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

Submission date
18/12/2018

Recruitment status
No longer recruiting

Registration date
27/12/2018

Overall study status
Completed

Last Edited
27/12/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

Funder(s)

Funder type
Industry

Funder Name
Delikia Fresh

Funder Name
Universitat de València

Alternative Name(s)
University of Valencia, UV

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

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