Evaluating an app to help people quit smoking

Submission date	Recruitment status	Prospectively registered	
08/10/2020	No longer recruiting	[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
15/10/2020	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
711117074	Other		

Plain English summary of protocol

Background and study aims

The majority of smokers want to stop smoking and many try to quit each year, but success rates are low. Methods of supporting smokers during a quit attempt that are low-cost and easy to access are needed. We are hoping to find out how likely smokers who are motivated to quit are to be successful in quitting, and how far this is influenced by how they try to quit. Specifically, we want to know whether offering a smoker a popular smartphone app can increase their chances of quitting successfully.

Who can participate?

People are eligible to take part in this study if they are aged 18 years or older, are able to provide informed consent, are an English speaker, own a smartphone, are a current cigarette smoker, are willing to be followed-up by email and complete four brief questionnaires after 1, 4 and 7 months and are interested in making a quit attempt in the next 30 days.

What does the study involve?

Participants will be asked to complete four brief online questionnaires: now, and in 1, 4 and 7 months' time. The first questionnaire is the longest, and will take around 10 minutes to complete. The other three are shorter and will take around 3-5 minutes. We will send an email to let them know when it is time to complete each survey.

What are the possible benefits and risks of participating?

Participating in the study will help us to understand more about how different tools can be used to help people quit smoking, making a valuable contribution to science and public health. On behalf of those who complete all four surveys we will make a £10 donation to Cancer Research UK or Macmillan Cancer Support, according to the participant's preference. We do not anticipate any problems related to participation in this study.

Where is the study run from?

University College London (UK). More information about the study team can be found at https://www.ucl.ac.uk/iehc/research/behavioural-science-health/research/tobacco-alcohol

When is the study starting and how long is it expected to run for? August 2018 to December 2021

Who is funding the study?
This study is part of a large programme of work funded by Cancer Research UK (UK)

Who is the main contact?

Dr Sarah Jackson, s.e.jackson@ucl.ac.uk

Prof. Jamie Brown, jamie.brown@ucl.ac.uk

Study website

http://www.uclsmokingstudy.co.uk

Contact information

Type(s)

Scientific

Contact name

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Type(s)

Scientific

Contact name

Prof Jamie Brown

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CEHP/2016/556

Study information

Scientific Title

Effectiveness of an offer of the Smoke Free smartphone application for smoking cessation compared with no support: the App for Smoking ceSsation Evaluation Trial (ASSET)

Acronym

ASSET

Study objectives

In Englishspeaking adult smokers willing to quit in the next 4 weeks who are recruited online or have previously used the Smoke Free app and agreed to be followedup and in an unrestricted setting, an offer to use the app plus followup (intervention) will increase selfreported smoking cessation for at least 26 weeks, assessed 30 weeks after enrolment, compared with no offer of the app and followup only (comparator).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/09/2019, UCL Research Ethics Committee (University College London, 2 Taviton St, London WC1E 6BT, UK. +44 (0)207 6798717; ethics@ucl.ac.uk), ref: CEHP/2016/556

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

http://www.uclsmokingstudy.co.uk

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

This will be a twoarm individually randomized controlled effectiveness trial. Participants will be adult smokers who are intending to quit in the next 4 weeks, willing to participate in a 30week study of their smoking and able to provide consent.

Those who are eligible and consent to participate in the trial will be randomized at that point to intervention or comparator conditions. Randomization will be 1:1 at the individual level with no restriction (i.e. no blocking) and will be automated using a random number function.

After consenting, participants in the comparator condition will receive a message encouraging them to make a quit attempt within the next 4 weeks and reminding them of the importance of responding to followup requests which are designed to track their progress.

Participants in the intervention condition will receive the same advice as those in the comparator condition plus offer of the full version of the Smoke Free app free of charge, encouragement to use the app and a link to download it. The Smoke Free app is based on behaviour change techniques that would be expected from theory and evidence with facetoface support to aid smoking cessation. It guides smokers through the first month of their quit attempt by helping them to maintain their resolve by setting a clear goal, monitoring their progress towards that goal and becoming aware of benefits of being smokefree achieved to date. The app has several components:

- 1. A calculator which tracks the total amount of money not spent on buying cigarettes and the number of cigarettes not smoked ('Dashboard')
- 2. A calendar which tracks the amount of time elapsed since cessation ('Dashboard')
- 3. A scoreboard which awards virtual 'badges' to users for not smoking ('Badges')
- 4. Progress indicators which inform users of the health improvements made since the start of their quit attempt (e.g. pulse rate, oxygen levels, carbon monoxide levels; 'Dashboard')
- 5. A diary which tracks the frequency, strength, location and triggers of cravings to smoke ('Diary')
- 6. A graph which displays the frequency, location, strength and triggers of cravings to smoke ('Cravings')
- 7. Daily missions which are assigned from the start of a user's quit date for one calendar month ('Missions')
- 8. A chatbot which delivers evidencebased guidance about quitting smoking via a conversational interface which resembles text messaging ('Chatbot')
- 9. 24/7 online expert support

The investigators will be blinded to participants' treatment allocation until all data have been collected.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Smoke Free app

Primary outcome measure

Selfreported smoking cessation for at least 26 weeks, assessed 30 weeks after enrolment

Secondary outcome measures

Assessed using self report:

- 1. Having made at least one quit attempt in the 4 weeks following enrolment in the study
- 2. Smoking cessation for at least 12 weeks, assessed 4 weeks after enrolment
- 3. Downloading or using the Smoke Free app at least once, assessed 30 weeks after enrolment

Overall study start date

01/08/2018

Completion date

30/12/2021

Eligibility

Key inclusion criteria

- 1. Aged at least 18 years
- 2. Able to provide consent
- 3. English speaker
- 4. Owns a smartphone
- 5. Current cigarette smoker
- 6. Willing to be followedup by email and complete online questionnaires after 1, 4 and 30 weeks
- 7. Interested in making a quit attempt within the next month

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

3,116

Total final enrolment

3143

Key exclusion criteria

1. Used the Smoke Free app in the past 6 months

Date of first enrolment

20/08/2020

Date of final enrolment

30/04/2021

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

Bermuda

Bhutan

Belarus

Belgium

Belize

Benin

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

Costa Rica
Croatia
Cuba
Curação
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

Cook Islands

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
Могоссо
Mozambique
Myanmar
Namibia

Nauru
Nepal
Netherlands
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
Реги
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 University College London 1-19 Torrington Place London United Kingdom WC1E 7HB

Sponsor information

OrganisationUniversity College London

Sponsor details

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Sponsor type

University/education

Website

http://www.ucl.ac.uk/

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. (Open Science Framework, https://osf.io/umec4/). Anonymised data will be shared without restriction upon submission of the trial report to a peer-reviewed journal.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/11/2019	08/10/2020	Yes	No
Preprint results	results	12/01/2023	18/01/2023	No	No
Results article		15/11/2024	27/11/2024	Yes	No