

Comparing the effect of pictorial warnings on tobacco products in Saudi Arabia with other international pictorial warnings

Submission date 20/03/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/03/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Cigarette smoking is highly addictive and is one of the biggest causes of illness and death worldwide. The best way to reduce the amount of tobacco-related deaths is by encouraging people to quit smoking or not to start in the first place. Governments in different countries have used a range of strategies to reduce smoking such as increasing tax on cigarettes, banning smoking in public places and the use of pictures showing the damaging effects of smoking (pictorial warnings) on tobacco products. In Gulf Cooperation Council (GCC) countries, including Saudi Arabia, the use of pictorial warnings is readily enforced. The aim of this study is to find out how people in Saudi Arabia respond to these warnings and which pictures are the most emotionally provoking and best at encouraging people to quit smoking.

Who can participate?

Adults who live in Saudi Arabia and speak Arabic.

What does the study involve?

Participants are randomly allocated to one of three groups. Each group views a set of three pictorial warnings (from the GCC, UK or Australia), and are asked to read the accompanying information about what the warnings are about. After this, participants are asked to rate the warnings in order of emotional impact. Before seeing the pictures, immediately after seeing the pictures and again two weeks later, participants complete a survey in order to assess their knowledge about the harmful effects of smoking and their attitudes towards smoking. After two weeks, participants in all groups are also asked to complete a short, five minute survey in order to find out how well they remember the pictorial warnings and if they have quit smoking (if they are a smoker).

What are the possible benefits and risks of participating?

Participants will benefit from learning more about the effects of smoking on health. There are no notable risks involved with taking part in this study.

Where is the study run from?

The study is run from King Saud University and Saudi Electronic University (Saudi Arabia) and takes place online.

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

September 2015 to May 2017

Who is funding the study?

Deanship of Scientific Research at Saudi Electronic University (Saudi Arabia)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

U1111-1180-7781

Study information

Scientific Title

Evaluating the impact of Pictorial Warnings on tobacco products in Saudi Arabia against other International pictorial warnings: An online double-blind randomised parallel trial

Acronym

EPWI

Study objectives

The aim of this study is to evaluate the impact of pictorial warnings on tobacco products in Saudi Arabia against selected international pictorial warnings.

Null hypothesis:

There are no differences between pictorial warnings implemented in Saudi Arabia and those implemented in other countries in terms of the stimulating quit attempts, improving knowledge about smoking, changing attitude about smoking, and initiate negative emotional effect about smoking.

Ethics approval required

Old ethics approval format

Ethics approval(s)

King Saud University Research Ethics Committee, 05/10/2015, ref: 4/2015

Study design

Online double-blind randomized parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

<http://shproject.net/PIS-EPWI-RCT.docx>

Health condition(s) or problem(s) studied

Cigarette smoking

Interventions

Participants are randomly allocated to one of three groups automatically by the study website, which also stratifies for age, gender and smoking status.

Group 1: Participants are shown a set of three pictorial warnings originating from GCC and to read the associated information. They are asked to rate the warnings in order of emotional impact.

Group 2: Participants are shown a set of three pictorial warnings originating from Australia and to read the associated information. They are asked to rate the warnings in order of emotional impact.

Group 3: Participants are shown a set of three pictorial warnings originating from the UK and to read the associated information. They are asked to rate the warnings in order of emotional impact.

After 2 weeks, all participants are asked to complete a follow up questionnaire including questions about recent quit attempts, knowledge about smoking, attitude about smoking, and recalling the pictorial warnings seen in the randomization group. The follow up process will take approximately 5 minutes.

Intervention Type

Behavioural

Primary outcome measure

Self-rated impact and emotional responses to the pictorial warnings is measured using the valence and arousal scales of the Self-Assessment Manikin and the Brief Worry Scale about Smoking directly after the intervention.

Secondary outcome measures

1. Knowledge about smoking health related outcomes are measured using a participant survey designed for this study at baseline, directly after the intervention and 14 days after the intervention
2. Attitude toward smoking is measured using a participant survey designed for this study at baseline, directly after the intervention and 14 days after the intervention
3. Smoking behavior for smokers including quitting attempts are measured using a participant survey designed for this study at 14 days after the intervention
4. Recall of the pictorial warnings are measured using a participant survey designed for this study at 14 days after the intervention

Overall study start date

20/09/2015

Completion date

01/05/2017

Eligibility

Key inclusion criteria

1. Aged 18 years and over
2. Residents of Saudi Arabia
3. Arabic language speakers

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1554

Key exclusion criteria

1. Aged under 18 years
2. Non-Saudi residents
3. Non-Arabic language speakers

Date of first enrolment

01/05/2016

Date of final enrolment

01/08/2016

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre**King Saud University**

P. O. BOX 2454

Riyadh

Saudi Arabia

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Study participating centre**Saudi Electronic University**

Saudi Arabia - Riyadh - Abu Bakr Street

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Sponsor information**Organisation**

Saudi Electronic University

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Funder(s)

Funder type
University/education

Funder Name
Deanship of Scientific Research at Saudi Electronic University

Results and Publications

Publication and dissemination plan
The results of the trial will be published in peer-reviewed journals according to the Consolidated Standards of Reporting Trials (CONSORT) statement.

Intention to publish date
01/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request