

Priests' sermon and sugar-sweetened beverage choices in Catholic parishes

Submission date 25/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 08/05/2017	Overall study status Completed	
Last Edited 19/12/2019	Condition category Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

In regions with large Catholic populations such as Latin America, it is possible that faith-based interventions may help reduce the consumption of sugar-sweetened beverages (e.g., soda). The aim of this study is to assess the impact of a sermon provided by priests during a service on the choice of a bottle of soda instead of a bottle of water immediately after the service, the maintenance of this effect two weeks later, and the effect on soda purchasing patterns two weeks after the first service.

Who can participate?

Church attendees, aged 18 and over, of 12 parishes in the city of Chimbote, Peru.

What does the study involve?

Participating parishes are randomly allocated to either the control group or the intervention group. For the intervention group parishes, during the first service the priest reads a sermon about the importance of protecting one's health. The six parishes allocated to the control group do not receive the sermon. At the end of the first service, in all parishes, the priests ask attendees to pick up a drink of their choice at the entrance of the parish. Those attending the service choose between receiving a bottle of soda or a bottle of water for free. This choice is repeated at a second service two weeks later. Attendees' names and telephone numbers are also collected at the first service so that attendees can be contacted by telephone two weeks later to ask if they have bought soda during the last week.

What are the possible benefits and risks of participating?

Participants receive no benefits other than the bottle of soda or water. The participants are not at risk of harm by participating.

Where is the study run from?

1. Universidad Peruana Cayetano Heredia (Peru) (lead centre)
2. Universidad Católica Los Ángeles de Chimbote, Ancash (Peru)
3. Duke University (USA)

When is the study starting and how long is it expected to run for?
December 2016 to May 2017

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

peruvianparishes

Study information

Scientific Title

The effect of a faith-based intervention on sugar-sweetened beverage choices in Catholic parishes in Peru: a cluster randomized controlled trial

Study objectives

Current hypothesis as of 04/09/2017:

The sermon provided by priests during a mass service will have an immediate impact on the attendee's choice of drinks.

Previous hypothesis:

Among attendees of twelve parishes in the city of Chicla, Peru, the sermon provided by priests during a service will have an impact on:

1. The choice of a bottle of soda instead of a bottle of water immediately after the service [first service compared to baseline]
2. The choice of a bottle of soda instead of a bottle of water two weeks after the first service [second service compared to baseline]
3. The choice of a bottle of soda instead of a bottle of water will be maintained two weeks after the experiment [second service compared to first service, intervention group only]
4. Soda purchasing patterns (self-reported) over the last week [self-reported, two weeks after the first service]

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Research Ethics Committee, Universidad Católica los Ángeles de Chicla, 27/02 /2017, ref: INFORME N° 003 -2017-CIEI-ULADECH-Católica

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Sugar-sweetened beverage choices

Interventions

This experiment is based on the first morning service on Sundays and it will consist of a baseline assessment, a first service (intervention/experiment, 7 days from baseline) and a second service (follow-up/maintenance evaluation, 21 days from baseline).

Randomization

For the randomization, six pairs of parishes will be formed. Each pair would have a similar number of attendees and a similar percentage of persons choosing a bottle of soda instead of a bottle of water after the service, according to a baseline evaluation. Randomization subsequently will be used to allocate each of the parishes within each pair to either the control group or the intervention group.

For the intervention, delivered during the first service, the priest of each of the six parishes allocated to the intervention group will read a sermon regarding the importance of protecting one's health, following the end of the homily, approximately 30 minutes into the service. This will only happen once. The six parishes allocated to the control group will not receive the intervention. The sermon will be delivered in Spanish, and includes the following sermon:

"Dear parishioners, before finishing the homily, I would like to share a short reflection with you. Family plays an important role in the Catholic community, the family must strive to achieve the health and well-being of all of its members. A sick society is the result of a sick family. Therefore, it is time to protect the physical health of the family, which we should act upon starting today. What kind of food are we choosing? What is our family eating? Excessive consumption of sugary drinks, such as sodas and boxed juices, undermine our physical health. These beverages contain more sugar than what the body needs to be healthy. In my role as a priest I want to invite you to improve and change the selection of our food. We can choose what is good for us. Let's choose health, let's choose water or sugar-free drinks."

This text was constructed with the input of health communicators, psychologists and anthropologists, and revised by priests, attendees of the parishes who will not participate in the study. The sermons will be recorded and analyzed by the investigators of the study, to ensure that the message will not vary greatly between the priests.

At the end of the service, in all parishes, the priests will ask attendees to pick up a drink of their choice at the entrance of the parish. Those attending the service will choose between receiving a bottle of 500mL of soda or a bottle of 500mL of water for free. This procedure will occur in all evaluations: baseline, first service and second service.

At the end of the first service, whilst participants collect their drink of choice, the name and telephone number of these individuals will be collected. Attendees of the first service will be subsequently contacted over telephone, two weeks later from the first service, to ask if they had bought soda for their consumption during the last week.

Consent procedures

Due to the nature of the study, informing participants of the objectives of the intervention could alter their responses. Participants being informed of the purpose and the outcome variables of the study, as well as the knowledge that they are being observed, may lead to social desirability bias and thus to an alteration of the results, such as an increase in the choice of water bottles rather than soda bottles. For this reason, a deception approach was used. Deception is a methodological alternative for low-risk studies. It involve concealing the study objectives from participants during the experiment, and communicating them promptly upon completion of the study. For this study, participants will not hear beforehand about the purpose of the study, but four to five weeks after completion of the study, a debriefing session will be conducted in each of the parishes. For this, staff related to the study will attend to a first Sunday service to reveal to the attendees the purpose of the study and justify why this information was not delivered earlier. In this manner, the debriefing session will be made to the Catholic community in general.

Data analysis

For the outcomes related to choice of beverages immediately after the service, cluster summaries will be used to calculate the difference in the proportion of soda selection between the baseline and the one collected immediately after the intervention. In addition, differences will be also estimated between the baseline and two weeks after the intervention, for both control and intervention groups; and between data collected immediately after the intervention and two weeks after the intervention, for the intervention group. Differences in each parish will be compared between the intervention and control group using Wilcoxon test. On the other hand, the proportion of individuals self-reporting buying soda over the last week, assessed two weeks after the intervention, will be compared between the intervention and control group using Student's t-test or Mann-Whitney as required.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 04/09/2017:

The proportion of individuals that choose a bottle of soda instead of a bottle of water immediately after the first service in the intervention compared to the control group.

Previous primary outcome measures:

The choice of a bottle of soda instead of a bottle of water immediately after the first service compared to baseline

Secondary outcome measures

Current secondary outcome measures as of 04/09/2017:

1. The proportion of individuals that choose a bottle of soda instead of a bottle of water two weeks after the first service in the intervention compared to the control group
2. The self-report of having bought soda for personal consumption during the last week in the intervention compared to the control group
3. The self-report of having bought soda for household consumption during the last week in the intervention compared to the control group

Previous secondary outcome measures:

1. The choice of a bottle of soda instead of a bottle of water two weeks after the first service compared to the baseline
2. The choice of a bottle of soda instead of a bottle of water two weeks after the experiment

[intervention group only]

3. The self-report of having bought soda during the last week, two weeks after the first service

Overall study start date

01/12/2016

Completion date

24/05/2017

Eligibility

Key inclusion criteria

1. All attendees to the first Sunday morning service in participating parishes
2. ≥ 18 years old

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Approximately 1000 participants in 12 participating parishes

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

30/04/2017

Date of final enrolment

24/05/2017

Locations

Countries of recruitment

Peru

Study participating centre

Universidad Católica Los Ángeles de Chimbote
Chimbote
Peru
Chimbote (02801)

Sponsor information

Organisation

Universidad Peruana Cayetano Heredia

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/03yczjf25>

Funder(s)

Funder type

University/education

Funder Name

Universidad Peruana Cayetano Heredia

Funder Name

Universidad Católica los Ángeles de Chimbote

Funder Name

Duke University

Alternative Name(s)

Duke, Universitas Dukiana, Brown School, Union Institute, Normal College, Trinity College, DU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United States of America

Results and Publications

Publication and dissemination plan

The publication of the paper is planned in a high-impact peer reviewed journal. The paper will be submitted in the last quarter of 2017, and to publish by mid 2018.

Intention to publish date

01/07/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository Figshare 6 months after completion of the data collection.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/05/2020	19/12/2019	Yes	No