackers, and yoghurts. The same 12 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), Nutri-Score (NUS group), traffic-light labelling (TFL group), guideline daily amounts (GDA group), or no FOP label (control group).

Intervention Type
Behavioural

Primary outcome(s)
Measured using 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. Product selection
2. Correct identification of sugars, sodium and/or saturated fats found to be in excess

Key secondary outcome(s))
Gender, age and education level measured by structured questionnaire after they were shown two-dimensional images of mock-up products

Completion date
22/01/2022

Eligibility

Key inclusion criteria
Adult supermarket shoppers residing in Costa Rica aged 18 years old or older.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
200 years

Sex
All

Total final enrolment
1351

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
14/01/2022

Date of final enrolment
22/01/2022

Locations

Countries of recruitment
Costa Rica

Study participating centre
Minsiterio de Salud - Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud (INCIENSA)
Laboratorio Tecnología Nutricional
Unidad de Salud y Nutrición
Apartado 4-2250
Tres Rios
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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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes