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Health warning labels on alcoholic beverages: a study in Mexican adolescents and young adults

Submission date
29/12/2022

Recruitment status
No longer recruiting

Registration date
03/01/2023

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Other

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

Plain English summary of protocol
Background and study aims.
Although alcohol consumption is a risk factor for multiple health conditions, there is low awareness of such risks. Evidence from randomized trials – mainly online studies from the United Kingdom, Australia, and Canada – shows that visible and up-to-date health warning labels on alcoholic beverages could prevent and control alcohol use. However, evidence from other contexts is lacking, particularly in populations where sociodemographic and cultural characteristics could modify the impact of warnings on alcohol use. This study aims to evaluate the deterrence capacity of warning labels in the selection of alcoholic beverages in adolescents and young adults in Mexico.

Who can participate?
Adolescents and young adults aged 18-30 years living in any of the states selected of nine regions in Mexico (Durango, Baja California Sur, Tamaulipas, Zacatecas, Morelos, Estado de México, Guanajuato, Ciudad de México, Veracruz, Guerrero, or Yucatán). Adolescents and young adults should be studying at a public or private school of upper-middle or higher level and have access to a smart mobile device or a computer with an internet connection.

What does the study involve?
The study consists of an anonymous online questionnaire with an average duration of 5 minutes. The first section contains the informed consent that the Ethics Committee approved. Individuals who consent proceed to the next stage of the survey, verifying that they are over 18 years of age. If they meet the selection criteria, they are asked basic sociodemographic questions (for example, gender, educational level, number of household members, and number of sleeping rooms). Then, participants are randomly presented with an image of an alcoholic beverage and a series of questions related to the image. Finally, the frequency of alcohol consumption is asked. The participants have the right not to answer questions they do not want and can stop the survey at any time.

What are the possible benefits and risks of participating?
Participants do not have any benefit at an individual level. However, it is expected that the overall results obtained will allow the discussion of the potential use of health warning labels on alcoholic beverages as an additional structural measure to prevent and reduce alcohol

consumption in the population.
The online questionnaire includes questions about the frequency of alcohol consumption that can make the participant uncomfortable. Moreover, these questions could raise awareness among the participants about their alcohol consumption habits. Therefore, at the end of the questionnaire, information is provided on where the participants can receive help for alcohol consumption. Likewise, the participants who randomly receive the image of a beer can with warning legends could perceive the risk that the consumption of alcoholic beverages may have on their health. Since the exposure to the image is only once and for a short period (maximum 10 minutes), the potential perception of risk is expected to be in the short term.
Finally, this study implies a time load for the respondent that is considered brief, on average, 5 minutes. In conclusion, minimal risks are expected from this study.

Where is the study run from?
The National Institute of Public Health (Mexico)

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

Who is funding the study?
The Pan American Health Organization

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
FWA 00031322

Study information

Scientific Title
Evaluation of the deterrent capacity of warning labels in the selection of alcoholic beverages in Mexican adolescents and young adults

Acronym
HWL-alcohol

Study objectives
1. More participants in the intervention groups (that observed images of a can of beer with a health warning label) think about the health risks of drinking beer than the control group
2. Fewer participants in the intervention groups have the intention to purchase or consume the can of beer presented than in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/11/2021, Consorcio de Investigación en Salud (Health Research Consortium) Research Ethics Committee (Dwight Morrow #8, Int. 7-A, Centro, 62000, Cuernavaca, Morelos México; +52 (0)777 372 2241; comite.etica@cisidat.org.mx), ref: FWA 00031322

Primary study design

Interventional

Study design
Single-center double-blinded pilot randomized experiment

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Perceived risk and intention to change the consumption of alcohol among Mexican students aged 18-30 years

Interventions
The study includes three arms: 1) control, 2) health warning label in red (HWL red), and 3) health warning label in yellow (HWL yellow), where participants are allocated through simple randomization. In the control group, participants are shown an image of the front of a conventional can of beer (355 ml), where warning labels are not visible. In the intervention groups, pictograms and legends are located at the top, covering one-third of the front of the package as proposed by WHO Europe. In the HWL red group, the legends are presented in red font with white background, also proposed by WHO Europe, while the HWL yellow uses a black font with a yellow background, similar to the warning labels on cigarette packages in Mexico.

Intervention Type
Behavioural

Primary outcome(s)
Perceived risk and intention to change the consumption of the can of beer presented are measured at a single timepoint using the following questions: 1) Did you think about the health risks involved in drinking it?; 2) How likely are you to buy it?; 3) How likely are you to consume it?

Key secondary outcome(s)
1. Product attractiveness measured using the question "How attractive do you find the product shown?" at a single timepoint
2. Visual avoidance measured using the question "Looking at the image shown, did you avoid seeing the label?" at a single timepoint. “Label” referred to the brand in the control group and the health warning label in the intervention groups.

Completion date
17/01/2022

Eligibility

Key inclusion criteria
1. Mexican men and women between 18 to 30 years old
2. Studying at public and private schools of upper-middle and higher level
3. Have access to a smart mobile device or a computer with an internet connection

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
628

Key exclusion criteria
1. Participants that report not having consumed beer in the last 12 months. This exclusion criterion is considered since the image used for the study is a beer can, the most consumed alcoholic beverage in Mexico.
2. Women pregnant or breastfeeding because they could have changed their alcohol intake patterns

Date of first enrolment
09/11/2021

Date of final enrolment
09/12/2021

Locations

Countries of recruitment
Mexico

Study participating centre
Instituto Nacional de Salud Pública
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Sponsor information

Organisation
Pan American Health Organization - Mexico

Funder(s)

Funder type
Research organisation

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

Results and Publications

Individual participant data (IPD) sharing plan
Participant-level data will not be available due to a lack of ethical approval for a data-sharing policy.

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	results	15/06/2023	16/06/2023	Yes	No
Participant information sheet			03/01/2023	No	Yes
Protocol file			03/01/2023	No	No