

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 25/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/04/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

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.alertagrume.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 (Ministry 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