ISRCTN39840514 https://doi.org/10.1186/ISRCTN39840514

A randomised controlled trial to assess the effectiveness of the Breaking Free from Smoking online intervention for offenders in UK prisons

Submission date
09/02/2018

Recruitment status
Stopped

Registration date
12/02/2018

Overall study status
Stopped

Last Edited
04/07/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Tobacco use contributes to about 100,000 deaths a year in the UK alone. Although the rates of smoking have decreased to an average of 16.9% in community populations, the rates of smoking in UK prisons currently stands at around 80%. At present, the UK government is putting into place legislation to make all inside areas of UK prisons completely smoke free. However, this proposal is currently hindered by a major shortage of prison staff, limiting the support available to offenders to help them to quit smoking. Breaking Free from Smoking is the first internet-based smoking cessation programme to be offered to offenders in the UK. This intervention is designed to support offenders to have a greater chance of success in their quit attempts by providing appropriate strategies to support them to change their smoking behaviours. This study therefore aims to examine the effectiveness of the Breaking Free from Smoking programme when delivered alongside standard prison smoking cessation support currently provided in UK prisons.

Who can participate?
Offenders aged 18 and over who are currently smoking tobacco and attending the standard stop smoking programme

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives the Breaking Free from Smoking online programme plus standard smoking cessation support, and the other group receive standard smoking cessation support only. Self-reported smoking is assessed after an 8-week period of smoking cessation support and at 3 months and 6 months follow-up.

What are the possible benefits and risks of participating?
The possible benefits to participants are that they may be supported to quit smoking, and therefore experience multiple health benefits including better heart health, reduced chance of lung diseases, and overall better health. The risks for participants are largely around the

intervention not being successful in supporting participants to quit smoking, therefore leaving them at risk of the multiple health problems associated with smoking.

Where is the study run from?
Breaking Free Group (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Breaking Free Group (UK)

Who is the main contact?
Dr Sarah Elison-Davies

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Elison-Davies

Contact details
Breaking Free Group
274 Deansgate
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2

Study information

Scientific Title
A randomised controlled trial to assess the effectiveness of the Breaking Free from Smoking online intervention for offenders in UK prisons

Study objectives
It is hypothesised that, compared to participants using the standard stop smoking programme only:

1. The BFS online programme will be effective in encouraging smoking cessation
2. The BFS online programme will be effective in promoting decreases in cigarette dependence, including the frequency and strength of cigarette cravings
3. The BFS online programme will be effective in promoting increases in offenders' overall quality of life ratings

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West – Greater Manchester West Research Ethics Committee, 22/05/2017, REC ref: 17/NW /0214

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Participants will be assigned to one of the study groups following the generation of a random allocation sequence via the Research Randomizer (from the Social Psychology Network-Urbaniak and Plous, 2011), which uses the "Math. Random" method within the JavaScript programming language for web browsers. The sponsor's authorised personnel will prepare the sequentially numbered opaque sealed envelopes containing the treatment group that the participant will be allocated to. The sealed envelopes will be delivered by the principal investigator to the research sites prior to commencement of the study. The participant number will be determined according to the order of enrolment in the study. The site investigator or service worker will assign and open one sealed envelope, containing the type of treatment, with the participant on the day of screening. This way, investigational site and participant will be aware of the treatment to follow from the day of screening (no blinding is applicable).

Participants will be allocated randomly to either an active control (standard stop smoking behavioural and medication based support only) or intervention group (BFS online programme, plus the standard stop smoking programme) on the first session of the standard stop smoking programme in prison.

The intervention group will receive the same standard prison smoking cessation support as the participants in the control group, including standard prison smoking cessation support and stop smoking medication. In addition to this, participants who are randomly assigned to the intervention group will also complete the internet-based Breaking Free from Smoking programme.

The control group will receive standard prison smoking cessation support, which incorporates evidence-based behavioural support as specified by the National Centre for Smoking Cessation Training (NCSCT), alongside stop smoking medications (e.g., nicotine patches, lozenges).

Both programmes last for a 12-week duration and require participants to attend weekly sessions provided in the prison by trained health care or prison staff. Assessments will be taken throughout the treatment period from baseline, after the 12-week programme, and at three-months, and six-months following the programme completion.

Intervention Type
Behavioural

Primary outcome measure
Self-reported smoking at baseline, following treatment engagement at 8 weeks, then at 3 months and 6 months follow-up

Secondary outcome measures
Measured at baseline, following the 8-week intervention period, and at 3 and 6 months follow-up:
1. Quality of life, measured using two items from the World Health Organisation Quality of Life scale (WHOQOL-BREF)
2. Biopsychosocial functioning, measured using six items from the Recovery Progression Measure (RPM)

Overall study start date
09/01/2017

Completion date
01/12/2019

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Currently smoking tobacco
3. Attending the standard stop smoking programme
4. Willing to make a quit attempt in the next 14 days

5. Willing to complete the assessment measures
6. Willing to complete an online programme
7. Able to read and understand materials written in the English language
8. Not scheduled for release within 12 weeks of enrolment to the study

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total sample size of 128 participants has been predicted in order to find a medium effect size [d = .50, 31] between the control and the intervention condition on the primary outcome (quit status), at an alpha level of .05 (95% confidence that the results are not predicted by chance), and a power of at least 80% (allowing for a possible 20% dropout at follow-up) at 6-month follow-up.

Key exclusion criteria
1. Aged 17 or under
2. Not smoking tobacco at the attendance to the first stop smoking session of the standard prison smoking cessation support
3. Not willing to make a quit attempt in the next 14 days
4. Not willing to complete the assessment measures
5. Not willing to complete an online programme
6. Unable to read and understand materials written in the English language
7. Release or transfer pending within the next 12 weeks

Date of first enrolment
01/06/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Breaking Free Group
274 Deansgate
Manchester
United Kingdom
M3 4JB

Sponsor information

Organisation
Breaking Free Group

Sponsor details
274 Deansgate
Manchester
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Sponsor type
Industry

Website
www.breakingfreegroup.com

Funder(s)

Funder type
Industry

Funder Name
Breaking Free Group

Results and Publications

Publication and dissemination plan
The protocol is not yet published but will be submitted for publication. In the meantime, any requests for the protocol, statistical plan etc, can be sent to Dr Sarah Elison-Davies. Findings from the study will be disseminated following final data collection analyses from October 2019. Findings will be disseminated via high impact academic journals, presentation at conferences, and via other social and digital media methods.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No