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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 Bolivia

Submission date 04/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/07/2023	**Overall study status** Completed	
Last Edited 14/10/2025	**Condition category** Other	

Plain English summary of protocol

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

Who can participate?
Adult supermarket shoppers aged 18 years old or older, that reside in Bolivia, 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:
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 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?
The study will take place in four different provinces in Bolivia.

When is the study starting and how long is it expected to run for?
June 2022 to September 2023

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

Who is the main contact?
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Additional identifiers

Protocol serial number
PAHOERC.0380.04

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 Bolivia: 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 by 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 02/05/2023, Pan American Health Organization Ethics Review Committee (PAHOERC) (525 23rd St NW, Washington DC, 20037, United States of America; +12029743548; pahoerc@paho.org), ref: PAHOERC.0380.04

2. Approved 14/04/2023, National Bioethics Committee - Research Ethics Commission (Comité Nacional de Bioética - Comisión de Ética de la Investigación_ (Av. Villazón N° 1995, Plaza del Bicentenario - Zona Central, La Paz, -, Bolivia; +591-2-2612298; informate@umsa.bo), ref: CNBCEI 01/2023

Primary study design
Interventional

Study design
Single-center interventional single-blind parallel-group-assignment randomized controlled trial

Study type(s)
Efficacy

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
The randomisation of the experimental conditions and groups is 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.
Allocation is random at an equal rate (1/3) to three study groups (two experimental and the control 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 in random and balanced orders between and within categories of products. The mock-up products do not correspond to real commercial products available in the Bolivian 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, flavoured milk, crackers, and yoghurts. The same 12 mock-up products are used in each group; the only difference across groups is the front-of-package labelling (FOPL) 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), text traffic-light labelling (TFL group), or no FOPL (control group).

Intervention Type
Other

Primary outcome(s)
Contribution of the different front-of-package labeling (FOPL) schemes to improving 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 at one timepoint

Key secondary outcome(s)
The impact of sociodemographic variables, such as gender, age, and education level, on the differences observed in the performance of various front-of-package labeling schemes. This assessment was measured by administering a structured questionnaire to respondents after they were shown mock-up products and provided their responses. The questionnaire captured their opinions and perceptions of the labeling schemes at one timepoint. The goal was to determine the extent to which sociodemographic factors contribute to the variations observed in the respondents' evaluations of the labeling schemes.

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Adult supermarket shoppers
2. Residing in Bolivia
3. 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
100 Years

Sex
All

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
17/07/2023

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Bolivia

Study participating centre
Ministerio de Salud y Deportes
Unidad de Alimentación y Nutrición
Edificio Víctor, calle Fernando Guachalla y 20 de octubre
La Paz
Bolivia
NA

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
The datasets generated during and/or analysed during the current study are not expected to 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?
Protocol article		13/10/2025	14/10/2025	Yes	No