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Complete List of Authors:	BinDhim, Nasser; University of Sydney, Public Health; Saudi Electronic University, Health Informatics McGeechan, Kevin; The University of Sydney, School of Public Health; Trevena, Lyndal; University of Sydney, School of Public Health
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The Smartphone Smoking Cessation App (SSC APP) Trial: a multi-country double-blind automated randomised control trial of a smoking cessation decision aid 'app'

Authors:

Nasser F BinDhim, PhD[1,2]

Kevin McGeechan, PhD[2]

Lyndal Trevena, MBBS(Hons) MPhilPH PhD[2]

Affiliations

[1]Health Informatics Department, College of Health Sciences, Saudi Electronic University, Riyadh, Saudi Arabia

[2]School of Public Health, University of Sydney, New South Wales, Australia

Corresponding author:

Lyndal Trevena

Room 321b Edward Ford Building (A27)

University of Sydney

NSW 2006 Australia

Ph: +61 2 93517788

Email: lyndal.trevena@sydney.edu.au

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Abstract

Objective: To assess the efficacy of an interactive smoking cessation decision-aid app compared with a smoking cessation static information app on continuous abstinence.

Design: Automated double-blind randomized controlled trial with 6 months follow up (2014-2015).

Setting: Smartphone-based.

Participants: 684 Participants (daily smokers of cigarettes, 18 years old or over) recruited passively from app stores in the USA, Australia, UK and Singapore and randomized to one of two sub-apps.

Intervention(s): Behavioral, decision-aid.

Main Outcome(s): Continuous abstinence at 10 days, 1 month, 3 months and 6 months.

Results: Smokers who received the decision aid app were more likely to be continuously abstinent at one month compared with the information only app (28.5% versus 16.9%; RR 1.68; 95%CI 1.25-2.28). The effect was sustained at 3 months (23.8% versus 10.2%; RR 2.08; 95%CI 1.38-3.18) and 6 months (10.2% versus 4.8%; RR 2.02; 95%CI 1.08-3.81). Participants receiving the decision aid app were also more likely to have made an informed choice (31.9% versus 19.6%) and have lower decisional conflict (19.5% versus 3.9%).

Conclusion: A smartphone decision aid app with support features significantly increasing smoking cessation and informed choice. With an increasing number of smokers attempting to quit unassisted evidence-based decision aid apps can provide an effective and user-friendly option to many who are making quit decisions without health care professionals.

Trial registration number: ACTRN12613000833763 URL: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12613000833763

Article Summary

Strengths and Limitations

- This is the first fully-powered efficacy trial of a smoking cessation decision aid app
- The design deliberately reflects the real-world setting recruiting through App stores
- It compares 'state of the art' decision aid design and support with passive information-only apps
- The trial was a novel fully-automated design across four countries
- The decision aid with support app significantly improved continuous abstinence at 6 months compared with information-only app.

Introduction

Just over one-fifth of the world's adult population continues to smoke despite significant declines in smoking rates over the past decades. [1] Smoking is responsible for the deaths of around 6 million people per year and costs the global economy around US$500 billion annually. [1]

Smoking cessation programs are accessible to only 15% of the population globally [2] despite more people attempting to quit. Approximately two-thirds of smokers in the US attempted to quit in 2014, [3] 11% of male Chinese smokers mainly aged 15-24 years attempted to quit [4] and a range of tobacco control policies have been increasing quit attempts in low and middle income countries. [5] We also know that most quit attempts are likely to be unassisted [6] and that the reasons for this may relate to personal and societal values of independence and autonomy which influence smokers' beliefs and decisions about quitting. [7]

Mobile phone interventions have become a new but effective way to help smokers quit. A recently updated Cochrane review [8] includes twelve studies, showing that these, mainly text message-based interventions significantly improved continuous abstinence at six months compared with control interventions of information only. The authors also remarked on the lack of research on smartphone applications despite the plethora of these available to the public. As we have previously shown, a smartphone app was able to reach 1751 smokers in the United States, Australia, and the United Kingdom over a period of 12 months. Most of these people were not seeking professional help and were ready to quit in the next 30 days. [9]

Smartphones with their advanced processing capabilities, rapid global uptake, proximity to the user, and push-notifications (a short message service (SMS)–like function that is free of cost and more interactive), [10] are potentially an ideal vehicle for health interventions. [11]

In addition, smartphone applications (apps) have shown feasibility across diverse ranges of health conditions. [9, 12-14] Although app stores have hundreds of smoking and tobacco-related apps, the majority are of low quality, very few provide evidence-based content, and some are actually pro-smoking apps. [15-17]

The efficacy of smartphone apps as an intervention for smoking cessation remains untested, although three small pilot studies have shown a potential effect on short-term abstinence rates. [12, 18, 19] This study, the Smartphone Smoking Cessation App (SSC App) trial therefore, is the first that we are aware of to assess the efficacy of a smartphone smoking cessation app in a full-scale, longer-term trial. It tests the efficacy of an interactive smoking cessation decision-aid app compared with a smoking cessation static information app on quit rates.

Methods

Study design

This is an automated, double-blind, randomised control trial (RCT) to determine the efficacy of a smartphone smoking cessation decision-aid app with support features compared with an app that contains only smoking cessation information. An overarching app was developed that included the baseline questionnaire and two sub-apps - the intervention and control apps. The participants from the United States Australia, Singapore, and the United Kingdom, were randomised over a five-month period. The countries were selected based on our feasibility findings. [9] The trial was approved by the University of Sydney's Human Ethics Committee (Project No. 2013/513), and was registered on the Australian New Zealand Clinical Trial Registry as trial number ACTRN12613000833763. The study app was published on the Apple App Store during the recruitment period and was the main portal of advertising the

trial. We also advertised the app as an (In-app) advertisement to Apple iPhone users while they are using other apps, allowing for demographic targeting.

Participants

Users of the Apple App Store in the four countries were recruited passively via the app's download page in the Apple App Store. The eligibility criteria were daily smokers of cigarettes, 18 years old or over and from the included countries. Occasional smokers and users of other tobacco products were excluded.

Patient involvement

Patients were not directly involved in the design of this study. However, a previous study has explored the potential participants' characteristics to inform this study design. [9]

Baseline registration and data collection

When a participant opened the app for the first time, the app assigned them a unique device identifier and registered the user's smartphone device in our secure remote database. The unique device identifier could not change if the user deleted the study app and re-installed it. This allowed anonymous data collection, prevented duplicate enrolments and contamination between groups. As this study is fully automated, not being able to ensure that some users may download the app from another device is an unavoidable limitation. However, to monitor users who download the app onto two devices, we have implemented a server-side internet protocol that can identify the users who use different devices connected to the same internet network at similar times. This may not completely eliminate the possibility of contamination but will reduce it. To increase the response rate to the baseline questionnaire, we have implemented a reminder function that will send a notification to the user to complete the baseline questionnaire. The baseline questionnaire included socio-demographic variables

(age, sex, educational level, marital status and income level) and tobacco consumption (e.g. number of cigarettes smoked per day and nicotine dependence as measured by the Fagerström test). [20]

Randomisation and Blinding

The study app automatically randomised eligible participants (daily cigarette smokers, aged 18 years and above, and from the four countries) to either the intervention or the control sub-app using stratified block (age, gender, country) randomisation. The strata were defined by age, country and gender. Participants and all investigators were blinded to group allocation (double blind).

Intervention and Control App Components

Both apps motivated the participant to set a quit date. The intervention app included four main components that made optimal use of smartphone features - (1) Mandatory information about quitting options, with their benefits and harms; (2) Daily motivational messages using push-notifications sent from the study server, (3) A quitting diary, and (4) A quitting benefits tracker. The intervention app could thus be described as a smartphone 'decision aid with additional support' because it included structured content on the options, benefits and harms of smoking cessation, along with ongoing support and motivation for the implementation and adherence to a quit decision.

The control app included non-mandatory information about quitting options, benefits and harms, similar to those available in the intervention app. It did not provide any structured process for considering options, benefits and harms of quitting methods nor did it provide ongoing support for adherence to a quit decision. This could therefore be described as a smartphone app with information only. As stated earlier, both the intervention and control

apps encouraged users to set a quit date. Full details about the study design, the intervention and control apps are available in the published protocol. [11]

The follow-up data were collected by pushing a notification to the participants that were received even if the app was not running. Participants could also click on a follow-up button inside the app to initiate the follow-up process if the follow-up time had come. The follow up notification generated an automated process where participants could click 'yes' or 'no' to answer the follow up questions.

Outcomes

The primary outcome was the proportion of participants who remained completely abstinent after one month. Participants were asked the question "Have you been totally smoke-free ('not even a puff') for the last (x days/months)?" at 10 days, 1 month, 3 months and 6 months. Secondary outcomes were the proportion who made quitting attempts of at least 24 hours, abstinence rates at 10 days, 3 months, and 6 months, the proportion who made an informed choice (based on the Multidimensional Measure of Informed Choice – MMIC – 10 days after quitting) (Supplementary File) and the proportion with low decisional conflict (SURE score of less than 4 measured 10 days after quitting). [21]

Statistical analysis

We calculated a sample size of 672 participants to achieve 80% power at a 0.05 significance level to detect a change in continuous abstinence after one month from 5% to 15% allowing for 20% loss to follow-up. [11] All analyses were undertaken on an intention-to-treat basis. To account for the non-responses at follow-up, four multiple imputation models were constructed for the non-responses at the follow-up at 10 days, 1 month, 3 months, and 6 months continuous abstinence. The covariates that were included in the models were: age,

gender, educational level, income level, nicotine dependence, intervention group, selected quitting method, and country. Ten imputed datasets were generated based on Rubin's formula for relative efficiency to produce about 99% efficiency. [22] We also conducted a sensitivity analysis with the assumption that all participants with missing outcome data were smokers. [23] Effect measures were Relative Risk (RR) and 95% Confidence intervals (CI). We assessed whether the effect of the intervention on abstinence rates was mediated by choice of quitting method or use of particular app components like the use of the benefit tracking function by applying the method of Baron and Kenny. [24]

Results

The recruitment process started on 5th May 2014 and continued until the required sample size was reached on 1st September 2014. The 684 participants were randomly assigned via our automated randomisation algorithm to the intervention or control group (Figure 1). Treatment groups were balanced with respect to baseline characteristics (Table 1). Chi-square analysis to examine the non-response at one month follow up association with intervention groups revealed that non-response was independent of the intervention groups χ^2 (1, n = 684) = 1.2, p = .27. However, turning off the app push-notification function (8.6% of the participants) was associated with non-response χ^2 (1, n = 684) = 11.1, p<.001.

(Insert Figure 1)

The majority of participants in both groups decided to quit unassisted, followed by nicotine replacement therapy (NRT) (Table 1). Only 2.3% of the participants changed their selected quitting method within the first 10 days.

(Insert Table 1)

The multiple imputations results showed that self-reported continuous abstinence at 10 days, one, three and six months was significantly increased by the intervention app (Table 2). At one month, 28.5% of those in the intervention arm were completely abstinent compared to 16.9% in the control arm. Similar results were obtained when the participants who were lost to follow-up were treated as smokers (Table 3) at the main outcome one month (continuous abstinence 13.2% (45/342) control vs. 26.0% (89/342) intervention; RR 1.97, 95%CI: 1.41 – 2.79, p<.001), and when excluded (Table 3) (continuous abstinence 14.2% (45/317) control vs. 27.4% (89/325) intervention; RR 1.92, 95%CI: 1.39 – 2.66, p<.001).

(Insert Tables 2 & 3)

In all countries, abstinence rates at one month were higher in the intervention group compared to the control group (United States (RR 1.83, 95%CI: 1.04 – 3.25), Australia (RR 2.29, 95%CI: 1.13 – 4.64), United Kingdom (RR 1.97, 95%CI: 1.10 – 3.55), and Singapore (RR 1.56, 95%CI: .71 – 3.44). There was no statistically significant difference in the effect of the intervention between the countries but the increase was not statistically significant in Singapore (P = 0.09).

The effect of quitting method on continuous abstinence at one month, was assessed in a logistic regression analysis using the imputed data adjusting for (age, gender, educational level, country, treatment groups). None of the quitting methods were associated with abstinence compared to 'No treatment (quitting unassisted)'. The quitting method did not mediate the impact of the intervention since method chosen was not associated with abstinence (P=0.99) and inclusion of method did not alter the estimate of the intervention effect.

Finally, we measured the effect of 'app component use' on quitting, using a logistic regression model with the imputed data at 1 month and 6 months. The model included the

quitting benefit tracker use, quitting diary use, and the self-reported reading of the compulsory information adjusting for (age, gender, educational level, country, quitting support method). Only the quitting benefit tracker was significantly associated with continuous abstinence at one month (OR 3.85; CI: 2.15 – 6.91) and 6 months (OR 4.27; CI: 1.53 – 11.88). Mediator analysis was not preformed because the quitting benefit tracker was only available in the intervention app which violated the mediation analysis assumptions.

In terms of the decisional conflict 19.5% of the participants in the intervention group had low decisional conflict compared to 3.9% in the control group $\chi 2$ (1, n = 684) = 28.4, p<.001. Table 4 shows the (MMIC) at 10 days after quitting with participants receiving the decision aid app more likely to make an informed choice than those getting the information only app (31.9% versus 19.6%), $\chi 2$ (1, n = 684) = 12.8, p<.001.

Discussion

The results of this fully-automated RCT show that continuous abstinence from smoking at one, three and six months was significantly increased by a smartphone decision-aid that included behavioural support compared with a simple non-mandatory information-only app. This effect was significant in three out of four countries. Most of the participants chose to quit via 'No treatment (unassisted)' with intervention recipients being more likely to make an informed choice and have low decisional conflict than those receiving the information only app. We have also shown that smartphone apps can be used successfully used in an RCT design, with good follow up response rates in both groups. Turning off the app push-notification was associated with follow up non-response.

We believe this is the first study to investigate the efficacy of a smartphone smoking cessation app. The one-month and six-month continuous abstinence rates (28.5% and 10.2% respectively) are comparable to other mobile phone-based smoking cessation interventions

which report six-month abstinence rates of 9.3%. [25] [8] However, unlike these interventions that used Short Messaging Service (SMS) our intervention app sent these messages via a free push-notifications feature. Our intervention app also sent progress tracking messages based on the user's progress and allowed the user to write a quitting diary. We understand that the combined effect of these smartphone-unique features on health behaviour change has not yet been assessed and this study is the first to do so. [9]

Strengths

A strength of our intervention was that it incorporated patient decision aid features which significantly increased the proportion of people who made an informed choice that was concordant with their personal values and significantly reduced decisional conflict about their quit decision. Comparing our results to a previous paper-based smoking cessation decision aid RCT, [26] our study has also shown comparable results at short-term and long-term follow up period but has the added convenience of smartphone accessibility.

Importantly about 56.0% of the participants in this study (in both groups) had made a previous quit attempt that had lasted at least 24 hours. This is relatively consistent with our finding in the feasibility study where the majority (75.6%) of participants that had used smoking cessation apps in the past had made a quitting attempt that lasted at least 24 hours using an app. [9] It supports the notion that smartphone apps are an effective way of reaching serious 'quitters' who tend to quit 'unassisted'. [26] Interestingly, our study participants who used NRT had similar results to those who quit unassisted. Although, this study was not powered for sub-group analyses, our intervention was effective in three countries out of four.

Furthermore, 77.3% of those who downloaded the app, completed the eligibility test and of those eligible 92.2% completed the baseline questionnaire. The introduction of the push-notification reminders in this study may have contributed to this high response rate, with

other studies reporting similar results with this method [14, 27]. By contrast, our feasibility study only generated a response rate of 36.8% without reminders. [9] Our trial retention rate was good with one month follow up 93.9% and six month 85.2%. Another study comparing a smartphone app with a website found that trial retention was 93% at 6 months in the smartphone group, compared with 55% in the website group.[13] Turning off the app push-notification feature was associated with loss to follow up, In future, the app could include an in-app reminder to the user to turn on the push-notification.

Limitations

One of the limitations of this study is that continuous abstinence was measured via self-report which is less rigorous than a biochemically verified abstinence. Our study was not funded for this. The second limitation is the possibility of contamination between groups although we took measures to minimise this through the unique Internet Protocol feature. [11] Finally, we recognize that the participants in this study were likely to be more motivated than other smokers because they were searching for smoking cessation apps during the recruitment period.

Generalizability

This study has used a novel approach for conducting an automated RCT via a smartphone app, and thereby simulated the 'real world' setting, recruiting via the app store in multiple countries. This automated process eliminated hours of recruitment time, and cost, it reached various ages, education levels and income groups, including 31% of the participants who low-incomes but still used an expensive smartphone device.

Future challenges

Unlike web technology where the intervention can be developed and hosted on the producer's resources, smartphone apps are hosted on the publishers' servers (e.g. Apple app store or Google Play) and thus subjected to their changing regulation policies and technical specifications. For example, in this project the app was released on an iPhone operating system version that did not require the user to provide permission to receive local notifications (Used in the quitting benefit tracker function). However, new versions of the iPhone operating system required the app producer to implement a user permission function to use local notifications. In this case, some users may disable the local notifications and the utilization may be reduced. Thus, future interventions may need to come up with new solutions to improve the utilization of specific app functions. The same issue was faced in another project that uses the location detection function to follow up travellers for infection control purposes. [28]

Other smartphone operating systems such as Android allows the app producer to publish their apps via email or self-hosted web links. Although the producer may lose the mass exposure advantage by publishing their apps on the official app stores, they at least can avoid the changing policies issue.

Conclusions

A smartphone decision aid app significantly increased smoking cessation rates with greater informed choice and lower decisional conflict across three out of four countries. It shows that the benefits of earlier mobile phone smoking cessation interventions can potentially be transferred to the more contemporary and user-friendly smartphone interface. We have also demonstrated the feasibility of conducting an RCT entirely using smartphone technology. Evidence-based decision aid apps should be promoted to smokers who are thinking of quitting.

Contributors All authors made substantial contributions to editing and revising of the manuscript. NFB was responsible for the conceptual development, the app design and development, and drafting of the manuscript. NFB and LT were responsible for the study design. NFB and KM were responsible for the statistical analysis. All authors read and approved the final manuscript.

Competing interests None.

Ethics approval University of Sydney Human Ethics.

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Data sharing: Relevant anonymised patient level data are available on reasonable request from the authors.

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Table 1: Baseline data of participants and self-reported quitting method (*n*= 684)

Characteristics	*Control* *n (%)*	*Intervention* *n (%)*	*Total* *n (%)*
Age (mean (S.D)) (years)	28.8 (9.8)	27.9 (10.2)	28.3 (10.0)
Sex			
Female	181 (52.9)	195 (57.0)	376 (55.0)
Male	161 (47.1)	147 (43.0)	308 (45.0)
Country			
Australia	84 (24.6)	89 (26.0)	173 (25.3)
Singapore	87 (25.4)	79 (23.1)	166 (24.3)
United Kingdom	83 (24.3)	88 (25.7)	171 (25.0)
United States	88 (25.7)	86 (25.1)	174 (25.4)
Education			
Graduate level or above	188 (55.0)	179 (52.3)	367 (53.7)
Less than Graduate level	154 (45.0)	163 (47.7)	317 (46.3)
Income level			
Less than $20K/year	111(32.5)	104 (30.4)	215 (31.4)
$21-49K/Year	168 (49.1)	164 (48.0)	332 (48.5)
More than $50K/year	63 (18.4)	74 (21.6)	137 (20.0)
Marital Status			
Married or de facto	100 (29.2)	95 (27.8)	195 (28.5)
Others (Single, Widowed, etc)	242 (70.8)	247 (72.2)	489 (71.5)
Nicotine dependency (Fagerström)			
Very low - Low (0 - 4)	163 (47.7)	176 (51.5)	339 (49.6)
Medium (5)	50 (14.6)	44 (12.9)	94 (13.7)
High - Very High (6-10)	129 (37.7)	122 (35.7)	251 (36.7)
Selected Quitting Method			
No treatment used (unassisted)	124 (36.3)	102 (29.8)	226 (33.0)
Any NRT	58 (17.0)	53 (15.5)	111 (16.2)
Self-help materials in the App	15 (4.4)	56 (16.4)	71 (10.4)
Other Self-Help	25 (7.3)	32 (9.4)	57 (8.3)
Aversion therapy	20 (5.8)	21 (6.1)	41 (6.0)
Herbal therapy	22 (6.4)	19 (5.6)	41 (6.0)
Acupuncture	22 (6.4)	13 (3.8)	35 (5.1)
Hypnosis	10 (2.9)	20 (5.8)	30 (4.4)
Varenicline	9 (2.6)	0 (0)	9 (1.3)
Bupropion	0 (0)	4 (1.2)	4 (0.6)
Others	37 (10.8)	22 (6.4)	59 (8.6)

Table 2: Primary and secondary outcomes (number of imputations=10)

	Control(%)	*Intervention(%)*	*Relative risk (95% CI)*	*P Value*
Self-reported quit attempt (lasted 24 hour)	52.8	59.0	1.12 (.97 – 1.28)	0.120
Self-reported 10 days continuous abstinence	20.8	32.2	1.55 (1.19 – 2.03)	<.001
*Self-reported 1 month continuous abstinence	16.9	28.5	1.68 (1.25 – 2.28)	<0.001
Self-reported 3 month continuous abstinence	10.2	23.8	2.08 (1.38 – 3.18)	<0.001
Self-reported 6 month continuous abstinence	4.8	10.2	2.02 (1.08 – 3.81)	0.024

* Primary outcome

Table 3: Self-reported abstinence (Intention to treat analysis).

	Control(%)	*Intervention(%)*	*Relative risk (95% CI)*	*P Value*
Lost to follow-up treated as smokers Self-reported 10 days continuous abstinence	19.0	30.9	1.63 (1.23 – 2.17)	<0.001
Self-reported 1 month continuous abstinence	13.2	26.0	1.97 (1.41 – 2.79)	<0.001
Self-reported 3 month continuous abstinence	7.9	17.3	2.19 (1.39 – 3.46)	<0.001
Self-reported 6 month continuous abstinence	3.2	7.3	2.27 (1.09 – 4.86)	0.026
Lost to follow-up excluded Self-reported 10 days continuous abstinence	19.9	31.8	1.59 (1.21 – 2.12)	<0.001
Self-reported 1 month continuous abstinence	14.2	27.4	1.92 (1.39 – 2.66)	<0.001
Self-reported 3 month continuous abstinence	8.9	18.9	2.13 (1.36 – 3.36)	0.001
Self-reported 6 month continuous abstinence	3.8	8.5	2.23 (1.08 – 4.77)	0.029

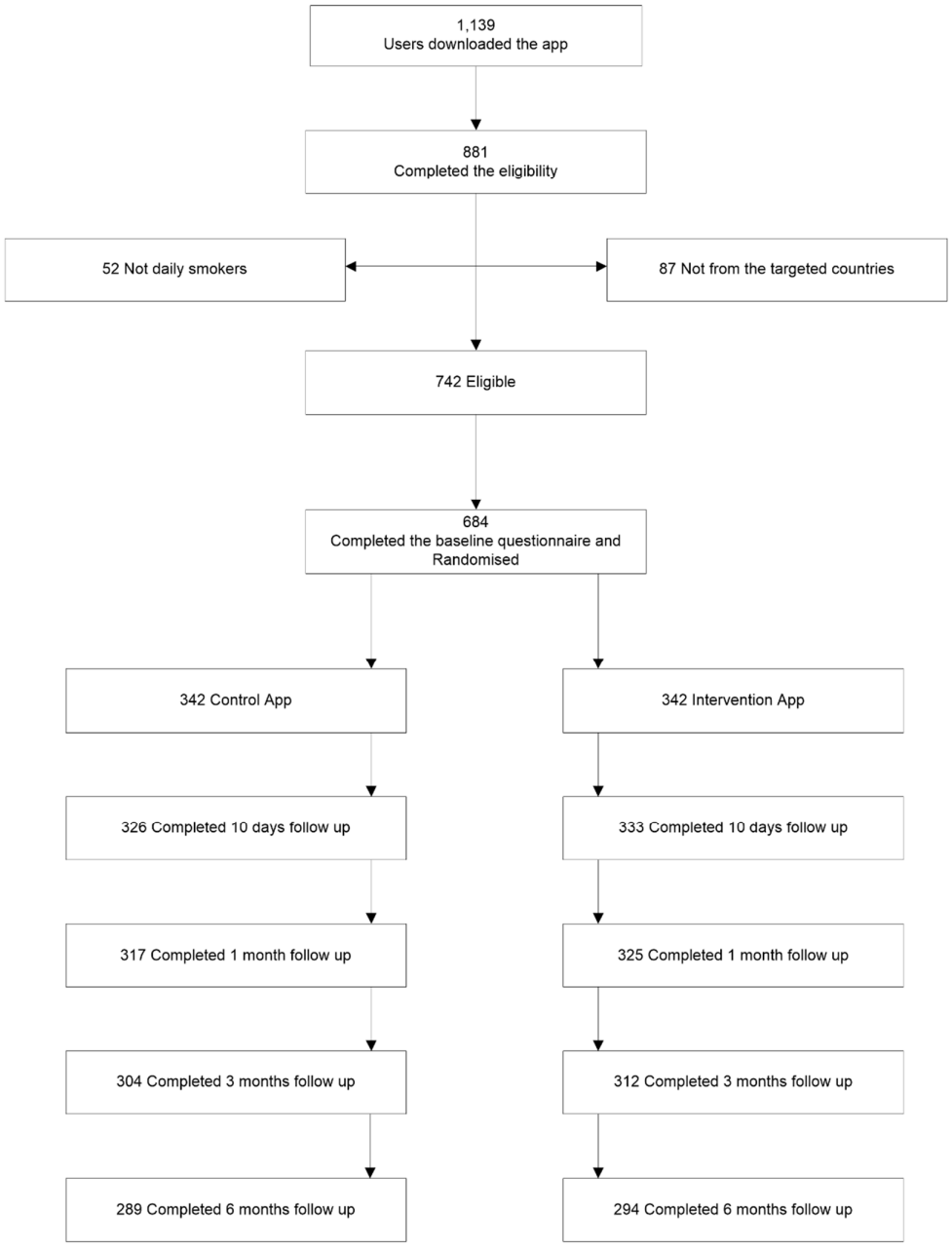
Table 4: Rates of Informed and Uninformed Choice – Intervention and Control

Choice	Intervention n= 342 (%)	Control n=342 (%)
Informed*	109 (31.9)	67 (19.6)
Uninformed**	233 (68.1)	275 (80.4)

*Informed Choice = Good knowledge with Attitudes consistent with Behaviour

** Uninformed Choice = Poor knowledge with Attitudes NOT consistent with Behaviour

Figure 1: Study flow diagram



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	20
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	21
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	21
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The Smartphone Smoking Cessation App (SSC APP) Trial: a multi-country double-blind automated randomised control trial of a smoking cessation decision aid 'app'

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The Smartphone Smoking Cessation App (SSC APP) Trial: a multi-country double-blind automated randomised control trial of a smoking cessation decision aid 'app'

Authors:

Nasser F BinDhim, PhD[1,2]

Kevin McGeechan, PhD[2]

Lyndal Trevena, MBBS(Hons) MPhilPH PhD[2]

Affiliations

[1]Saudi Food and Drug Authority,Riyadh, Saudi Arabia

[2]School of Public Health, University of Sydney, New South Wales, Australia

Corresponding author:

Lyndal Trevena

Room 321b Edward Ford Building (A27)

University of Sydney

NSW 2006 Australia

Ph: +61 2 93517788

Email: lyndal.trevena@sydney.edu.au

Word count:

Abstract = 215, Main text = 3099, Tables = 4, Figures = 1, Supplementary File = 1

Abstract

Objective: To assess the efficacy of an interactive smoking cessation decision-aid app compared with a smoking cessation static information app on continuous abstinence.

Design: Automated double-blind randomized controlled trial with 6 months follow up (2014-2015).

Setting: Smartphone-based.

Participants: 684 Participants (daily smokers of cigarettes, 18 years old or over) recruited passively from app stores in the USA, Australia, UK and Singapore and randomized to one of two sub-apps.

Intervention(s): Behavioral, decision-aid.

Main Outcome(s): Continuous abstinence at 10 days, 1 month, 3 months and 6 months.

Results: Smokers who received the decision aid app were more likely to be continuously abstinent at one month compared with the information only app (28.5% versus 16.9%; RR 1.68; 95%CI 1.25-2.28). The effect was sustained at 3 months (23.8% versus 10.2%; RR 2.08; 95%CI 1.38-3.18) and 6 months (10.2% versus 4.8%; RR 2.02; 95%CI 1.08-3.81). Participants receiving the decision aid app were also more likely to have made an informed choice (31.9% versus 19.6%) and have lower decisional conflict (19.5% versus 3.9%).

Conclusion: A smartphone decision aid app with support features significantly increasing smoking cessation and informed choice. With an increasing number of smokers attempting to quit unassisted evidence-based decision aid apps can provide an effective and user-friendly option to many who are making quit decisions without health care professionals.

Trial registration number: ACTRN12613000833763 URL: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12613000833763

Article Summary

Strengths and Limitations

- This is the first fully-powered efficacy trial of a smoking cessation decision aid app
- The design deliberately reflects the real-world setting recruiting through App stores
- It compares 'state of the art' decision aid design and support with passive information-only apps
- The trial was a novel fully-automated design across four countries
- The decision aid with support app significantly improved continuous abstinence at 6 months compared with information-only app.

Introduction

Just over one-fifth of the world's adult population continues to smoke despite significant declines in smoking rates over the past decades. [1] Smoking is responsible for the deaths of around 6 million people per year and costs the global economy around US$500 billion annually. [1]

Smoking cessation programs are accessible to only 15% of the population globally [2] despite more people attempting to quit. Approximately two-thirds of smokers in the US attempted to quit in 2014, [3] 11% of male Chinese smokers mainly aged 15-24 years attempted to quit [4] and a range of tobacco control policies have been increasing quit attempts in low and middle income countries. [5] We also know that most quit attempts are likely to be unassisted [6] and that the reasons for this may relate to personal and societal values of independence and autonomy which influence smokers' beliefs and decisions about quitting. [7]

Mobile phone interventions have become a new but effective way to help smokers quit. A recently updated Cochrane review [8] includes twelve studies, showing that these, mainly text message-based interventions significantly improved continuous abstinence at six months compared with control[9] interventions of information only. The authors also remarked on the lack of research on smartphone applications despite the plethora of these available to the public. As we have previously shown, a smartphone app was able to reach 1751 smokers in the United States, Australia, and the United Kingdom over a period of 12 months. Most of these people were not seeking professional help and were ready to quit in the next 30 days. [10]

Smartphones with their advanced processing capabilities, rapid global uptake, proximity to the user, and push-notifications (a short message service (SMS)–like function that is free of cost and more interactive), [11] are potentially an ideal vehicle for health interventions. [12] In addition, smartphone applications (apps) have shown feasibility across diverse ranges of

health conditions. [10 13-15] Although app stores have hundreds of smoking and tobacco-related apps, the majority are of low quality, very few provide evidence-based content, and some are actually pro-smoking apps. [9 16 17]

The efficacy of smartphone apps as an intervention for smoking cessation remains untested, although three small pilot studies have shown a potential effect on short-term abstinence rates. [13 18 19] This study, the Smartphone Smoking Cessation App (SSC App) trial therefore, is the first that we are aware of to assess the efficacy of a smartphone smoking cessation app in a full-scale, multi-country, longer-term trial. It tests the efficacy of an interactive smoking cessation decision-aid app compared with a smoking cessation static information app on quit rates.

Methods

Study design

This is an automated, double-blind, randomised control trial (RCT) to determine the efficacy of a smartphone smoking cessation decision-aid app with support features compared with an app that contains only smoking cessation information. An overarching app was developed that included the baseline questionnaire and two sub-apps - the intervention and control apps. The participants from the United States Australia, Singapore, and the United Kingdom, were randomised over a five-month period. These countries were selected because of high smartphone coverage, English language, high income and good access to smoking cessation treatments across different geographical regions globally. [10] The trial was approved by the University of Sydney's Human Ethics Committee (Project No. 2013/513), and was registered on the Australian New Zealand Clinical Trial Registry as trial number ACTRN12613000833763. The study app was published on the Apple App Store during the recruitment period and was the main portal of advertising the trial. We also advertised the app

as an (In-app) advertisement to Apple iPhone users while they are using other apps, allowing for demographic targeting.

Participants

Users of the Apple App Store in the four countries were recruited passively via the app's download page in the Apple App Store. The App Store description advised them that by downloading the app they would be participating in the study, that they could read the provided information about smoking and options for quitting, complete a questionnaire to find out their nicotine dependency test score, rate the information for its helpfulness in motivating them to quit. The app would collect anonymous data about how often the app was used and how long it was used for, their IP address would be collected only to identify duplication of data in our database and then deleted permanently. No personal identifying information would be collected through the app or the questionnaire. All anonymous data including the questionnaire responses, information ratings, frequency/ duration of use and IP address would be sent directly from the app in their phone to an online secure research database. The eligibility criteria were daily smokers of cigarettes, 18 years old or over and from the included countries. Occasional smokers and users of other tobacco products were excluded.

Patient involvement

Patients were not directly involved in the design of this study. However, a previous study has explored the potential participants' characteristics to inform this study design. [9]

Baseline registration and data collection

When a participant opened the app for the first time, the app assigned them a unique device identifier and registered the user's smartphone device in our secure remote database. The

unique device identifier could not change if the user deleted the study app and re-installed it. This allowed anonymous data collection, prevented duplicate enrolments and contamination between groups. As this study is fully automated, not being able to ensure that some users may download the app from another device is an unavoidable limitation. However, to monitor users who download the app onto two devices, we have implemented a server-side internet protocol that can identify the users who use different devices connected to the same internet network at similar times. This may not completely eliminate the possibility of contamination but will reduce it. To increase the response rate to the baseline questionnaire, we have implemented a reminder function that will send a notification to the user to complete the baseline questionnaire. The baseline questionnaire included socio-demographic variables (age, sex, educational level, marital status and income level) and tobacco consumption (e.g. number of cigarettes smoked per day and nicotine dependence as measured by the Fagerström test). [20]

Randomisation and Blinding

The study app automatically randomised eligible participants (daily cigarette smokers, aged 18 years and above, and from the four countries) to either the intervention or the control sub-app using stratified block (age, gender, country) randomisation. The strata were defined by age, country and gender. Participants and all investigators were blinded to group allocation (double blind).

Intervention and Control App Components

Both apps motivated the participant to set a quit date. The intervention app included four main components that made optimal use of smartphone features - (1) Mandatory information about quitting options, with their benefits and harms; (2) Daily motivational messages using push-notifications sent from the study server, (3) A quitting diary, and (4) A quitting benefits

tracker. The intervention app could thus be described as a smartphone 'decision aid with additional support' because it included structured content on the options, benefits and harms of smoking cessation, along with ongoing support and motivation for the implementation and adherence to a quit decision through the use of push notifications, motivational messages, a diary and benefits tracker. Unlike many existing smoking cessation services through mobile phones and quit-lines, the decision aid app allowed smokers to freely choose a quit method through a structured process of weighing up the available options and their benefits and harms. The decision aid design was based on the Ottawa Decision Support Framework that draws on a number of psychological and behavioural theories (https://decisionaid.ohri.ca/odsf.html)

The control app included non-mandatory information about quitting options, benefits and harms, similar to those available in the intervention app. It did not provide any structured process for considering options, benefits and harms of quitting methods nor did it provide ongoing support for adherence to a quit decision. This could therefore be described as a smartphone app with information only. As stated earlier, both the intervention and control apps encouraged users to set a quit date. Full details about the study design, the intervention and control apps are available in the published protocol. [12] A public version of the intervention app called 'Quit Advisor Plus' is available for downloading free of charge from the Apple App Store.

The follow-up data were collected by pushing a notification to the participants that were received even if the app was not running. Participants could also click on a follow-up button inside the app to initiate the follow-up process if the follow-up time had come. The follow up notification generated an automated process where participants could click 'yes' or 'no' to answer the follow up questions.

Outcomes

The primary outcome was the proportion of participants who remained completely abstinent after one month. Participants were asked the question "Have you been totally smoke-free ('not even a puff') for the last (x days/months)?" at 10 days, 1 month, 3 months and 6 months. Secondary outcomes were the proportion who made quitting attempts of at least 24 hours, abstinence rates at 10 days, 3 months, and 6 months, the proportion who made an informed choice (based on the Multidimensional Measure of Informed Choice – MMIC – 10 days after quitting) (Supplementary File) and the proportion with low decisional conflict (SURE score of less than 4 measured 10 days after quitting). [21]

Statistical analysis

We calculated a sample size of 672 participants to achieve 80% power at a 0.05 significance level to detect a change in continuous abstinence after one month from 5% to 15% allowing for 20% loss to follow-up. [12] All analyses were undertaken on an intention-to-treat basis. To account for the non-responses at follow-up, four multiple imputation models were constructed for the non-responses at the follow-up at 10 days, 1 month, 3 months, and 6 months continuous abstinence. The covariates that were included in the models were: age, gender, educational level, income level, nicotine dependence, intervention group, selected quitting method, and country. Ten imputed datasets were generated based on Rubin's formula for relative efficiency to produce about 99% efficiency. [22] We also conducted a sensitivity analysis with the assumption that all participants with missing outcome data were smokers. [23] Effect measures were Relative Risk (RR) and 95% Confidence intervals (CI). We assessed whether the effect of the intervention on abstinence rates was mediated by choice of quitting method or use of particular app components like the use of the benefit tracking function by applying the method of Baron and Kenny. [24]

Results

The recruitment process started on 5th May 2014 and continued until the required sample size was reached on 1st September 2014. The 684 participants were randomly assigned via our automated randomisation algorithm to the intervention or control group (Figure 1). Treatment groups were balanced with respect to baseline characteristics (Table 1). Chi-square analysis to examine the non-response at one month follow up association with intervention groups revealed that non-response was independent of the intervention groups χ^2 (1, n = 684) = 1.2, p = .27. However, turning off the app push-notification function (8.6% of the participants) was associated with non-response χ^2 (1, n = 684) = 11.1, p<.001.

(Insert Figure 1)

The majority of participants in both groups decided to quit unassisted, followed by nicotine replacement therapy (NRT) (Table 1). Only 2.3% of the participants changed their selected quitting method within the first 10 days.

(Insert Table 1)

The multiple imputations results showed that self-reported continuous abstinence at 10 days, one, three and six months was significantly increased by the intervention app (Table 2). At one month, 28.5% of those in the intervention arm were completely abstinent compared to 16.9% in the control arm. Similar results were obtained when the participants who were lost to follow-up were treated as smokers (Table 3) at the main outcome one month (continuous abstinence 13.2% (45/342) control vs. 26.0% (89/342) intervention; RR 1.97, 95%CI: 1.41 – 2.79, p<.001), and when excluded (Table 3) (continuous abstinence 14.2% (45/317) control vs. 27.4% (89/325) intervention; RR 1.92, 95%CI: 1.39 – 2.66, p<.001).

(Insert Tables 2 & 3)

In three countries, abstinence rates at one month were significantly higher in the intervention group compared to the control group (United States (RR 1.83, 95%CI: 1.04 – 3.25), Australia (RR 2.29, 95%CI: 1.13 – 4.64), United Kingdom (RR 1.97, 95%CI: 1.10 – 3.55), but not Singapore (RR 1.56, 95%CI: 0.71 – 3.44). There was no statistically significant difference in the effect of the intervention *between* the countries.

The effect of quitting method on continuous abstinence at one month, was assessed in a logistic regression analysis using the imputed data adjusting for (age, gender, educational level, country, treatment groups). None of the quitting methods were associated with abstinence compared to 'No treatment (quitting unassisted)'. The quitting method did not mediate the impact of the intervention since method chosen was not associated with abstinence (P=0.99) and inclusion of method did not alter the estimate of the intervention effect.

Finally, we measured the effect of 'app component use' on quitting, using a logistic regression model with the imputed data at 1 month and 6 months. The model included the quitting benefit tracker use, quitting diary use, and the self-reported reading of the compulsory information adjusting for (age, gender, educational level, country, quitting support method). Only the quitting benefit tracker was significantly associated with continuous abstinence at one month (OR 3.85; CI: 2.15 – 6.91) and 6 months (OR 4.27; CI: 1.53 – 11.88). Mediator analysis was not preformed because the quitting benefit tracker was only available in the intervention app which violated the mediation analysis assumptions.

In terms of the decisional conflict 19.5% of the participants in the intervention group had low decisional conflict compared to 3.9% in the control group $\chi 2$ (1, n = 684) = 28.4, p<.001. Table 4 shows the (MMIC) at 10 days after quitting with participants receiving the decision

aid app more likely to make an informed choice than those getting the information only app (31.9% versus 19.6%), $\chi 2$ (1, n = 684) = 12.8, p<.001.

Discussion

The results of this fully-automated RCT show that continuous abstinence from smoking at one, three and six months was significantly increased by a smartphone decision-aid that included behavioural support compared with a simple non-mandatory information-only app. Most of the participants chose to quit via 'No treatment (unassisted)' with intervention recipients being more likely to make an informed choice and have lower decisional conflict than those receiving the information only app. We have also shown that smartphone apps can be successfully used in an RCT design, with good follow up response rates in both groups. Turning off the app push-notification was associated with follow up non-response.

We believe our intervention app was successful in achieving the 28.5% six-month continuous abstinence rates because it combined features of previously evaluated smoking cessation interventions that were shown to be effective – i.e. decision aids *and* mobile phone interventions. Willemson [25] conducted a randomised controlled trial of a smoking cessation decision aid over a decade ago. Whilst the aid increased six-month continuous abstinence rate to 20.2% compared with no decision aid (13.6%) it consisted of a box with leaflets a video and some treatment samples which were posted to the home. The researchers reported an increase in knowledge, a more positive attitude, an increase in confidence about quitting and feedback that the decision aid helped them decide on a quit method. Secondly, there has been increasing evidence for the efficacy of mobile phone interventions (mainly text-messages or counselling). [8] We hypothesise that our six-month abstinence rate of 28.5% is due to the combined effect of decision support and the convenience of mobile technology. In addition,

the effect if smartphone-unique features on health behaviour change has not yet been assessed and this study is the first to do so. [10]

Strengths

A strength of our intervention was that it incorporated patient decision aid features which significantly increased the proportion of people who made an informed choice that was concordant with their personal values and significantly reduced decisional conflict about their quit decision. Comparing our results to a previous paper-based smoking cessation decision aid RCT, [25] our study has also shown comparable results at short-term and long-term follow up period but has the added convenience of smartphone accessibility.

Importantly about 56.0% of the participants in this study (in both groups) had made a previous quit attempt that had lasted at least 24 hours. This is relatively consistent with our finding in the feasibility study where the majority (75.6%) of participants that had used smoking cessation apps in the past had made a quitting attempt that lasted at least 24 hours using an app. [10] It supports the notion that smartphone apps are an effective way of reaching serious 'quitters' who tend to quit 'unassisted'. [25] Interestingly, our study participants who used NRT had similar results to those who quit unassisted. Although, this study was not powered for sub-group analyses, our intervention was effective in three countries out of four.

Furthermore, 77.3% of those who downloaded the app, completed the eligibility test and of those eligible 92.2% completed the baseline questionnaire. The introduction of the push-notification reminders in this study may have contributed to this high response rate, with other studies reporting similar results with this method [15 26]. By contrast, our feasibility study only generated a response rate of 36.8% without reminders. [10] Our trial retention rate was good with one month follow up 93.9% and six month 85.2%. Another study comparing a smartphone app with a website found that trial retention was 93% at 6 months in the

smartphone group, compared with 55% in the website group.[14] Turning off the app push-notification feature was associated with loss to follow up, In future, the app could include an in-app reminder to the user to turn on the push-notification.

Limitations

One of the limitations of this study is that continuous abstinence was measured via self-report through the app questionnaires which is less rigorous than a biochemically verified abstinence. [27] Our study was not funded for the latter. The second limitation is the possibility of contamination between groups although we took measures to minimise this through the unique Internet Protocol feature. [12] Finally, we recognize that the participants in this study were likely to be more motivated than other smokers because they were searching for smoking cessation apps during the recruitment period.

Generalizability

This study has used a novel approach for conducting an automated RCT via a smartphone app, and thereby simulated the 'real world' setting, recruiting via the app store in multiple countries. This automated process eliminated hours of recruitment time, and cost, it reached various ages, education levels and income groups, including 31% of the participants who low-incomes but still used an expensive smartphone device. However, the study sample was limited to four high-income countries and the findings may not be generalizable to smokers with smartphones in other settings.

Future challenges

Unlike web technology where the intervention can be developed and hosted on the producer's resources, smartphone apps are hosted on the publishers' servers (e.g. Apple app store or Google Play) and thus subjected to their changing regulation policies and technical

specifications. For example, in this project the app was released on an iPhone operating system version that did not require the user to provide permission to receive local notifications (Used in the quitting benefit tracker function). However, new versions of the iPhone operating system required the app producer to implement a user permission function to use local notifications. In this case, some users may disable the local notifications and the utilization may be reduced. Thus, future interventions may need to come up with new solutions to improve the utilization of specific app functions. The same issue was faced in another project that uses the location detection function to follow up travellers for infection control purposes. [28]

Other smartphone operating systems such as Android allows the app producer to publish their apps via email or self-hosted web links. Although the producer may lose the mass exposure advantage by publishing their apps on the official app stores, they at least can avoid the changing policies issue.

Conclusions

A smartphone decision aid app significantly increased smoking cessation rates with greater informed choice and lower decisional conflict across three out of four countries. It shows that the benefits of earlier mobile phone smoking cessation interventions can potentially be transferred to the more contemporary and user-friendly smartphone interface. We have also demonstrated the feasibility of conducting an RCT entirely using smartphone technology. Evidence-based decision aid apps should be promoted to smokers who are thinking of quitting.

Contributors All authors made substantial contributions to editing and revising of the manuscript. NFB was responsible for the conceptual development, the app design and development, and drafting of the manuscript. NFB and LT were responsible for the study design. NFB and KM were responsible for the statistical analysis. All authors read and approved the final manuscript.

Competing interests None.

Ethics approval University of Sydney Human Ethics.

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Data sharing: Relevant anonymised patient level data are available on reasonable request from the authors.

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Table 1: Baseline data of participants and self-reported quitting method (*n*= 684)

Characteristics	*Control* *n (%)*	*Intervention* *n (%)*	*Total* *n (%)*
Age (mean (S.D)) (years)	28.8 (9.8)	27.9 (10.2)	28.3 (10.0)
Sex			
Female	181 (52.9)	195 (57.0)	376 (55.0)
Male	161 (47.1)	147 (43.0)	308 (45.0)
Country			
Australia	84 (24.6)	89 (26.0)	173 (25.3)
Singapore	87 (25.4)	79 (23.1)	166 (24.3)
United Kingdom	83 (24.3)	88 (25.7)	171 (25.0)
United States	88 (25.7)	86 (25.1)	174 (25.4)
Education			
Graduate level or above	188 (55.0)	179 (52.3)	367 (53.7)
Less than Graduate level	154 (45.0)	163 (47.7)	317 (46.3)
Income level			
Less than $20K/year	111(32.5)	104 (30.4)	215 (31.4)
$21-49K/Year	168 (49.1)	164 (48.0)	332 (48.5)
More than $50K/year	63 (18.4)	74 (21.6)	137 (20.0)
Marital Status			
Married or de facto	100 (29.2)	95 (27.8)	195 (28.5)
Others (Single, Widowed, etc)	242 (70.8)	247 (72.2)	489 (71.5)
Nicotine dependency (Fagerström)			
Very low - Low (0 - 4)	163 (47.7)	176 (51.5)	339 (49.6)
Medium (5)	50 (14.6)	44 (12.9)	94 (13.7)
High - Very High (6-10)	129 (37.7)	122 (35.7)	251 (36.7)
Selected Quitting Method			
No treatment used (unassisted)	124 (36.3)	102 (29.8)	226 (33.0)
Any NRT	58 (17.0)	53 (15.5)	111 (16.2)
Self-help materials in the App	15 (4.4)	56 (16.4)	71 (10.4)
Other Self-Help	25 (7.3)	32 (9.4)	57 (8.3)
Aversion therapy	20 (5.8)	21 (6.1)	41 (6.0)
Herbal therapy	22 (6.4)	19 (5.6)	41 (6.0)
Acupuncture	22 (6.4)	13 (3.8)	35 (5.1)
Hypnosis	10 (2.9)	20 (5.8)	30 (4.4)
Varenicline	9 (2.6)	0 (0)	9 (1.3)
Bupropion	0 (0)	4 (1.2)	4 (0.6)
Others	37 (10.8)	22 (6.4)	59 (8.6)

Table 2: Primary and secondary outcomes (number of imputations=10)

	Control(%)	*Intervention(%)*	*Relative risk (95% CI)*	*P Value (2-sided)*
Self-reported quit attempt (lasted 24 hour)	52.8	59.0	1.12 (.97 – 1.28)	0.120
Self-reported 10 days continuous abstinence	20.8	32.2	1.55 (1.19 – 2.03)	<.001
*Self-reported 1 month continuous abstinence	16.9	28.5	1.68 (1.25 – 2.28)	<0.001
Self-reported 3 month continuous abstinence	10.2	23.8	2.08 (1.38 – 3.18)	<0.001
Self-reported 6 month continuous abstinence	4.8	10.2	2.02 (1.08 – 3.81)	0.024

* Primary outcome

Table 3: Self-reported abstinence (Intention to treat analysis).

	Control(%)	*Intervention(%)*	*Relative risk (95% CI)*	*P Value (2-sided)*
Lost to follow-up treated as smokers Self-reported 10 days continuous abstinence	19.0	30.9	1.63 (1.23 – 2.17)	<0.001
Self-reported 1 month continuous abstinence	13.2	26.0	1.97 (1.41 – 2.79)	<0.001
Self-reported 3 month continuous abstinence	7.9	17.3	2.19 (1.39 – 3.46)	<0.001
Self-reported 6 month continuous abstinence	3.2	7.3	2.27 (1.09 – 4.86)	0.026
Lost to follow-up excluded Self-reported 10 days continuous abstinence	19.9	31.8	1.59 (1.21 – 2.12)	<0.001
Self-reported 1 month continuous abstinence	14.2	27.4	1.92 (1.39 – 2.66)	<0.001
Self-reported 3 month continuous abstinence	8.9	18.9	2.13 (1.36 – 3.36)	0.001
Self-reported 6 month continuous abstinence	3.8	8.5	2.23 (1.08 – 4.77)	0.029

Table 4: Rates of Informed and Uninformed Choice – Intervention and Control

Choice	Intervention n= 342 (%)	Control n=342 (%)
Informed*	109 (31.9)	67 (19.6)
Uninformed**	233 (68.1)	275 (80.4)

*Informed Choice = Good knowledge with Attitudes consistent with Behaviour

** Uninformed Choice = Poor knowledge with Attitudes NOT consistent with Behaviour

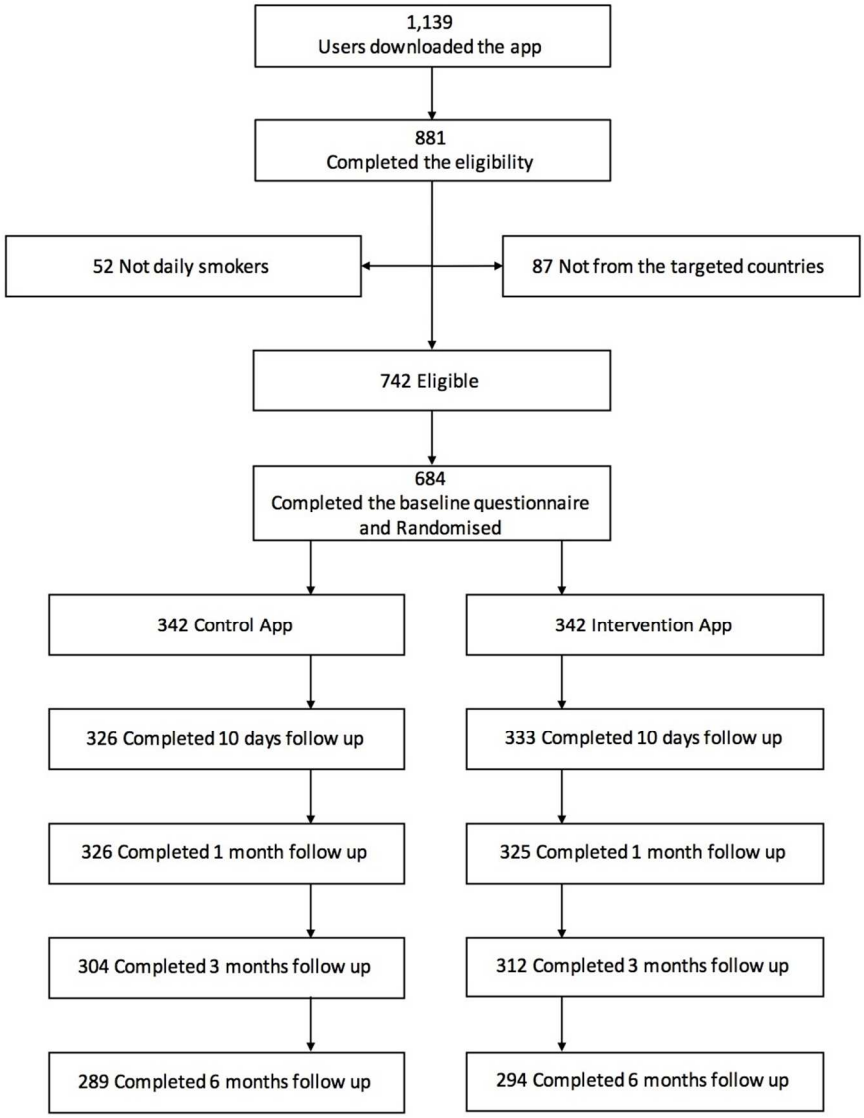

Figure 1 - Flowchart for Trial

190x244mm (150 x 150 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	20
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	21
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	21
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.