

(COVER PAGE)

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

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Precis

Quitting smoking is challenging and relapse is likely. Smokers may perceive temptation to smoke as threatening if they think it suggests that they are unable to meet the challenges of cessation. When individuals experience such a threat to their sense of self-identity (e.g., to their sense that they have integrity and/ or competence), they often respond defensively. Individuals have a tendency to react defensively to information that informs them that their behavior increases risk for a particular disease or negative health consequences. Self-affirmation – a process through which individuals focus on their strengths and values – can offset threats to the self and promote healthier behaviors, including smoking cessation. To the extent that relapse or difficulty quitting is perceived as a threat to self-identity, when individuals are presented with the opportunity to self-affirm they may perceive failure as less threatening, mitigating the motivation to downplay the importance of quitting. Preliminary evidence suggests that self-affirmation can be feasibly incorporated into an existing smoking cessation text message-based intervention, and may bolster cessation rates among users motivated to quit smoking. Here, we propose to extend that research by examining whether the addition of self-affirmation text messages to a smoking cessation app (Smoke Free UK) promotes smoking cessation, compared to standard of care (i.e., existing app content only). Importantly, self-affirmation material will be incorporated into the current app and will not change the goals or nature of the original texting program. We predict that the individuals in the self-affirmation condition will be more likely to report being smoke-free at the 1-month and 3-month follow-ups.

Introduction

Quitting smoking is challenging and relapse is likely (Hughes, Keely, & Naud, 2004). Smokers may perceive temptation to smoke as threatening if they think it suggests that they are unable to meet the challenges of cessation. When individuals experience such a threat to their sense of self-identity (e.g., to their sense that they have integrity and/ or competence), they often respond defensively (Jemmott, Ditto, & Croyle, 1986; Kunda, 1987). For example, when presented with information that smoking confers risk for health threats like lung cancer and cardiovascular disease, smokers may discount the information as less credible in an attempt to protect their self-identity as a smoker and their sense of themselves as good and morally adequate people. If individuals perceive failure as threatening to the self, they may be motivated to downplay the importance of quitting, thus leading to fewer subsequent attempts to quit.

Self-affirmation (Steele, 1988) – a process through which individuals focus on their strengths and values – can offset threats to the self and promote healthier behaviors (Cohen & Sherman, 2014; Epton et al., 2015; Sweeney & Moyer, 2015), including smoking cessation (Armitage et al., 2008; Epton et al., 2014; Harris et al., 2007). To the extent that relapse or difficulty quitting is perceived as a threat to self-identity, when individuals are presented with the opportunity to self-affirm they may perceive failure as less threatening, mitigating the motivation to downplay the importance of quitting. Thus, smokers who self-affirm may be more successful at quitting, because such temptation may be seen as less threatening to competence or self-control.

Effective smoking cessation treatments, including those delivered via mobile health platforms, have been empirically validated and are widely available (Fiore et al., 2008; Fraser et al., 2014; Spohr et al., 2015). Preliminary evidence suggests that incorporating a self-affirmation component into a standard text-message-based smoking cessation intervention is a feasible, low-cost, and potentially efficacious way of bolstering the content of that intervention (Taber et al., under review). Specifically, self-affirmation content was associated with increased self-reported quit rates among smokers who reported being most motivated to quit at baseline.

Moreover, the scalability of self-affirmation interventions has been demonstrated in other domains (i.e., education; Cohen et al., 2006; 2009). Indeed, self-affirmations have promise for dissemination, given that affirmation exercises require little time and effort but have lasting effects (Cohen et al., 2009; Logel & Cohen, 2012). Although lasting effects from such a “low touch” intervention are surprising, self-affirmation seems to work not continuously but rather by engaging recursive processes, such that self-affirmation engages motivation and reduces threat associated with temptation in a way that allows individuals to take advantage of resources or infrastructure already in place to facilitate change (Cohen et al., 2009). Thus, implementing brief affirmations into an existing, scalable cessation intervention may bolster the effectiveness of the intervention by maximizing the likelihood that individuals will engage with and benefit from the content of that intervention.

Here, we propose to extend this line of research by examining whether self-affirmation is an effective way of bolstering the content of an existing mobile app intervention intended to facilitate smoking cessation. We will incorporate self-affirmation intervention content into a UK-based smoking cessation mobile app. Individuals who sign up for the app will be randomly assigned to receive the self-affirmation content in addition to the existing app content—at the beginning of the intervention (questionnaire self-affirmation condition), delivered throughout the course of three-month engagement with the app (integrated self-affirmation condition), or both (questionnaire and integrated self-affirmation condition)—or to receive only the standard app content (standard of care control condition).

We predict that inducing self-affirmation will result in additional smoking-related benefits compared to standard of care. We expect that those who receive affirmation will be more likely to report being smoke-free at the 1-month and 3-month follow-ups. The nature of the self-affirmation will either be in the form of an affirmation quiz upon enrollment—which is the most frequent way to affirm—or through booster texts through the program (or both). The proposed design will allow us to determine whether there are unique effects of different types of affirmation, although we do not have specific hypotheses regarding the type/nature of the affirmation inductions.

Study Design and Methods

Participants (18+ years of age) who download the Smoke Free UK app during a particular period of time will be enrolled into the study. Participants will be randomly assigned to one of 4 conditions as part of a 2 (Integrated affirmation: Affirmation texts present versus absent) X 2 (Baseline affirmation: questionnaire present versus absent) design (these affirmations are described below). Those in the control condition will receive no changes to the app (standard of care control condition). All participants will have access to the “smoke free pro” materials that users typically pay for. We will be able to track usage of these materials through <https://mixpanel.com/>.

Upon enrollment, participants will answer demographic, smoking-related, and mood questions in the app. Participants will be sent follow-up surveys at 1- and 3-months. Participants also provide a quit date. Participants will be informed that if they agree to participate they will be entered into a lottery for a \$100 Amazon voucher. We expect that 50% of participants will complete each survey.

When participants download the app, they will be given information about the app that describes it as part of an “on-going project on smoking cessation” and told that they are “invited to participate in a study

looking at smoking cessation.” Participants who agree to the terms outlined then provide informed consent by selecting “I understand and wish to participate.”

Booster affirmation texts: Participants in the integrated self-affirmation conditions will receive two self-affirmation text messages per day. Participants will also be informed that they can access the self-affirmation messages every time they spontaneously report experiencing a craving. These will show up in a screen that shows “Tips.” We will be able to assess how many times participants reported experiencing a craving and thus saw a craving booster message.

Baseline kindness affirmation quiz: Participants in this condition will complete a standard 5-item kindness quiz as part of the consent screen when they enroll in the trial (Reed & Aspinwall, 1998; below). This self-affirmation manipulation has been frequently used, has face validity, and is easy to implement (McQueen & Klein, 2006). Prior data from this app have shown that approximately 60% of people set their quit date for the day they download the app, around 30% quit before they download it, and around 20% quit after they download it.

Enrollment items: Upon enrollment, participants provide their age, gender, the number of years they’ve been smoking, number of cigarettes they smoke each day, the smoking cessation aids (if any) they are currently using, and are asked to provide their quit date. For the present study, we are adding four items (below) assessing craving level at baseline, readiness to quit, nicotine dependence, and race/ethnicity, for exploratory reasons. These measures moderated the effect of booster affirmations on self-reported cessation in pilot work.

What's your craving level? Reply: HI, MED, or LOW

Congratulations! By downloading this app you’ve taken the first step to quit smoking. You are stronger than you think so stay positive. Are you ready? Reply: READY or NOT

Follow-up surveys at 1- and 3-months: Data will be collected through surveys sent 1 and 3 months after enrollment through the app; participants will have the option to complete the survey through either of these modalities (see Appendix C). These questions assess smoking in past month, past week, and current number of cigarettes smoked per day, use of other smoking cessation aids, whether participants would recommend the app to others, and allow participants to leave a comment. Less than 10% of respondents are expected to complete the surveys.

Inclusion and exclusion criteria

Because the app is designed to assist with smoking cessation, all smokers are eligible to participate. Subjects are eligible if they are 18+ years of age.

Criteria for Withdrawal of Subjects from the Study

Subjects will complete the questionnaires from wherever they choose to access the app. Subjects can choose not to complete the study simply by exiting the surveys. We will conduct analyses with and without the non-completers to explore how each group differed. Although we anticipate a large sample size, we will add additional smokers as needed. Moreover, the informed consent page will inform subjects that should they want to withdraw from the study after they have completed the entire survey, they should contact Smoke Free UK and request that their data not be included in the final dataset provided to NCI.

No subjects will be withdrawn by the researchers, although data from a given subject may be excluded from the study if key response variables are missing (i.e., if the subject chooses not to answer the questions necessary to calculate a score for a study outcome).

Data analysis

Data gathered will be analyzed using ANOVA to determine whether there are significant differences among key outcomes between the self-affirmation and standard of care conditions. The primary outcomes are number of quit attempts and self-reported smoking status (i.e., how often the participant reports smoking after using the app). The intermediate outcomes will include smoking attitudes, number of smoke-free days and type of tobacco products (e.g., switching to low nicotine tobacco).

We will attempt to recruit 5000 smokers with the aim of having 500 complete the surveys, thus accounting for a 90% attrition rate in completion of the surveys. Because this study will take place through an app, we were more conservative in power calculations, given that effect sizes may be smaller in online studies compared to laboratory studies (due to less experimental control). Using a small effect size estimate (.15), a sample of 500 will yield high (.90) power to detect differences in a study involving 4 groups (2x2) (calculated with G*Power, a publicly available software package).

Human Subject Protections

Rationale for Subject Selection: Individuals will only be eligible if they are 18+ years of age. All ethnic and race categories will be eligible to participate in the study.

Evaluation of Benefits and Risks/Discomforts: Participants will help contribute to the body of knowledge in tobacco control research. Minimal risks include any discomfort participants may feel answering questions about quitting smoking (i.e. cravings). Given the minor risks in comparison to the importance of the scientific knowledge that may reasonably be expected to result from this study, risks to subjects are reasonable.

Adverse Event Reporting and Data Monitoring

Not applicable; no adverse events are anticipated. This is not a clinical trial, and as such, a data monitoring and safety plan is not necessary.

Collection and Storage of Human Specimens or Data

The anonymized data will be stored on a government server, which can only be accessed by the designated user (the PI) and system administrators. No personally identifying information will be collected. No human specimens will be collected or stored. Once the protocol is completed, the anonymized data will continue to be stored for potential secondary analyses.

Remuneration/Compensation

Participants who provide an e-mail address will be entered into a lottery to win a \$100 Amazon voucher. This study does not include any medical procedures, and presents minimal risk. Participants will not receive any additional remuneration or compensation for participating in the study.

Consent and Assent Processes and Documents

Consent will take place entirely online. When participants download the app, they are given information about the app that describes it as part of an “on-going project on smoking cessation” and told that they are “invited to participate in a study looking at smoking cessation.” Participants who agree to the terms outlined then provide informed consent by selecting “I understand and wish to participate.” The investigators’ names and contact information will be listed.

Limitations

We recognize one limitation of this study is the high attrition rate. Although participants will be randomized to condition, attrition may be related to quitting success and may not be comparable across groups. However, if self-affirmation is successful for the participants who remain in the texting program, this has the potential to inform future research about a technique that can work for smokers who are very engaged comparable cessation programs.

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Appendix A

Baseline Kindness Affirmations

Get ready to quit smoking with something positive. These questions refer to behaviors that YOU have performed for other people.

1. Have you ever been considerate of another person's feelings? If yes, spend a moment thinking of a specific time. Reply: Yes or No
2. Have you ever attended to the needs of another person? If yes, spend a moment thinking of a specific time. Reply: Yes or No
3. Have you ever forgiven another person when they have hurt you? If yes, spend a moment thinking of a specific time. Reply: Yes or No
4. Have you ever tried not to hurt the feelings of another person? If yes, spend a moment thinking of a specific time. Reply: Yes or No
5. Have you ever been generous and selfless to another person? If yes, spend a moment thinking of a specific time. Reply: Yes or No

Appendix B

Booster Affirmations

	Affirmation text
1.	When you feel like you might relapse, focus on your good experiences. Think about a time you made someone laugh.
2.	When you feel threatened by a craving to smoke, focus on your strengths. Think of a time you worked hard on something you care about.
3.	When you feel anxious about staying smokefree, think about a time you were loyal to someone you care about.
4.	When you feel anxious about quitting smoking, focus on your values! Think of a time you showed compassion for another person, even if it was hard.
5.	When you can't take your mind off of smoking a cigarette, think of a time when you tried to add some humor to something you were doing.
6.	Quitting is hard! When you feel a craving, focus on a positive aspect of yourself. Think of a time you helped someone less fortunate than you are.
7.	When you feel anxious about quitting smoking, focus on your values! Think of a time you stood up for what you believe in, even if it was hard.
8.	Quitting is hard! When you feel a craving, think of a time you learned from a mistake.
9.	Quitting is hard! When you feel a craving, focus on what you stand for. Think of a time you treated people equally, regardless of who they were.
10.	When you feel like you might relapse, focus on your good experiences. Think about a time that you learned something new.
11.	When you feel anxious about staying smokefree, think about a time when someone else looked to you for advice.
12.	When you feel threatened by a craving to smoke, focus on something important to you. Think of a time you helped a friend, even if you felt busy.
13.	When you feel like you might relapse, think of a time you were honest with someone, even when it was hard. Reflect on that experience instead!
14.	When you can't take your mind off of smoking a cigarette, think of a time when you looked out for another person's interests before your own.
15.	When you feel like you might relapse, think of a time you helped someone feel better about a bad situation. Reflect on that experience instead!

Control Push Notifications

	Control Text
1.	Keep the golden rule: Not another puff, no matter what
2.	Remember the four Ds: Delay, Drink water, Deep breathing, Do something
3.	All cravings pass. Your mission is to get through the next 15 minutes without smoking
4.	Doing something will improve your mood, relieve stress and distract you from cravings. It also stimulates brain chemicals that fight the desire to smoke
5.	If you're having prolonged or severe cravings try nicotine replacement therapy
6.	Take extra care of yourself. Drink plenty of water, eat good food, get enough sleep
7.	Make a commitment to call someone before you light up
8	Get some exercise: take a walk, go for a run. Physical activity helps relieve stress, reduces cravings and gets you fitter. It also helps shed any excess weight you may have gained
9.	Short on time? No problem, even quick bursts of activity help. Walk up and down stairs a few times.
10	If physical activity doesn't feel right do some housework, file papers, call a friend
11.	Have a book on hand on a subject you want to learn about. Read a few pages and make notes. You'll be occupying your hands and your mind
12.	Go online and read something, anything
13.	Picture your lungs filling with fresh, clean, air
14.	You're saving money by not smoking. Spend the new few minutes thinking about all the money you saved.
15.	Why do you want to stop smoking? Bring some reasons to mind right now.

Appendix C: Baseline, 1-month and 3-month Follow-Up Questionnaires

Baseline Demographic Questions

1. Please enter your age: text box that allow participant to enter age
2. Gender: forced choice Male or Female
3. How strong is your desire to smoke, right now? Not at all to Extremely (11 pt. scale)
4. About how old were you when you started smoking regularly? Free Text
5. On average, how many cigarettes do you smoke a day? Free text
6. Are you currently? using medications, counseling, or aids to help you quit? Yes/No
7. How soon after you wake up do you smoke your first cigarette?
 - Within 5 minutes
 - 6 to 30 minutes
 - 31 to 60 minutes
 - After 60 minutes
8. Readiness to Quit (Diclemente et al. 1991)
 - a. In the last year, how many times have you quit smoking for at least 24 hours? _____
 - b. Are you seriously thinking of quitting smoking?
 - Yes, within the next 30 days
 - Yes, within the next 6 months
 - No, not thinking of quitting

- | | All of the
time | Most of the
Time | Some of the time | A little of the time | None of the time |
|-------------|--------------------|---------------------|------------------|----------------------|------------------|
| a. Happy?. | | | | | |
| b. Angry? | | | | | |
| c. Anxious? | | | | | |
| d. Hopeful? | | | | | |
| e. Sad? | | | | | |
9. In the past 30 days, how often have you felt...

- | | All of the
time | Most of the
Time | Some of
the time | A little of
the time | None of the
time |
|--|--------------------|---------------------|---------------------|-------------------------|---------------------|
| a. When I feel threatened or anxious I find myself thinking about my strengths | | | | | |
| b. When I feel threatened or anxious I find myself thinking about my values. | | | | | |
| c. I'm always optimistic about my future | | | | | |

10. How much do you agree or disagree with each of the following statements?

1-month Questionnaire

11. Have you smoked at all in the past month? [users can choose only one]
No, not a puff
1-5 cigarettes
More than 5 cigarettes

12. Have you smoked at all in the past week? [users can choose only one]
No, not a puff
1-5 cigarettes
More than 5 cigarettes

If participants answered yes to question 11 then ask 13-14. If no, then skip to question 15.

13. On average, how many cigarettes do you smoke a day? [users can only choose one]
None
1-9
10-19
20-29
30-39
40+

14. How soon after you wake up do you smoke your first cigarette?
After 60 min
31-60 min
6-30 min
Within 5 min

15. Are you using aids other than this app? [users can choose more than one]
None
Electronic cigarette
NRT (eg. patches/gum/inhaler)
[If selected]
On prescription?
Yes
No
Champix/Chantix (Varenicline)
Zyban
Group, phone, 1-2-1 behavioural support
Other app
Other aid

16. How likely is it that you would recommend this app to a friend or colleague?
[Likert 0-10;]
0 = Not at all
10 = Very much

17. Over the past month, how often did you engage in the activities recommended by the “Tips” (e.g. “Think of a time when you helped a friend”)?

Never

1-3 times

4– 6 times

7 - 9 times

10 or more times

18. In the past 30 days, how often have you felt...

]

‘ Most of the

‘ Time

Some of the time

A little of the time

None of the time

a. Happy?.

b. Angry?

c. Anxious?

d. Hopeful?

e. Sad?

19. Would you like to leave a comment?

[Text entry field]

3-month Questionnaire

20. Have you smoked at all in the past month? [users can choose only one]

No, not a puff

1-5 cigarettes

More than 5 cigarettes

21. Have you smoked at all in the past week? [users can choose only one]

No, not a puff

1-5 cigarettes

More than 5 cigarettes

If participants answered yes to question 11 then ask 13-14. If no, then skip to question 15.

22. On average, how many cigarettes do you smoke a day? [users can only choose one]

None

1-9

10-19

20-29

30-39

40+

23. How soon after you wake up do you smoke your first cigarette?

After 60 min

31-60 min

6-30 min

Within 5 min

24. Are you using aids other than this app? [users can choose more than one]

None

Electronic cigarette

NRT (eg. patches/gum/inhaler)

[If selected]

On prescription?

Yes

No

Champix/Chantix (Varenicline)

Zyban

Group, phone, 1-2-1 behavioural support

Other app

Other aid

25. How likely is it that you would recommend this app to a friend or colleague?

[Likert 0-10;]

0 = Not at all

10 = Very much

26. Over the past month, how often did you engage in the activities recommended by the “Tips” (e.g. “Think of a time when you helped a friend”)?

Never

1-3 times

4– 6 times

7 - 9 times

10 or more times

27. In the past 30 days, how often have you felt...

- | | All of the time | Most of the
Time | Some of the time | A little of the time | None of the time |
|-------------|-----------------|---------------------|------------------|----------------------|------------------|
| a. Happy?. | | | | | |
| b. Angry? | | | | | |
| c. Anxious? | | | | | |
| d. Hopeful? | | | | | |
| e. Sad? | | | | | |

28. Would you like to leave a comment?

[Text entry field]

