# PREVENCANADOL project: impact of a website and some mobile phone SMS on behavioral risk of cancer in school population and its adult environment

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
25/02/2013		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/03/2013	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
28/04/2015	Cancer			

#### Plain English summary of protocol

Background and study aims

The overall number of cancer cases is increasing and, therefore, strengthening cancer prevention has become a priority. The recommendations for primary prevention include advices, such as: not smoking, following a healthy diet, doing daily physical exercise or avoiding overweight, among others. Adolescence is a period of adoption and/or consolidation of health behaviors, and both school- and family-based interventions have proven effective to improve them. Furthermore, online and mobile phone educational interventions are encouraging. The main aims of the study are:

From a broad focus, to explore the capacity that the web and SMS provide to prevent cancer risk behaviors in adolescents and in their adult environment.

From a narrow focus, (a) to assess the diffusion capacity of an educational intervention based on new technologies, (b) to measure the beneficiary capture and (c) to describe cancer behavioral risk.

#### Who can participate?

Adolescents of Secondary Education who are aged between 12 and 16 years, and the adults of their environment (i.e. their relatives and teachers) who have voluntarily accepted to participate.

#### What does the study involve?

Participants will be randomly allocated to intervention and control group. The implementation and assessment of a complex online program, entitled Prevencanadol, supplemented with the delivery of SMS. The study factor is comprised of a tailor made website (www.alertagrumete. com) and of the delivery of SMS, which try to prevent cancer risk. A mixed group of (a) specialists in Preventive Medicine and (b) Secondary School teachers designed the educational contents (which are currently being taught at the schools by means of a specially prepared website) as well as the text of the SMS (related to the advantages of healthy behaviors and the skills to refuse invitations that can carry out risk behaviors).

What are the possible benefits and risks of participating?

Some benefits of participating in the study can be the following: a) to know the European Code against Cancer, whose recommendations are similar to those of other guidelines; b) to be influenced by the received information (using scientific methods of proven effectiveness) and consequently to follow the prevention advices; c) to integrate prevention activities in their daily lives, transversely. Thus, in general, the program will facilitate the meeting of several aims pointed out by the WHO for non communicable diseases. If the effectiveness of the educational intervention is confirmed, it will reduce the number of risk behaviours and their incorporation into the lifestyle of adolescents. Reducing the incidence of cancer is the expected result (if we achieve to control the behavioral risk factors included in the European Code against Cancer). Then, an improvement in quality of life and a reduction of the costs of cancer diagnosis and treatment will be the expected long term consequences. There are no evident risks for participants, but anticipating risks is very difficult due to this initiative's novelty, but other similar tools have not reported any problems for participants.

Where is the study run from?

The study is taking place in Spain and Mexico.

When is the study starting and how long is it expected to run for? The study started at the beginning of 2010 and it is expected to run until the end of 2013 (incorporation of subjects). In 2014 we will perform a follow-up and an evaluation procedure.

Who is funding the study?

Ministerio de Ciencia e Innovación - Fondo de Investigación Sanitaria del Instituto de Salud Carlos III (Minisitry of Science and Innovation - Health Research Fund of the Institute of Health Carlos III)

Who is the main contact? Dr. Alberto Lana Pérez lanaalberto@uniovi.es

# Study website

http://www.alertagrumete.com

# Contact information

Type(s)

Scientific

#### Contact name

Dr María Luisa López

#### Contact details

Avda. Julián Clavería s/n. Facultad de Medicina Oviedo Spain 33006

# Additional identifiers

#### **EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

FISS08PI080544

# Study information

#### Scientific Title

PREVENCANADOL project: impact of a website and some mobile phone SMS on behavioral risk of cancer in school population and its adult environment - a randomized controlled trial

#### Acronym

**PREVENCANADOL** 

#### **Study objectives**

PREVENCANADOL [(PREVENCANADOL = PREVENtion - CANcer - ADOLescents)]

A multicomponent and complex educative intervention, based in the primary prevention advices of the European Code against Cancer and in the attitude-social influence-efficacy (ASE) Model, delivered by a website and supplemented with mobile phones, reduces cancer behavioral risk in adolescents and adults.

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Clinical Research Ethics Committee of Asturias Regional [Comité Ético de Investigación Clínica Regional del Principado de Asturias], 27/02/2009, ref: 19/09

# Study design

Randomized controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Other

# Study type(s)

Prevention

### Participant information sheet

http://www.alertagrumete.com/como-participar

#### Health condition(s) or problem(s) studied

Cancer risk behaviors

#### **Interventions**

This randomized controlled trial has two arms: subjects of the experimental group have free access to the whole sections of the website during one academic course and will receive around 40 mobile phone text messages (one per week). The website includes: 40 challenges or problems to be solved, which are adapted to the school curriculum and to cancer prevention, discussion forums, games, information and links, diet analysis and 40 educational videos.

Participants of the control group will have limited access to the described sections and they do not receive the messages.

#### Intervention Type

Behavioural

#### Primary outcome measure

Global cancer behavioral risk indicator

#### Secondary outcome measures

Cancer risk behaviors (smoking, diet, alcohol consumption, sun exposure, sedentarism and overweight)

#### Overall study start date

01/10/2009

#### Completion date

30/06/2013

# **Eligibility**

#### Key inclusion criteria

- 1. Students of Secondary Education, aged between 12 and 16, either sex, who have voluntarily accepted to participate
- 2. To have access to the Internet

#### Participant type(s)

Patient

#### Age group

Child

#### Lower age limit

12 Years

#### Upper age limit

16 Years

#### Sex

Both

# Target number of participants

Around 3,000

#### Key exclusion criteria

Does not meet inclusion criteria

#### Date of first enrolment

01/10/2009

#### Date of final enrolment

30/06/2013

# **Locations**

#### Countries of recruitment

Mexico

Spain

# Study participating centre

Avda. Julián Clavería s/n.

Oviedo Spain

33006

# Sponsor information

#### Organisation

Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

# Sponsor details

Calle Sinesio Delgado, 6 Madrid Spain 28019

#### Sponsor type

Government

#### Website

http://www.isciii.es/

#### **ROR**

https://ror.org/00ca2c886

# Funder(s)

# Funder type

Government

#### **Funder Name**

Instituto de Salud Carlos III (Ministerio de Ciencia e Innovación - España) (Spain) Number FISS08PI080544

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/04/2013		Yes	No
Results article	results	01/02/2014		Yes	No