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# Integrating self-affirmation content into a smoking cessation mobile app

**Submission date**
11/02/2021

**Recruitment status**
No longer recruiting

**Registration date**
12/02/2021

**Overall study status**
Completed

**Last Edited**
08/03/2021

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
Most smokers attempt to stop using cigarettes numerous times before successfully quitting. Cigarette cravings may undermine perceived competence to quit and thus constitute psychological threats to the self-concept. Self-affirmation may promote smoking cessation by offsetting these threats. This study examines whether self-affirmation is associated with smoking cessation in the context of a cessation app. A total of two types of self-affirmation are examined: tendency to spontaneously self-affirm and self-affirmation inductions added to a publicly available smoking cessation app (Smoke-Free Quit Smoking Now). This study had three aims: to assess the effect of induced self-affirmation conditions on smoking cessation outcomes (aim 1) and to assess the associations of spontaneous self-affirmation with smoking cessation outcomes (aim 2), and an exploratory aim to assess baseline optimism and baseline mood states (happiness, anger, anxiousness, hopefulness, sadness) as potential predictors and moderators of the relationship between affirmation conditions and cessation outcomes (aim 3).

Who can participate?
A random subset of adults (18-98) who downloaded the free version of the Smoke Free-Quit Smoking Now mobile application during the study period are shown a consent form and invited to participate. To be included, app users had to be adults (between the ages of 18-98), select a cessation date after the day they downloaded the app but not more than 14 days in the future and complete the baseline assessment.

What does the study involve?
Half of the participants are randomly allocated to complete a self-affirmation induction upon study entry. Participants are also randomly allocated to either receive self-affirming text notifications during their quit attempt or to receive conventional notifications. The induction and the text notifications are fully automated, and all data are collected through self-assessments in the mobile application, including the 1- and 3-month follow-up surveys.

What are the possible benefits and risks of participating?
Participants may experience an enhanced smoking cessation experience with the self-affirmation content.

Where is the study run from?
The study is conducted entirely online through the Smoke Free-Quit Smoking Now mobile application. The Smokefree mobile app was developed by Dr David Crane of 23 Ltd, based in London (UK).

When is the study starting and how long is it expected to run for?
January 2015 to March 2019

Who is funding the study?
National Cancer Institute (USA)

Who is the main contact?
1. Dr Bill Klein
kleinwm@nih.gov
2. Dr Elizabeth Seaman
eseaman@cdcfoundation.org

# Contact information

### Type(s)
Scientific

### Contact name
Dr Elizabeth Seaman

### ORCID ID
http://orcid.org/0000-0001-5218-4540

### Contact details
600 Peachtree St NE #1000
Atlanta
United States of America
30308
+1 (0)4438524139
eseaman@cdcfoundation.org

### Type(s)
Public

### Contact name
Dr Elizabeth Seaman

### ORCID ID
http://orcid.org/0000-0001-5218-4540

### Contact details
600 Peachtree St NE #1000
Atlanta
United States of America

30308
+1 (0)4438524139
eseaman@cdcfoundation.org

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
17CN039

# Study information

### Scientific Title
Integrating the use of self-affirmation content into a mobile app to promote quit attempts with text-based smoking cessation intervention messaging

### Acronym
SAMASC (Self-Affirmation in a Mobile App for Smoking Cessation)

### Study objectives
This study had two primary aims: to assess the effect of induced self-affirmation conditions added into the Smoke Free-Quit Smoking Now mobile application on smoking cessation outcomes (aim 1) and to assess the associations of spontaneous self-affirmation with smoking cessation outcomes (aim 2).

It is hypothesized that two types of self-affirmation opportunities - a baseline kindness quiz and self-affirming push notifications in the subsequent months - would promote cessation. It is also hypothesized that individuals with a tendency to spontaneously self-affirm at baseline would be more likely to successfully quit smoking.

Finally, an exploratory aim (aim 3) was to assess baseline optimism and baseline mood states (happiness, anger, anxiousness, hopefulness, sadness) as potential predictors and potential moderators of the relationship between affirmation conditions and cessation outcomes.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 12/04/2018, the National Institutes of Health Intramural Institutional Review Board (Office of Human Subjects Research Protections, 6700B Rockledge Drive, Suite 4300, Bethesda, MD 20817, USA; +1 301 402 3713; irb@od.nih.gov), ref: #17CN039

### Study design

Randomized 2 x 2 factorial design (integrated affirmation: affirmation texts present versus absent; baseline affirmation: questionnaire present versus absent)

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Internet/virtual

## Study type(s)
Prevention

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet (shared with participants through mobile application screen)

## Health condition(s) or problem(s) studied
Smoking cessation among current smokers

## Interventions
Two types of self-affirmation inductions (Integrated, Baseline) were added to a publicly available smoking cessation mobile application (Smoke-Free Quit Smoking Now). All users who met the inclusion criteria, provided consent to participate and completed a baseline assessment, were randomized to 1 of 4 conditions. Half of the participants were randomly assigned to complete a self-affirmation induction upon study entry. Orthogonally, half of the participants were randomly assigned to receive self-affirming text notifications during their quit attempt or to receive conventional notifications. The induction and the text notifications were fully automated, and all data were collected through self-assessments in the mobile application. Self-reported smoking cessation was assessed 1 month and 3 months following study entry.

## Intervention Type
Behavioural

## Primary outcome measure
Smoking cessation measured through self-assessments in the mobile application: past-week cessation at 1 month, past-month cessation at 1 month, past-week cessation at 3 months, and past-month cessation at 3 months

## Secondary outcome measures
Optimism and baseline mood states (happiness, anger, anxiousness, hopefulness, sadness) measured through self-assessments in the mobile application at baseline

## Overall study start date
12/01/2015

## Completion date
06/03/2019

# Eligibility

### Key inclusion criteria
A randomly selected proportion of users who downloaded the free version of the Smoke Free-Quit Smoking Now mobile application during the study period (initially 10% and then increased to 30% to achieve recruitment goals) are shown a consent form and invited to participate in this study. Once participants who opted in completed the baseline assessment, their eligibility was determined. In order to participate, app users had to be:
1. Adults (between the ages of 18-98)
2. Selected a cessation date after the day they downloaded the app but not more than 14 days in the future
3. Completed the baseline assessment

### Participant type(s)
Other

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
98 Years

### Sex
Both

### Target number of participants
A sample size of 500 at the 1-month follow-up was calculated to be able to detect a small effect size estimate (F=.15), with high (.90) power using an analysis of variance (ANOVA) with 4 groups (calculated with G*Power)

### Total final enrolment
7899

### Key exclusion criteria
1. Under 18 years or over 98 years old
2. Selected a quit date more than 14 days in the future or more than 1 day in the past
3. Paid for additional app features (Pro users)
4. Did not complete the baseline assessment

### Date of first enrolment
07/03/2018

### Date of final enrolment
05/02/2019

# Locations

## Countries of recruitment

Afghanistan

Albania

Algeria

American Samoa

Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda

Argentina

Armenia

Aruba

Australia

Austria

Azerbaijan

Bahamas

Bahrain

Bangladesh

Barbados

Belarus

Belgium

Belize

Benin

Bermuda

Bhutan

Bolivia

Bonaire Saint Eustatius and Saba

Bosnia and Herzegovina

Botswana

Bouvet Island

Brazil

British Indian Ocean Territory

Brunei Darussalam

Bulgaria

Burkina Faso

Burundi

Cabo Verde

Cambodia

Cameroon

Canada

Cayman Islands

Central African Republic

Chad

Chile

China

Christmas Island

Cocos (Keeling) Islands

Colombia

Comoros

Congo

Congo, Democratic Republic

Cook Islands

Costa Rica

Croatia

Cuba

Curaçao

Cyprus

Czech Republic

Côte d'Ivoire

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

England

Equatorial Guinea

Eritrea

Estonia

Eswatini

Ethiopia

Falkland Islands

Faroe Islands

Fiji

Finland

France

French Guiana

French Polynesia

French Southern Territories

Gabon

Gambia

Georgia

Germany

Ghana

Gibraltar

Greece

Greenland

Grenada

Guadeloupe

Guam

Guatemala

Guernsey

Guinea

Guinea-Bissau

Guyana

Haiti

Heard Island and McDonald Islands

Holy See (Vatican City State)

Honduras

Hong Kong

Hungary

Iceland

India

Indonesia

Iran

Iraq

Ireland

Isle of Man

Israel

Italy

Jamaica

Japan

Jersey

Jordan

Kazakhstan

Kenya

Kiribati

Korea, North

Korea, South

Kosovo

Kuwait

Kyrgyzstan

Lao People's Democratic Republic

Latvia

Lebanon

Lesotho

Liberia

Libya

Liechtenstein

Lithuania

Luxembourg

Macao

Madagascar

Malawi

Malaysia

Maldives

Mali

Malta

Marshall Islands

Martinique

Mauritania

Mauritius

Mayotte

Mexico

Micronesia, Federated States of

Moldova

Monaco

Mongolia

Montenegro

Montserrat

Morocco

Mozambique

Myanmar

Namibia

Nauru

Nepal

Netherlands

Netherlands Antilles

New Caledonia

New Zealand

Nicaragua

Niger

Nigeria

Niue

Norfolk Island

North Macedonia

Northern Mariana Islands

Norway

Oman

Pakistan

Palau

Palestine, State of

Panama

Papua New Guinea

Paraguay

Peru

Philippines

Pitcairn

Poland

Portugal

Puerto Rico

Qatar

Romania

Russian Federation

Rwanda

Réunion

Saint Barthélemy

Saint Helena, Ascension and Tristan da Cunha

Saint Kitts and Nevis

Saint Lucia

Saint Martin (French part)

Saint Pierre and Miquelon

Saint Vincent and the Grenadines

Samoa

San Marino

Sao Tome and Principe

Saudi Arabia

Senegal

Serbia

Seychelles

Sierra Leone

Singapore

Sint Maarten (Dutch part)

Slovakia

Slovenia

Solomon Islands

Somalia

South Africa

South Georgia and the South Sandwich Islands

South Sudan

Spain

Sri Lanka

Sudan

Suriname

Svalbard and Jan Mayen

Sweden

Switzerland

Syria

Taiwan

Tajikistan

Tanzania

Thailand

Timor-Leste

Togo

Tokelau

Tonga

Trinidad and Tobago

Tunisia

Turkmenistan

Turks and Caicos Islands

Tuvalu

Türkiye

Uganda

Ukraine

United Arab Emirates

United Kingdom

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Åland Islands

**Study participating centre**
**Smoke Free (23 Ltd)**
This study took place entirely online - mobile app users from any country were able to participate. Most participants were from the United Kingdom, closely followed by the United States.
London
United Kingdom
WC2H 9JQ

# Sponsor information

### Organisation
National Cancer Institute

### Sponsor details
9609 Medical Center Drive
Rockville
United States of America
20850
+1 (0)800 422 6237
NCIinfo@nih.gov

### Sponsor type
Government

### Website
http://www.cancer.gov/

### ROR
https://ror.org/040gcmg81

## Funder(s)

### Funder type
Government

### Funder Name
National Cancer Institute

### Alternative Name(s)
Instituto Nacional del Cáncer, National Cancer Institute at the National Institutes of Health, Instituto Nacional del Cáncer de los Institutos Nacionales de la Salud, NCI

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United States of America

## Results and Publications

### Publication and dissemination plan

The researchers are preparing a manuscript to be published in the Journal of Medical Information Research (JMIR)

## Intention to publish date
01/03/2021

## Individual participant data (IPD) sharing plan
During study planning and protocol preparation, the researchers did not plan to make participant-level data available publicly and did not include this provision in the IRB application and in the trial information they sent to participants. At this point, it would be problematic to change the protocol for data sharing/availability without going back to the IRB and participants to get approval for this new plan. It would be impossible to re-contact participants to get their approval for their de-identified data to be shared, since all data collection took place through the smartphone application. Thus, the researchers are unable to change the protocol and study information to make participant-level data publicly available. Data will be held by study investigators on secure, password-protected laptops.

## IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | 1-month follow-up results | 05/03/2021 | 08/03/2021 | Yes | No |