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Internet based age progression simulation to promote smoking cessation facilitated in pharmacies in Australian primary care: A randomised controlled trial

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ABSTRACT

Background: Tobacco smoking leads to death or disability and a drain on national resources. The literature suggests that cigarette smoking continues to be a major modifiable risk factor for a variety of diseases and that smokers aged 18 – 30 years are relatively resistant to anti-smoking messages due to their widely held belief that they will not be lifelong smokers.

Objective: To conduct a randomised controlled trial (RCT) of a computer-generated ageing intervention to promote smoking cessation among young adult smokers within a community pharmacy setting.

Methods: A trial was designed with 80% power based on the effect size observed in a published pilot study, 160 subjects were recruited (80 allocated to the control group and 80 to the intervention group) from eight metropolitan community pharmacies geographically around Perth city centre, Western Australia. All participants received standardised smoking cessation advice. Intervention group participants were also digitally 'photo-aged' by the researcher using internet based APRIL® Face Aging Software so they could preview images of themselves as a lifelong smoker and a non-smoker. Due to the nature of the intervention the participants and researcher could not be blinded to the study. The main outcome measure was quit attempts at six-month follow-up, both self-reported and biochemically carbon monoxide (CO) validated, and nicotine dependence assessed via the Fagerström scale.

Results: At six-month follow-up, five out of 80 control group participants (6.3%) suggested they had quit smoking but only one out of 80 control group participants (1.3%) consented and was confirmed by carbon monoxide validation. In the intervention group, 22 out of 80 participants (27.5%) reported quitting, with 11 out of 80 participants (13.8%) confirmed by CO testing. This difference in biochemically confirmed quit attempts was highly significant ($P = .003$, Chi-square test). A repeated measures analysis suggested the average intervention group smoking dependence score had also significantly dropped compared to control participants ($P < .001$). These differences remained highly significant after adjustment for small differences in gender distribution and nicotine dependence between the groups. The mean cost of implementing the intervention was estimated at AUD 5.79 per

participant. The incremental cost-effectiveness ratio was AUD 46 per additional quitter. The mean cost which participants indicated they were willing to pay for the digital ageing service was AUD 20.25 (SD=15.32).

Conclusion: Demonstrating the detrimental effects on facial physical appearance using a computer-generated simulation may be both effective and cost-effective at persuading young adult smokers to quit.

Trial ID Number: Australian New Zealand Clinical Trials Registry ACTRN12609000885291
<http://www.anzctr.org.au/>

Keywords: Tobacco smoking; nicotine dependence; physical appearance intervention.

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INTRODUCTION

Tobacco smoking leads to premature death or morbidity and places a drain on national resources. Consequently, health professionals and governments stress the importance of smoking cessation and reduction in exposure to tobacco smoking [1,2].

The younger people are when they start smoking, the greater the risk of illness or death caused by smoking [3]. Approximately half of smokers die prematurely from their habit, with half of these in middle age [4]. Smoking reduces life expectancy by approximately seven years, with significant morbidity in the final years of a shortened life [4,5]. Even those who consume between one and four cigarettes per day triple their long-term risk of dying from cardiovascular disease or lung cancer [6]. Currently in Australia, 19.7% of males and 16.3% of females aged 20–29 years smoke on a daily basis [7]. The detrimental long-term health effects of smoking, such as cardiovascular diseases and a variety of cancers are generally well-known in Australia [8]. However, health promotion research shows that, in isolation, knowledge about the hazards of smoking is insufficient to deter smoking behaviours [9]. Young adults who smoke are generally not concerned about the long-term health consequences of smoking because they may believe they will give up the habit while still young [10]. A number of previous studies have investigated the potential of personalised, computer-generated, facial ageing software to prompt quit attempts in young adult smokers. These have generally found facial ageing interventions to have some impact [11-14].

The objectives of this randomised controlled trial were to test the efficacy and cost-effectiveness of an intervention based on personalised, vivid illustrations of 'smoker's face' amongst young smokers (18–30 years of age). Efficacy was assessed by comparing: successful quitting, number of quit attempts and change in smoking dependence (assessed by the Fagerström score), between the intervention and control groups. The study also aimed to explore the value (feasibility and cost) of an unfunded intervention within pharmacy practice.

METHODS

Study design and population:

This study was a randomised controlled trial (RCT) [Trial ID number: ACTRN12609000885291] recruiting 160 participants (80 participants assigned equally to both control and intervention groups) from eight metropolitan community pharmacies geographically around Perth city centre, Western Australia, when presenting to collect prescribed medications or over the counter (OTC) medications.

Eligibility criteria included:

- i) age range of 18–30 years old (self-report);
- ii) smokers (defined as smoking one or more cigarettes per day - self-report);
- iii) able to give consent;
- iv) available for follow-up at six months;
- v) no beards, moustaches or non-removable facial accessories;
- vi) no body dysmorphia;
[participants screened using the Body Dysmorphic Disorder Questionnaire (BDDQ)] [15]
- vii) not using nicotine replacement therapy (NRT) or taking oral drugs for nicotine dependence.

Sample size and strategy:

The sample size of 80 participants per group was calculated to observe a medium effect size ($d=0.5$), with 80% power and a type I error probability of 5%, and allowing for a 50% attrition rate. The anticipated effect size and attrition rates were based upon the results of a pilot study [16]. At each pharmacy participants were recruited and assigned by the researcher to the different arms of the study on alternate weeks to minimise contamination between intervention and control participants. The study aimed to recruit 10 participants from each of the eight pharmacies to each treatment arm (intervention or control). This stratification by pharmacy was performed in an attempt to avoid any bias due to socioeconomic factors.

The intervention:

April® Face Aging Software is an internet based 3D age progression software package which creates a stream of aged images of faces from a standard digital photograph (the wrinkling/ageing algorithms

based upon normative data from people of a broad variety of ages, ethnicities, lifestyle habits, as well as published data regarding facial changes associated with ageing). Additionally, the resulting aged images can be adjusted to compare how a person will age as a smoker versus a non-smoker (Figure 1 and 2).

Data collection:

At recruitment all participants were asked to complete a baseline questionnaire consisting of demographic data, the Fagerström Smoking Dependence Scale [score from 0–10] [17], questions concerning attitudes towards personal appearance, opinions about health risks associated with smoking, and perceived barriers to quitting smoking. Participants were only recruited if they were neither using NRT nor taking oral drugs for nicotine dependence. Participants in both the intervention and control groups received standard two minute smoking cessation advice from the pharmacist. Participants in the intervention group were also screened for body dysmorphia using the BDDQ. In addition, they were photographed and their images digitally aged as a smoker and non-smoker (using the internet based April® Face Aging software), and invited to view the age-processed images (Figure 3). They were also asked to complete a questionnaire about their willingness to pay (WTP) for the digital ageing service. The digitally-aged photograph was then sent to their nominated email address within 24 hours of the intervention. Follow-up surveys were undertaken via telephone at one, three and six months and took approximately three minutes to complete.

At the six-month follow-up, if participants stated that they had quit smoking, they were reviewed within 48 hours to undertake a carbon monoxide (CO) breath test to validate their non-smoking status. The CO monitor utilised was a Pico+Smokerlyzer® (portable and battery operated; manufactured by Bedfont Scientific Ltd, Kent, England) and it provided a CO level reading in ppm (parts per million).

Primary outcomes measured:

- i) the effect of the intervention using successful quitting, quit attempts, progression along the transtheoretical “stages of change” model;
- ii) nicotine dependence using the Fagerström scale.

These were measured at the following stages: baseline, one, three and six months follow-up.

The demographic and baseline smoking habit profiles of the recruited subjects were compared between groups using Fisher's exact test and Pearson's chi-square test for categorical variables, and Student's t-test for continuous variables. The primary endpoints of the study at the six-month follow-up were analysed using chi-square tests to compare percentages of quitters in each group, or t-tests to compare smoking dependence levels. Percentages of quitters in each group were compared both as 'self-reported' values and as 'CO-validated' values. A logistic regression model was used to analyse the percentage of quitters in the two groups after adjustment for any possible differences between groups on the basis of demographic or baseline data. A repeated measures analysis (random effects regression model) was used to identify any changes in the Fagerström dependence score over the entire course of the study, using one- and three-month follow-up surveys in addition to baseline and six-month data. Data were analysed using SAS v9.2 software with $P < .05$ taken to indicate a statistically significant association.

Secondary outcomes measured:

- i) the cost-effectiveness of the intervention from a health sector perspective in terms of the incremental cost per additional quitter and per additional lifetime quitter;
- ii) the business viability of delivering the intervention in a community pharmacy.

These were calculated at the conclusion of the study.

Two perspectives were adopted: a health sector perspective and the perspective of a community pharmacy on the assumption that the intervention was not government funded. The direct costs of providing the digital ageing service over and above providing standard cessation advice were calculated based on the time taken to provide the service and the cost to a pharmacy of purchasing tokens to use online software to 'photo-age' participants. The cost of a pharmacist's time was valued based on award rates of pay in Western Australia [18] and tokens were costed based on market price [19]. Time taken that was protocol driven was excluded. Potential cost offsets from a reduction in health care costs of quitters were used to calculate net intervention costs. Cost offsets were based on the Quit Benefits Model, which is a tool developed in Australia to predict the difference in health care costs of smokers and non-smokers for males and females by age group after 10 years follow-up [20].

This follow-up period was considered long enough to show the beneficial impact of quitting but short enough to remain within the time frame of policy-makers. Cost offsets were discounted at a rate of 3% as recommended by the US Panel on Cost-Effectiveness in Health and Medicine [21]. All costs were expressed in 2011 Australian dollars. The cost of the tokens was converted from United States dollars to Australian dollars based on the average exchange rate in 2011 [22]. The number of lifetime quitters was calculated assuming a long-term smoking relapse rate of 37% within 10 years [23]. Smoking relapse after 10 years of abstinence has been found to be less than 1% per year [24]. To assess the robustness of the study results, a scenario sensitivity analysis with the ‘best-case’ and ‘worst-case’ scenario was performed [25]. The parameters varied were the pharmacist’s time spent providing the service, the exchange rate for converting the cost of tokens from US dollars to Australian dollars and the discount rate (Table 1).

Table 1. Parameter values: base case and sensitivity analysis

Item	Base case	Scenario sensitivity analysis	
		‘Best-case’	‘Worst-case’
Pharmacist time per participant to deliver service (mins)	4.8	3.6	6.0
Award wage rate per week for a pharmacist (AUD)	907.40	-	-
Cost of a token (AUD)	3.87	3.63	6.53
Exchange rate	USD 1 = AUD 0.9687	USD 1= AUD 0.9067	USD 1 = AUD 1.6321
Discount rate (%)	3	0	5

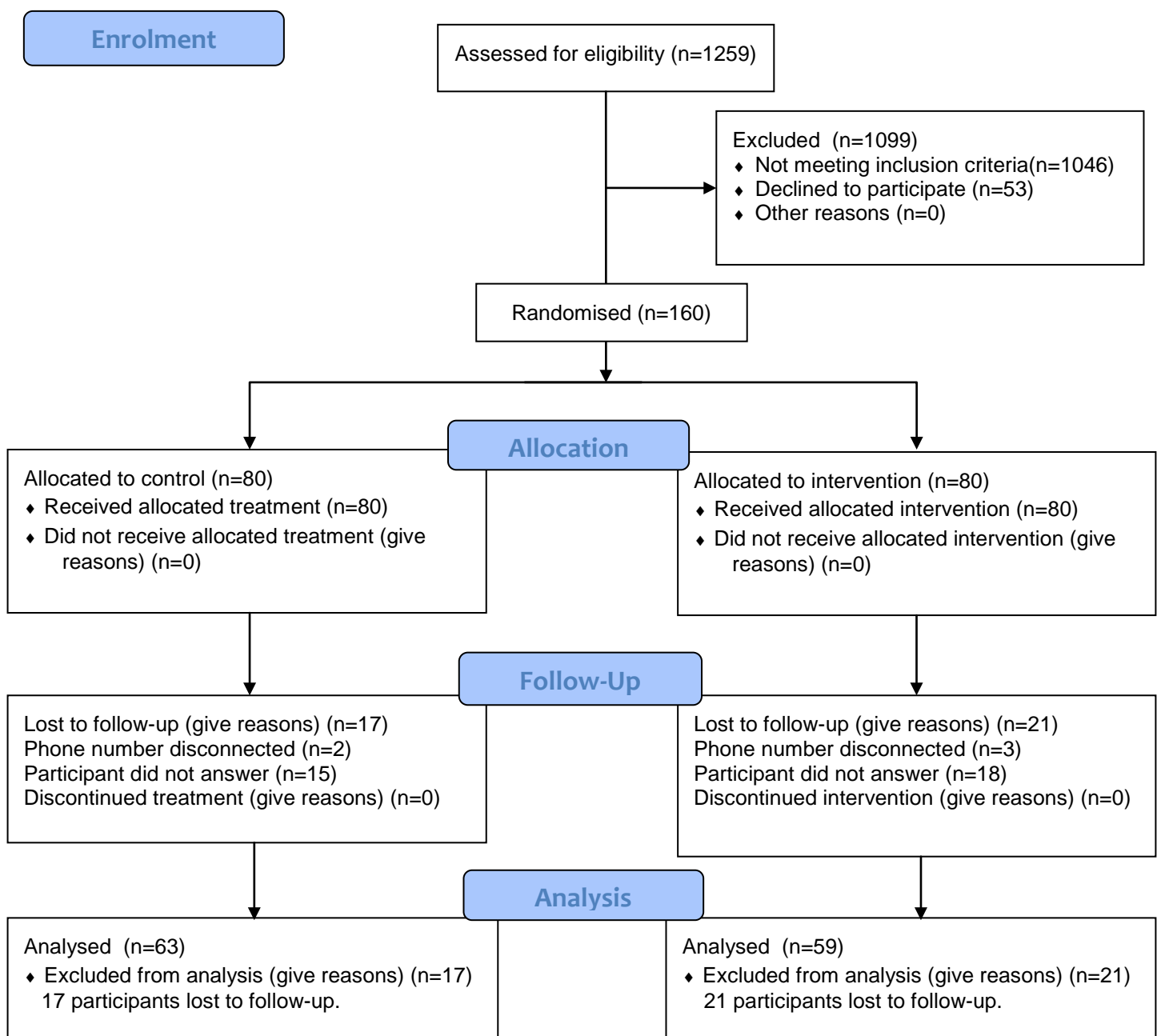
In the ‘best-case’ scenario the pharmacist’s time was adjusted down by 25%, the exchange rate for converting US dollars to Australian dollars was varied to the lowest in the past five years, and a discount rate of 0% was used [22]. In the ‘worst-case’ scenario the pharmacist’s time was adjusted up by 25%, the exchange rate was varied to the highest in the past five years, and a discount rate of 5% was used. The quantitative data from the customer survey (WTP questionnaire) were analysed using SPSS v17 software. Customers’ perceptions about the value of the intervention and its impact on loyalty intentions and potential future sales were analysed using simple descriptive statistics.

RESULTS

Study design and population:

Customers were screened for eligibility to the RCT from eight community pharmacies (Figure 4):

Figure 4: Profile of the randomised controlled trial (using CONSORT guideline)



Sample size and strategy:

In total, 1259 customers were screened for eligibility; 213 customers were eligible and 160 were recruited. Eighty participants were recruited to the control group and 80 to the intervention group.

The intervention:

The 'smoker's face' simulations were created using a digital photograph (6.0 megapixels) taken of the intervention participants and uploaded to April® Face Aging Software (Version 2.5) on a laptop computer.

Data collection:

The RCT was conducted between January 2010 and December 2010 and all follow-up surveys were completed by June 2011. The final six-month follow-up showed a response rate of 78% for the control group and 73% for the intervention group. The demographic and baseline smoking behaviours of recruited participants are shown and compared between groups (intervention versus control) in Table 2.

Table 2. Demographic and baseline smoking profile of study participants. The *P*-value is based on the chi-square statistic (unless otherwise marked), and compares the treatment groups.

Variable	Control group (N=80) n (%)	Treatment group (N=80) n (%)	<i>P</i> -value
Male	35 (44%)	25 (31%)	.10
Age: mean (SD)	25.1 (4.1)	24.2 (4.1))	.16 ^a
Education:			.71
Year 10 high school	15 (19%)	17 (21%)	
Year 12 high school	31 (39%)	29 (36%)	
TAFE/ technical qualif	17 (22%)	22 (28%)	
Degree (univ/college)	16 (20%)	12 (15%)	
Cigarettes per day/last 30 days			.35
1	11 (14%)	19 (24%)	
2-5	9 (11%)	10 (13%)	
6-10	21 (26%)	14 (18%)	
11-20	27 (34%)	29 (36%)	
21+	12 (15%)	8 (10%)	
Fagerström score: Mean (SD)	2.96 (2.52)	2.87 (2.48)	.82 ^a
Fagerström dependency score:			.92
0-2	39 (49%)	39 (49%)	
3-4	19 (24%)	18 (23%)	
5	8 (10%)	10 (13%)	
6-7	10 (12%)	10 (13%)	
8-10	4 (5%)	2 (3%)	

^a t-test

There appeared a trend towards more females, and lighter smokers (smoking up to five cigarettes per day) in the intervention group however there were no statistically significant differences between control and intervention groups on demographic or smoking dependence variables at baseline. No participants were revealed with body dysmorphia. A number of questions on the survey were designed to gather the respondents' opinions of self-perceptions, and attitudes towards their smoking behaviour. These questions were taken from an earlier survey [11], and showed that the groups were generally well-matched. However, a greater proportion of the intervention group appeared to be concerned about their physical appearance (83% versus 68%; $P=.03$, Chi-square test), and believed that facial wrinkles were associated with smoking (99% versus 85%; $P=.002$, Chi-square test). There was no difference in the proportion of participants in each group who had made at least one attempt to quit smoking in the past (68% versus 71%, $P=.73$, Chi-square test).

Primary outcomes measured:

Table 3 shows the response rates to the follow-up surveys, and the change in smoking behaviour over the study. There was a significant difference in the proportion of participants self-reporting to have successfully quit smoking by the six-month survey. Assuming that participants who failed to complete the final follow-up survey continued to smoke, only one out of 80 control participants (1.3%, 95% Confidence Intervals 0% to 6.7%) were confirmed non-smokers, compared to 11 out of 80 participants (13.8%, 95% Confidence Intervals 7.8% to 22.9%) of the intervention group. This difference in confirmed quitting is highly statistically significant ($P=.003$, Chi-square test). The intervention group contained a larger proportion of subjects responding to the question: "I care about how people think I look". A logistic regression model was used to investigate the association between treatment group and self-reported quitting, after adjustment for this difference as well as the small differences between groups in gender and nicotine dependence. The P -value associated with the treatment group remained strongly significant after adjustment for these potentially confounding variables ($P=.003$).

A similar model, using 'confirmed quitting' as the dependent variable, showed an adjusted P -value for the treatment group of $P=.03$.

Table 3. Pattern of survey completion, and change in smoking behaviour at six months. The *P*-values are calculated using the Chi-square statistic unless otherwise specified.

Variable	Control group (N=80) n (%)	Treatment group (N=80) n (%)	<i>P</i> -value
Response to follow-up questionnaires			
All surveys completed	56 (70%)	48 (60%)	.38
Incomplete: Last survey completed:			
6 month	6 (8%)	10 (13%)	
3 month	8 (10%)	14 (18%)	
1 month	3 (4%)	4 (5%)	
No follow-up	7 (9%)	4 (5%)	
Quit smoking at 6 months:			
Self report (questionnaire)	5 (6.3%)	22 (27.5%)	<.001
Confirmed (CO)	1 (1.3%)	11 (13.8%)	.003
Change in Fagerstrom smoking dependence score at 6 months			<.001 [^]
Reduced dependence	11 (14%)	41 (51%)	
No change	68 (85%)	39 (49%)	
Increased dependence	1 (1%)	0	
Change in mean Fagerstrom score from baseline to:			<.001 [§]
1 month	-0.14	-0.83	
3 months	-0.38	-1.34	
6 months	-0.26	-1.88	

[^] Fisher's Exact test

[§] Obtained from a repeated measures analysis including all available surveys

Table 3 also shows changes in the Fagerström smoking dependence score. Firstly, the six-month score was grouped into the five broad dependence level categories, and compared with baseline data. There was a significant difference in change in smoking dependence between groups ($P < .001$, Chi-square test), with 14% of the control group moving to a lower category compared to 51% of the intervention group doing so.

A random effects regression model was used to model the mean change in Fagerström score from baseline, using data from all follow-up surveys. The control group did not experience a significant drop in Fagerström score over the study ($P = .36$), while the participants in the intervention group dropped by an average of approximately 1.9 points ($P = .002$). The change in mean scores over the whole study was very significantly different between treatment and control groups ($P < .001$, Table 3).

Although there were no differences between participants at baseline, the regression models were extended to adjust for the gender and age of the participant, and the number of cigarettes smoked at baseline. The models were fitted to the control and intervention group separately, as it was clear that changes in score appeared only in the intervention group. For the control group, there were no associations between change in score and age ($P=.14$), sex ($P=.72$) or baseline consumption ($P=.49$). However, for the intervention group, age ($P<.001$) and baseline consumption ($P<.001$) were significantly associated with the change in score while gender ($P=.34$) was not associated. Older participants were less likely to reduce their score than younger participants, suggesting that the intervention may have a greater effect on the younger participants. Participants who smoked more than 10 cigarettes per day showed a significant drop in score of at least one point on the Fagerström scale ($P<.001$), independently of age. Participants smoking 6–10 cigarettes per day showed a trend towards a lowering in score ($P=.07$), while light smokers (0–5 cigarettes per day) showed no change in score.

Secondary outcomes measured:

Total costs of implementing the intervention from a health sector perspective were AUD 463 or the equivalent of AUD 5.79 per participant (Table 4).

Table 4. Economic analysis of photo-ageing service

Item	Base case	Scenario sensitivity analysis	
		'Best-case'	'Worst-case'
Mean cost per participant of service (AUD)	5.79	5.07	8.93
Total cost of service – 80 participants (AUD)	463	406	714
Incremental cost-effectiveness ratio (ICER)			
- cost per additional quitter (AUD)	46	41	71
- cost per additional lifetime quitter (AUD)	74	64	113
Cost offset from reduction in health care costs (AUD)	2,144	2,660	1,867
Net total cost savings (AUD)	1,778	2,346	1,316
Mean willingness to pay for service (AUD) (SD)	20.25 (15.32)	-	-
Median willingness to pay for service (AUD) [IQR]	20.00 [10.00; 20.00]	-	-

With an additional 10 quitters confirmed in the intervention group compared with the control group (11 versus one respectively), the incremental cost-effectiveness ratio (ICER) was AUD 46 per additional

quitter, or the equivalent of AUD 74 per additional lifetime quitter. Cost offsets of AUD 2,144 from a reduction in the health care costs of quitters resulted in the intervention potentially generating net total cost savings of AUD 1,778. In the 'best-case' scenario the ICER was AUD 41 per additional quitter and net total cost savings were AUD 2,346. Corresponding figures for the 'worst-case' scenario were AUD 71 per additional quitter and AUD 1,316 respectively.

The mean cost which the participants indicated that they were willing to pay for the digital ageing service was AUD 20.25, which exceeded the mean cost per participant for delivering the service (AUD 5.79). The median cost they were willing to pay was AUD 20 which was similar to the mean value. Over 80% of participants said they would be more likely both to use the pharmacy to purchase future smoking cessation therapies and to use it more generally for other purchases. Over 80% of participants also thought their friends would be willing to pay for the service and all but two participants said they would recommend the photo-ageing intervention to one or more friends who were smokers.

DISCUSSION

Summary of findings:

The impact of the photo-ageing innovation on confirmed quit attempts by the young people recruited to this study was highly significant ($P=.003$, Chi-square test). The data further demonstrate that overall the photo-ageing intervention had a larger influence on younger participants. Also, the participants who did not make a quit attempt but who smoked more than 10 cigarettes per day, were likely to become less dependent on nicotine.

Strengths and weaknesses of the study:

The pharmacies selected to take part in the study were chosen to cover a range of socioeconomic areas and the equal number of study participants selected for each treatment group at each pharmacy aimed to diminish any potential biases. However due to the nature of the intervention the participants and researcher could not be blinded to the study group. Allocation to groups was not performed as eligible participants were recruited, but according to the treatment being used at the

pharmacy during that week. In this setting there was a substantial risk of contamination between treatment and control group if participants had been randomised at the point of recruitment rather than by week of attendance at the pharmacy.

The baseline comparisons showed that the two groups were very similar on smoking dependence scores, and the six-month follow-up response rate was high (over 70% for both groups). Follow-up to 12 months may have been preferable but impractical in this case. However follow-up at six months was augmented by biochemical verification of tobacco use and cessation [26]. If participants stated they had made a quit attempt at the six-month conclusion of the study, they were invited to undertake a CO monitor test to validate their non-smoking status. It was disappointing that so few participants in the control group agreed to CO verification. There are two possible reasons for this, it is possible that they continued to smoke or they were not as engaged in the project as the intervention group and were less amenable to follow-up. Nevertheless the self-reported smoking status data are interesting and although quite likely to be prone to socially desirable responses, the effect size is still substantial and on a par with other intervention trials.

We also noted a trend towards more females and light smokers in the intervention group, although on analysis this appeared not to diminish the very significant statistical association between treatment group and quitting smoking.

Strengths and weaknesses in relation to other studies:

While many individualised smoking cessation interventions have been implemented in the last few decades few have had as marked an impact as reported here. With the advent of digital technology, quit messages can now be delivered by mobile telephone, email, text messaging and online social networks [27].

To date, there have been few studies reporting on a personalised photo-ageing intervention [12-14], those published have only recruited females, and only one of these studies was an RCT which recruited a small number of female smokers who had been referred to a smoking cessation service [14].

Implications for clinicians and policy-makers:

The economic analysis demonstrates that this personalised smoking cessation intervention is cheap and cost-effective and it could be readily adopted in community pharmacies. It targets young smokers who are at significant risk of adverse effects of smoking if they continue lifelong smoking.

With an ICER of AUD 74 per additional lifetime quitter, the intervention is cost-effective compared with other individualised smoking cessation programs. For example, a systematic review of economic evaluations of a range of smoking cessation interventions found ICERs of between USD 260 to USD 3263 per lifetime quitter (US 2002) for counselling or self-help programs versus usual care [28]. These ICERs are of a similar order of magnitude as reported elsewhere for brief advice from a general practitioner to quit smoking and smoking cessation counselling of GBP 196 and GBP 653 per lifetime quitter respectively (GBPs 1999) [29]. Although these other studies calculated ICERs based on a societal perspective, additional non-health care costs of the photo-ageing interventions such as patient time input are minimal.

Unanswered questions and future research:

A review commissioned by the Australian Commonwealth Department of Health and Ageing concluded that interventions delivered by health care providers significantly increased the number and success of quit attempts made in Australia each year [30].

Health care providers such as pharmacists are accessible and highly trained [31]. They have an established role in delivering smoking cessation pharmacotherapies and other forms of cessation assistance [32, 33]. Could this intervention also be delivered by other health care providers in community settings such as family medicine or allied health clinics?

A significant development for the use of mass media in delivering anti-smoking messages is the advent of digital technology. Technologies such as the Internet, social networking sites and smart phones, have the potential to reach large populations of younger people [2, 28, 34]. Could this internet technology be delivered to the public without professional facilitation and would it have the same effect?

Further experimental research deploying photo-ageing technology is needed.

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