

# Lifestyles and profile of products consumed in vending machines by students of the University of Valencia

<b>Submission date</b> 18/12/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/12/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/12/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Lifestyle changes are the best way to prevent the main chronic diseases, through interventions that target sedentary lifestyle, eating habits, toxic habits and healthy sleeping. During the university period, changes in lifestyles may occur due to several factors: independence of the family home, coexistence with other students, the responsibility to decide what food to eat, the schedules, start or consolidation of toxic habits, and decreased physical activity. Therefore, this population group may be a risk group, which in the short or long term present risk factors related to the main chronic diseases. Because the University plays an important role in the acquisition and transmission of knowledge, this environment becomes an adequate space to carry out interventions to promote healthy lifestyles. Therefore, the aim of this study is to assess a lifestyle intervention in a sample of university students at the University of Valencia (Spain).

### Who can participate?

University students aged 18 to 27 with at least two of the following: sedentary lifestyle, smoking habit, daily consumption of at least two energy drinks, number of daily sleep hours less than 7 hours or changes in their study shift

### What does the study involve?

Participants are randomly allocated into two groups: the control group and the intervention group. The intervention group attend group and individual sessions focused on different aspects of lifestyle: healthy diet, physical activity, toxic habits, and sleeping. The education sessions are planned as follows: one group session of ten people per month and one individual session per month. No intervention is planned for the control group during the follow-up. The main lifestyle variables, including the profile of products consumed in vending machines, are assessed at the start of the study and after 3 months. In addition to the lifestyle questionnaires, body and blood pressure measurements are taken.

### What are the possible benefits and risks of participating?

The participant will be notified of their risk factors and how to address them to improve their

lifestyle and health. As this is an intervention study on lifestyles with scientifically proven recommendations that have been carried out for decades by different health organizations in the general population, no risks are foreseen.

Where is the study run from?  
University of Valencia (Spain)

When is the study starting and how long is it expected to run for?  
December 2018 to December 2019

Who is funding the study?  
1. Delikia Fresh (Spain)  
2. University of Valencia (Spain)

Who is the main contact?  
Dr Olga Portoles

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Olga Portolés

**Contact details**  
Av. Blasco Ibáñez 15  
Valencia  
Spain  
46010

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
OP-1

## Study information

**Scientific Title**  
Lifestyles and profile of products consumed in vending machines by students of the university of Valencia: a randomized clinical trial of the effects of an intervention to promote healthy lifestyles

**Acronym**

DELIHEALTH

### **Study objectives**

An intensive intervention to promote healthy lifestyles improves the risk profile associated with incorrect eating habits, reducing the consumption of toxic substances, as well as sedentary lifestyle, and improving sleep hygiene at the same time. As well as the profile of products consumed in vending machines by the students.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of Valencia university (human subjects), 13/12/2018, ref: H1543655762101

### **Study design**

Single-centre randomized controlled clinical trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled 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**

Nutrition and lifestyle for health promotion

### **Interventions**

Participants will be randomly assigned to the control arm or to the intensive intervention arm using a computer program. The control group will not have any type of intervention. The intensive intervention group will receive health education once a month for three months. This will consist of advice about healthy lifestyles consisting of: dietary habits, promoting the Mediterranean diet, practicing aerobic physical activity and promoting good sleep habits. Smokers will be given advice to quit smoking, and for those who consume alcoholic beverages, they will be suggested to reduce it to a minimum. In addition to the group sessions, in parallel and monthly, individual interventions adapted to the specific needs of each person will be carried out.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Changes in main life-style variables, as indicated by adherence to Mediterranean diet, will be measured using the 14 item Mediterranean Diet Scale (PREDIMED) at baseline and after three months.
2. Toxic habits (tobacco smoking and alcohol consumption) will be measured using specific validated questionnaires at baseline.
3. Physical activity will be measured using the Minnesota physical activity al Questionnaire, at baseline.
4. Sleep habits will be measured using the Pittsburg Quality of Sleep Questionnaire and the Epworth Drowsiness Questionnaire at baseline and after three months.
5. Weight, height, body composition (by bioimpedance), and blood pressure will be determined by direct measurement at baseline and after three months.

### **Secondary outcome measures**

In the preliminary sample of participants:

1. Changes in main life-style variables, as indicated by adherence to Mediterranean diet, will be measured using the 14 item Mediterranean Diet Scale (PREDIMED) at baseline and after three months.
2. Toxic habits (tobacco smoking and alcohol consumption) will be measured using specific validated questionnaires at baseline.
3. Physical activity will be measured using the Minnesota physical activity al Questionnaire, at baseline.
4. Sleep habits will be measured using the Pittsburg Quality of Sleep Questionnaire and the Epworth Drowsiness Questionnaire at baseline and after three months.
5. Weight and height will be measured using self-referred variables at baseline.

### **Overall study start date**

25/10/2018

### **Completion date**

31/12/2019

## **Eligibility**

### **Key inclusion criteria**

1. Students of the degree of Medicine
2. Both sexes
3. Aged between 18 and 27 years
4. Presenting at least two of the following conditions:
  - 4.1. Sedentary lifestyle
  - 4.2. Smoking habit
  - 4.3. Daily consumption of at least two energy drinks
  - 4.4. Number of daily sleep hours less than 7 hours or changes in their study shifts

### **Participant type(s)**

Healthy volunteer

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

From an initial sample of about 325 students 25% will be selected and randomly assigned to the two groups (41 students in control group and 41 in the intervention group)

**Key exclusion criteria**

1. Perform a job that implies schedules with rotating shifts
2. People who cannot follow the intensive lifestyle intervention established in the trial

**Date of first enrolment**

26/12/2018

**Date of final enrolment**

01/03/2019

**Locations****Countries of recruitment**

Spain

**Study participating centre**

University of Valencia

Av. Blasco Ibáñez 15

Valencia

Spain

46010

**Sponsor information****Organisation**

Delikia Fresh

**Sponsor details**

C/ Falconera 9

Gandía

Spain

46727

**Sponsor type**

Industry

# Funder(s)

## Funder type

Industry

## Funder Name

Delikia Fresh

## Funder Name

Universitat de València

## Alternative Name(s)

University of Valencia, 85|86

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

Spain

# Results and Publications

## Publication and dissemination plan

The main results are planned to be published in international journals, when the trial has been completed. In addition partial results will be presented in scientific meetings.

The study protocol is available under request. Researches who are interested in this study can contact the main investigator (Olga Portolés).

## Intention to publish date

02/02/2020

## Individual participant data (IPD) sharing plan

In accordance with the ethics board, the informed consent form signed by participants will state that their individually identifiable data will not be publicly available. The data will be saved in a protected file with a key known only to the principal investigator.

## IPD sharing plan summary

Not expected to be made available