

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

Submission date 06/07/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/07/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/07/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 aim of the study is to evaluate and compare the effectiveness of front-of-package nutritional labeling systems in changing the choice of consumers in Panama.

Who can participate?

Supermarket shoppers aged 18 years old or older who live in Panama and have no visual impairments

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:

1. Which product would you buy?
 2. Which is the product least harmful to health?
 3. 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 about 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 involve any risk to participants.

Where is the study run from?

1. Fundación Movimiento de Alimentación Saludable (Panama)
2. Food and Agriculture Organization of the United Nations (Panama)
3. Pan American Health Organization (USA)

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

Who is funding the study?

1. Food and Agriculture Organization of the United Nations (Panama)
2. Pan American Health Organization (USA)
3. Resolve to Save Lives (USA)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PAHOERC.0380.03-PAN

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 Panama: a 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 consumers' purchase intention reducing the choice for products with an excessive content of nutrients associated with non-communicable 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 (0) 2029743548; pahoerc@paho.org), ref: PAHOERC.0380.02

2. Approved 13/01/2022, Institutional Ethics Committee - Institute of Nutrition of Central America and Panama (INCAP; Comité Institucional de Ética - Instituto de Nutrición de Centro América y Panamá) (Calzada Roosevelt 6-25 zona 11, Guatemala, N/A, Guatemala; +502 (0)2315 7900; e-mail@incap.int), ref: CIE-REV 112/2021

Study design

Single-centre single-blinded parallel randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Front-of-package nutrition labelling systems

Interventions

Allocation is random at an equal rate (1/4) to four study groups (three experimental groups 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 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 Panamanian 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 products from each of five 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 measure

Contribution of the different front-of-package labeling (FOPL) schemes to improve the decision of participants to buy the least harmful option more often, the selection of the least harmful option more often and the correct identification of sugars, sodium and/or saturated fats found to be in excess in the products more often, measured comparing correct responses of participants to the stimuli in different experimental/control groups, 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

Secondary outcome measures

Contribution of sociodemographic variables, including gender, age and education level in explaining differences between the performance of the different front-of-package labeling schemes tested using responses obtained from respondents by the interviewers by means of the application of a structured questionnaire right after they were shown the mock-up products and answered the questions about them.

Overall study start date

14/09/2021

Completion date

19/05/2022

Eligibility

Key inclusion criteria

1. Adult supermarket shoppers residing in Panama
2. Aged 18 years old or older

Participant type(s)

Population

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1200

Total final enrolment

1200

Key exclusion criteria

1. Visually impaired people
2. Persons unable to give informed consent
3. People who deny being part of this study
4. People who do not meet the inclusion criteria

Date of first enrolment

28/04/2022

Date of final enrolment

19/05/2022

Locations

Countries of recruitment

Panama

Study participating centre

Fundación Movimiento de Alimentación Saludable

Ciudad de Panamá

Ciudad de Panamá

Panama

None available

Sponsor information

Organisation

World Health Organization Regional Office for the Americas

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.paho.org/hq/>

ROR

<https://ror.org/008kev776>

Organisation

Food and Agriculture Organization of the United Nations

Sponsor details

Representación de la FAO en Panamá
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None available
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Sponsor type

Other

Website

<https://www.fao.org/panama/fao-en-panama/en/>

ROR

<https://ror.org/00pe0tf51>

Funder(s)**Funder type**

Other

Funder Name

Food and Agriculture Organization of the United Nations

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/12/2023

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