School of Pharmacy

Delivering a personalised smoking cessation intervention by community pharmacists in Western Australia: A randomised controlled trial

Oksana J Burford

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Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgement has been made. This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signature: 

Date: 29/10/12

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.

Aims: This research project aimed to test a digital ageing intervention to promote smoking cessation among young adult smokers within a community pharmacy setting and explore the value of the unfunded intervention within pharmacy practice.

The primary outcomes were efficacy of the intervention measured by quit attempts and nicotine dependence and the secondary outcomes were cost-effectiveness of the intervention from a health sector perspective and community pharmacy business viability.

Methods: This research project was named 'Pharmacy **PAINT'** (**P**hoto-**A**geing **INT**ervention) and was conducted in community pharmacies in Perth, Western Australia in two trials:

i) a pilot study;
ii) a full Randomised Controlled Trial (RCT).

The research was underpinned by the Medical Research Council (MRC) – Framework for design and evaluation of complex interventions, to improve health and the complex intervention was delivered by a qualified, registered pharmacist.

Young smokers, aged 18 – 30 years who randomly entered the pharmacy, either to have a prescription dispensed or purchase an OTC (Over the Counter) medication were eligible to be recruited for the research if they were English speaking and able to give informed consent, did not have beards, moustaches or facial accessories that

couldn't be removed, were available for phone survey follow-ups and were not using Nicotine Replacement Therapy (NRT) or taking nicotine dependence medications.

Consenting participants were randomised into two groups: a control group and an intervention group with equal numbers in each. Allocation into the groups alternated weekly so that all participants recruited in any specific week received the same treatment.

Participants in the control group received standard smoking cessation advice from a pharmacist-researcher. Participants in the intervention group received the same standard smoking cessation advice from the pharmacist-researcher but in addition, they were photographed and their images digitally aged, as a smoker and non-smoker and then invited to view the age-processed images.

The intervention involved using a photo-ageing tool (APRIL® Age Progression Software, 3D age progression software based upon Canadian normative ageing data) to deliver the non-smoking message by exposing the young smokers to graphic images of the detrimental effects of smoking on their future facial appearance.

Results: The pilot study recruited 50 participants, 25 allocated to the control group and 25 to the intervention group and participants were followed-up for a three-month period. The pilot study was conducted between February 2008 to December 2008 and the results informed the feasibility, recruitment strategy, outcome measure, effect size and attrition rate for the subsequent RCT.

The RCT was conducted from January 2010 to June 2011 and involved 160 participants, with 80 allocated in each of the control and intervention groups. Participants were followed-up for a six-month period. At the final six-month follow-up, five (8%) in the control group declared that they had quit smoking, however, only one (1.3%) of these subjects was an objectively confirmed non-smoker (validated on carbon monoxide (CO) testing). For the intervention group, 22 (38%) declared they had quit, with 11 (13.8%) confirmed by CO testing. This difference in these proportions between groups was highly significant *($p = 0.005$* by Fisher's exact

test). Results for the change in nicotine dependence score using the Fagerström Scale, showed a greater proportion of the subjects in the intervention group moving to a lower smoking dependence score than the control subjects *($p<0.0001$)*.

Total costs of implementing the intervention from a health sector perspective were AUD 366 or the equivalent of AUD 4.58 per participant (Table 7). With an additional 10 quitters in the intervention group compared with the control group (11 versus one respectively), the incremental cost-effectiveness ratio (ICER) was AUD 37 per additional 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.

Participants indicated a mean willingness to pay for the digital ageing service of AUD 20.25, which exceeded the mean cost per participant for delivering the service of AUD 4.58. This suggested the service may be viable if the customer was charged in the pharmacy if not subsidised by government. The median willingness to pay of AUD 20.00 was similar to the mean value. Ten respondents thought aspects of the service could be improved and so made the following recommendations: to also provide information on methods to quit; to also offer a support program; to also show the effects of smoking on major organs. 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 the vast majority of participants said they would recommend photo-ageing to one or more friends who were smokers.

CONCLUSION: Emphasising the link of smoking to the detrimental effects on skin and physical appearance using a personalised promotion intervention can be an effective motivator to persuade younger adult smokers to quit. This intervention can be proactively and economically delivered by a pharmacist as primary health care counselling in a community pharmacy setting.

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Dedication

I would like to dedicate this thesis in honour of my parents,

Zirka Elizabeth and **Michael Doschak (**formerly **Doszczak)**

who always supported me in everything I did,
but did not live to witness this completed thesis.

Publications related to the thesis

Research papers:

Burford O, Jiwa M, Carter O, Parsons R, Hendrie D. Internet-Based Photoaging Within Australian Pharmacies to Promote Smoking Cessation: Randomized Controlled Trial. J Med Internet Res 2013;15(3):e64 doi 10.2196/jmir.2337

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Conference papers:

Jiwa M, McManus A, **Burford O,** Rieck A, Dumas C. Innovating across disciplines: report on a national workshop of stakeholders in Australia. Qual Prim Care. 2011;19(6):399-403.

Editorials:

Burford O. Recruiting to a photo-ageing study in community pharmacy: reflections of a recruiter. Australas Med J 2010; 3(11): 745.

International conference oral presentation related to the thesis

Peer reviewed abstract selected and oral presentation delivered:
40th NAPCRG (North American Primary Care Research Group)
Annual Meeting 2012. New Orleans, Louisiana USA. 1-5th December 2012.

National conference oral presentations related to the thesis

Royal Australian College of General Practitioners (RACGP)

National Conference,

Melbourne, 3rd October 2008

Australasian Pharmaceutical Science Association (APSA)

Annual Conference, Aus-CRS Symposium,

Hobart, 9-11th December 2009

HIC (Health Informatics Conference) 2011,

Brisbane, 2-4th August 2011

National conference poster presentations related to the thesis

"PHARMACY PAINT STUDY: Research for community pharmacy-based Intervention".

Burford O, Jiwa M and Carter O.

Pharmacy Australia Congress (PAC) National Conference,

Perth. 24-26th October 2008.

"Does photo ageing have a clinical value?"

Burford O, Jiwa M.

Australasian Computer Science Conference, Perth. 17-21 January 2011.

National coverage of PAINT research on ABC Television related to the thesis

Program – "Lateline" 24th October 2008

Abbreviations

AIHW	Australian Institute of Health and Welfare
AUD	Australian Dollars
BDDQ	Body Dysmorphic Disorder Questionnaire
COPD	Chronic Obstructive Pulmonary Disorder
DSM	Disease State Management
FS	Fagerström Score
F-U	Follow-Up
ICER	Incremental Cost-Effectiveness Ratio
ITT	Intention To Treat
LYG	Life Year Gained
MRC	Medical Research Council
NPM	Normalisation Process Model
NPT	Normalisation Process Theory
NRT	Nicotine Replacement Therapy
PAINT	Photo-Ageing INTervention
PAS	Pharmacists' Action on Smoking
PSA	Pharmaceutical Society of Australia
QA	Quit Attempt
RCT	Randomised Controlled Trial
SC	Smoking Cessation
SOC	Stages Of Change
TPB	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
TTM	Trans Theoretical Model
UK	United Kingdom
WA	Western Australia
WTP	Willingness To Pay

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CHAPTER 1: INTRODUCTION

SUMMARY

• Tobacco smoking has devastating effects on the health of individuals and the well-being of families and societies. Consequently health professionals and governments stress the importance of smoking cessation and reduction in exposure to tobacco smoking.

• The younger people are when they start smoking, the more likely they are to smoke heavily, and to be at increased risk of illness or death caused by smoking.

• According to the Australian 2010 National Drug Strategy Household Survey 18.0% of 20–29-year-olds smoke on a daily basis, including 19.7% of males and 16.3% of females.

• Young adult smokers are generally unconcerned about the long-term health consequences of their smoking because they intend to give up before middle age.

• Specifically tailored computer interventions, such as 'photo-ageing' which delivers personalised health promotion messages have been shown to increase the motivation of young adult smokers to make quit attempts.

• Photo-ageing as a health promotion tool is classed as a 'complex intervention'; therefore photo-ageing needs to be evaluated using a RCT (Randomised Controlled Trial) design guided by the NPT (Normalisation Process Theory) to establish if it will work in everyday practice.

• The PAINT project is an example of research delivering a complex intervention.

1.1 Introduction

Tobacco smoking has well-documented, detrimental effects on the health of individuals and the well-being of families and societies. It leads to death or disability and a drain on national resources. Consequently, health professionals and governments stress the importance of smoking cessation and reduction in exposure to tobacco smoking (1).

The younger people are when they start smoking, the more likely they are to smoke heavily, and to be at increased risk of illness or death caused by smoking (2). Approximately half of smokers die prematurely from their habit, with half of these in middle age (3). Put another way, smoking reduces life expectancy by approximately ten years, with many of the years leading up to premature death lived in poor health (3, 4). Even light smokers, who only consume between one and four cigarettes per day, triple their long-term risk of dying from cardiovascular disease or lung cancer (5).

According to the Australian 2010 National Drug Strategy Household Survey, 18.0% of 20–29 year-olds smoke on a daily basis, including 19.7% of males and 16.3% of females (6). The detrimental, long-term health effects of smoking such as cardiovascular diseases and a variety of cancers are generally well-known within Australia (7, 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 unconcerned about the long-term health consequences of their smoking because they plan to give up before middle age (10). Adolescents adhere to disengagement beliefs (rationalisations or justifications to continue smoking) and these negatively affect smoking cessation-related cognitions and practices (11).

Population-level strategies are important sources of motivation and support for young adult smokers and must continue to be delivered. These strategies include: providing smoke-free environments; graphic cigarette packet warnings and more recently plain packaging; increased cigarette prices; and well-funded media campaigns (12–15).

Computer-mediated smoking cessation programs may be effective at the individual level (16–18). Delivering specifically tailored computer interventions (e.g. photo-ageing) as personalised health promotion messages has been shown to increase the motivation of young adults to make quit attempts (19–22). However, the methodologies of these studies were limited as they solely recruited women, and only one of these studies was an RCT which recruited 70 female participants from a sample of smokers who had been referred to the "Quit for a New Life" free Stop Smoking Service in the UK (22).

The preliminary data as reported in the literature is promising but far from conclusive. Further photo-ageing research, in a formal experimental design, recruiting males and females from the general public with a suitable follow-up period was needed to demonstrate the effect on nicotine dependence and quitting attempts.

1.2 Aims

The aims of this research were:

i) to explore the challenges of proactively delivering a complex intervention in community pharmacy setting;

ii) to test the effectiveness of an intervention based on personalised, vivid illustrations of 'smoker's face' on nicotine dependence and quit attempts of young smokers aged 18–30 years;

iii) to measure the cost-effectiveness of the intervention in terms of cost per quitter and the estimated gain in life years from a health perspective.

1.3 Overview of the study

This photo-ageing research was guided by the framework for design and evaluation of complex interventions to improve health (23, 24). Complex interventions in health care can be therapeutic or preventative and include several components:

i) behaviours;
ii) frequency and timing of these behaviours; and
iii) methods by which these behaviours should be organised or delivered.

The complexity of the intervention is then governed by these components acting both independently and inter-dependently (23).

It is necessary to evaluate a complex intervention to establish if it will work in everyday practice as outlined by the Normalisation Process Theory (NPT) (25) and this is most appropriately achieved by designing a RCT. The RCT is the optimal study design for researchers to robustly investigate the impact of the intervention so that inferences can be drawn and implementation of successful interventions can be instituted (23).

There is a sequence of established phases when devising trials of complex interventions. These phases are:
Pre-clinical – Theory;
Phase I – Modelling;
Phase II – Exploratory trial;
Phase III – Definitive RCT; and
Phase IV – Long-term implementation (23).

These phases were delineated by the UK Medical Research Council (MRC) in response to challenges encountered in previous trials [Figure 1.1].

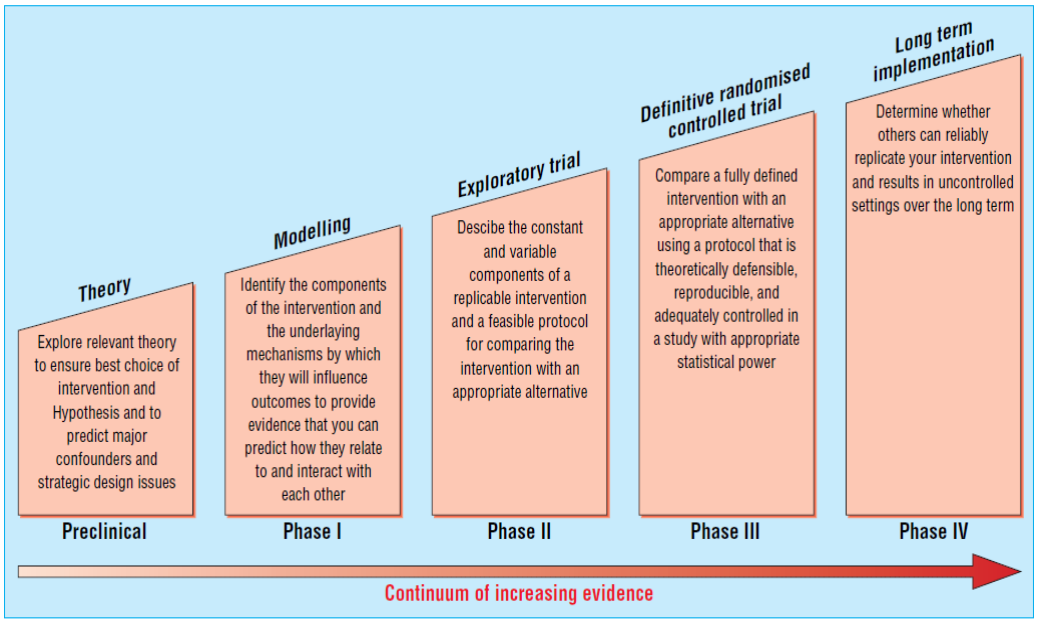

Figure 1.1: Sequential phases of developing RCTs of complex interventions (23)

Every phase has desired objectives which must be met before progressing to the next phase, however, it must be noted, that depending on the research, not all stages may be relevant and so this sequential framework is best viewed as an example of 'flexible guidance' for evaluating complex interventions. Depending on the nature of the intervention, more time can be spent in a particular phase, or combining phases together, or sometimes even omitting a phase (23).

The APRIL® Age Progression Software is an 'intervention'. However, in practice it is a 'complex intervention' because a number of issues impact on its success:

i) how and when people are recruited;

ii) how the intervention is delivered;

iii) how often it is delivered;

iv) if it is delivered with some other intervention (for example combined with smoking cessation advice);

v) who delivers the intervention.

The design of the PAINT research project was to deliver the APRIL® photo-ageing tool in a health care setting, the community pharmacy. Before the PAINT project commenced, the following was unknown:

i) Would the intervention be acceptable to pharmacists and participants?

ii) Could participants be recruited in community pharmacies?

iii) How should the intervention be delivered?

iv) How often should it be delivered?

v) Would the intervention have an impact on young adult smokers?

vi) What impact would it have on nicotine dependence and resultant quit attempts?

vii) How could it be delivered within a 'pay for service' business model?

The MRC framework for development and evaluation of RCTs for complex interventions (23) facilitated the design of the PAINT project and a comparison between the theoretical framework and the PAINT project described in the thesis is shown in Table 1.1.

Table 1.1: Overview of thesis compared with MRC framework

	THESIS	**MRC FRAMEWORK**
Chapter 1	Introduction	
Chapter 2	Literature review	**Preclinical:** Theory
Chapter 3	Pilot PAINT study	**Phase I:** Modelling **Phase II:** Exploratory pilot trial
Chapter 4	PAINT RCT	**Phase III:** Definitive RCT
Chapter 5	Economic analysis	(Economic analysis of the RCT)
Chapter 6	General discussion	
Chapter 7	Conclusions & recommendations for future research	**Phase IV:** Long-term Implementation

Models and theories relevant to the photo-ageing research such as The Normalisation Process Model (NPM) (25), the Stages of Change (SOC) model (26), the Theory of Planned Behaviour (TBP) (27) and Face perception (28) are discussed in Chapter 6.

1.4 Significance

This research tested an engaging quit message with particular appeal to teenagers and young adult smokers who have been exposed to computer technology to a greater extent than older people (29). The photo-ageing tool delivered the non-smoking message by offering participants graphic images of the detrimental effects of smoking on their own future facial appearance.

Secondly, it was delivered proactively by a pharmacist within a community pharmacy and this has important implications for community pharmacies as a setting for the delivery of health promotion, because further information on remunerated health promotion services are needed.

Therefore, this research has made a substantial and original contribution to knowledge in the area of health promotion by community pharmacists by:

i) testing the delivery of a personalised health promotion package by a community pharmacist;
ii) exploring the impact of personalised health promotion in community pharmacy on customer attitudes, customer loyalty intentions and potential future sales;
iii) examining the cost-effectiveness of community pharmacists delivering health promotion.

1.5 Hypotheses

This research project aimed to test the following hypotheses:

H1: Pharmacists in a community pharmacy setting using the photo-ageing intervention would increase quit attempts or reduce nicotine dependency in young smokers.

Research questions:

i) Could a community pharmacist deliver a complex intervention within a community pharmacy setting?

ii) Would the intervention be acceptable to young adult smokers?

iii) What would be the impact of the intervention on resultant quit attempts?

iv) Would the intervention be acceptable to pharmacists and staff?

H2: Pharmacists delivering primary healthcare counselling in a proactive manner, would have no detrimental impact on the financial viability of the business.

Research questions:

i) What would be the cost-effectiveness of the intervention from a health sector perspective?

ii) What would be the cost-effectiveness of the intervention from a community pharmacy business viability perspective?

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CHAPTER 2: LITERATURE REVIEW

LITERATURE SEARCH STRATEGY

Published Literature

Databases searched in the following literature review were: BIOMED Central, Cochrane Database, Elsevier Science Direct, EBSCOhost, Highwire BMJ, Informit, OKLUWERS, OVID, Proquest, PubMED, SAGE journals, SAGEpub, Springer Link, Wiley Online library. Early published articles (1960s–1970s) on 'skin ageing' and 'smoker's wrinkles' were obtained through the Document Delivery Service at the Robertson Library, Curtin University.

The search terms (keywords and mesh terms) used were:

- **Chapters 2.1, 2.2 and 2.3:** smoking cessation; smoking cessation messages; quit smoking messages; smoking cessation interventions; photo-ageing; photo-aging; photoaging; smokers' face; smoking + ageing + skin; smoking + ageing + collagen; tobacco smoke + skin ageing; smoking cessation intervention + tobacco; photo-ageing + smoking; smoking + aging; smoking + aging + skin; smoking + aging + skin + cessation; smoking + aging + skin + tobacco.
- **Chapter 2.4:** pharmacy support programs; pharmacy quit smoking programs; pharmacy services; pharmacy + professional services; pharmacy + professionally paid services; professional pharmacy services; pharmacy cost effectiveness studies; pharmacy willing to pay studies.

NB. A snowballing technique was also used to locate further references from relevant identified papers throughout the entire thesis writing period.

Grey Literature

Searches of the grey literature included health organisation websites and electronic and hard copy government reports. Websites searched were: the World Health Organization (WHO) for current smoking definitions; the Australian Institute of Health and Welfare (AIHW) for current smoking statistics in Australia; the Department of Health and Ageing (DOHA) and the Pharmacy Guild of Australia.

The 1984 WA Health Department evaluation study on "The Pretty Face" advertisement was obtained personally from Rob Donovan, Professor of Behavioural Research, Curtin University, CBRCC (Centre for Behavioural Research in Cancer Control).

SUMMARY

2.1 Health risks associated with smoking:

• The prevalence of tobacco smoking is the leading global cause of preventable death and is therefore a major challenge in health care.

• The earlier the uptake of smoking, the greater the likelihood of developing smoking-related illnesses in the long term and at an earlier age.

• Adolescents are generally not concerned about the long-term health consequences of smoking because they intend to give up the habit while still young.

2.2 Traditional quit messages:

• Human emotions play a role in the decision to smoke. Therefore, individuals must be encouraged to change behaviour and this encouragement needs strong emotional arousal.

• Health promotion research shows that, in isolation, knowledge about the hazards of smoking is insufficient to deter smoking behaviours. Consequently, many anti-smoking campaigns have developed around quit messages which contain pictorial imagery that try to elicit emotional responses.

• Graphic images and narratives that evoke visceral emotions such as fear, guilt and empathy have been demonstrated to be more effective in provoking quit responses.

2.3 An alternative message for young smokers:

• Youthful looking skin is an important factor for young people and therefore the side effect of premature skin ageing should be a motivator for behaviours to preserve this facial feature.

• Studies have now confirmed that cigarette smoking reduces capillary and arteriolar blood flow leading to oxygen deprivation causing wrinkle formation contributing to premature facial skin ageing.

• Over the years, a variety of smoking skin-ageing terms have been coined:

i) 'cigarette skin' by Ippen and Ippen in 1965 (30);

ii) 'wrinkle score' by Daniell in 1971 (31);

iii) 'smoker's face' by Model in 1985 (36).

• An overall hypothesis was postulated by researchers Grady and Ernster (39), Model (36), Kadunce *et al.*(37), Francès (38), Koh *et al.*(40) and Demierre *et al.*(41) that if

smokers were concerned about their physical image, then the fear of premature skin ageing could be a motivator for them to quit smoking.

• Photo-ageing research has used computer programs to provide personalised, science-based illustrations to show adolescents how smoking can affect facial appearance.

• The authors of a systematic review of numerous physical appearance intervention studies concluded that further well-designed studies are still needed to decide whether these types of interventions have an impact.

2.4 Expanding the role of the community pharmacist:

• Community pharmacists are health care professionals who have an established role in delivering primary health care and brief interventions.

• Good evidence exists to support the provision of smoking cessation services through community pharmacies and that structured interventions together with NRT and counselling create better cessation results than opportunistic interventions.

• There are only a limited number of studies to date evaluating the cost-effectiveness of community pharmacist quit smoking support programs.

• The community pharmacy is a health care setting where the public can easily access the advice of a registered health practitioner at no charge and with no appointment.

• Pharmacists have always embraced their role as primary health care practitioners, but the extra time spent counselling and delivering brief interventions to customers/patients must be balanced with the viability of running a community pharmacy business and therefore they are now keen to pursue remuneration for professional services.

• There are a limited number of economic studies in the community pharmacy setting evaluating what customers would be Willing To Pay (WTP) for a pharmacist provided service, with no WTP studies found in the smoking cessation area.

• Two recent Australian WTP studies conducted in community pharmacies in the clinical areas of diabetes (66) and asthma (68) demonstrated that customers would be WTP for a professional pharmacy service.

• More WTP studies conducted in community pharmacies are needed so that the results can be used to assist pharmacists and governments about making decisions for the future regarding professionally paid services.

2.1 Health risks associated with tobacco smoking

The prevalence of tobacco smoking is the leading global cause of preventable death (1) and therefore is a major challenge in health care. It harms almost every organ in the body and is a major risk factor for a large number of vascular and respiratory diseases and a variety of cancers (2). It kills nearly six million people a year (more than five million are smokers and ex-smokers and more than 600,000 are passive smokers) (3). On average, smokers die about 10 years younger than non-smokers (4). This premature death of smokers has enormous ramifications: it deprives their families of income; it raises the cost of health care and it retards the economic development of the country (3). Longer-term smokers live between five and 10 years less than non-smokers and early quitters and have significantly fewer healthy years (4, 5).

2.1.1 Australian perspective

In Australia the annual death toll from tobacco smoking in 2003 and 2004/2005 was 15,511 and 14,901 respectively (6, 7). The smoking rate for Australians aged 14 years and older has fallen to 15.1% [2.8 million] in 2010 from 25% in 1993, suggesting tobacco control measures in Australia have met with some success (8). However, nearly 20% of 20–29-year-olds still smoke daily and 13% of 18–19 year olds, suggesting there is still work to be done (8).

2.1.2 Young smokers' perspective

Most adolescents are naturally curious about smoking and if they have access to cigarettes, this will facilitate experimentation (9). Smoking initiation is also strongly linked to the normative and control factors of peer pressure, where "fitting in" with peers is an important social bonding experience (9). The earlier the uptake of smoking, the greater the likelihood of developing smoking-related illnesses in the long term and at an earlier age (10) although adolescents are generally not concerned about the long-term health consequences of smoking because they intend to give up the habit while still young (9).

2.1.3 Smoking definition and classifications

The definition for smoking with reference to this thesis is:

"This term refers to the smoking of tobacco, including manufactured (packet) cigarettes, roll-your-own cigarettes, cigars and pipes (but excludes chewing tobacco and smoking of non-tobacco products)" (11)

Categories of smokers with reference to this thesis are:

Current smoker (daily, weekly and other): *include those who reported smoking daily, weekly or less than weekly.*

Ex-smoker: *those who reported they did not currently smoke, but had regularly smoked daily, or had smoked at least 100 cigarettes, or smoked pipes, cigars, etc. at least 20 times in their lifetime.*

Never smoker: *those who reported they had never regularly smoked daily, had smoked less than 100 cigarettes in their lifetime, and had smoked pipes, cigars, etc. less than 20 times in their lifetime.* (11)

2.2 Traditional quit messages

Tobacco companies have long been aware of the role emotions play in decisions to smoke. Strong emotional impact from an advertisement increases the chances of a company's product being bought as it enhances a favourable attitude towards the advertisement, the brand and subsequently, purchase intention (12). Individuals must therefore be encouraged to change behaviour and this encouragement needs strong emotional arousal (13). Therefore, information that elicits visceral responses, such as fear or guilt, seems to be particularly effective in initiating behaviour change (14, 15).

Health promotion research shows that, in isolation, knowledge about the hazards of smoking is insufficient to deter smoking behaviours (16). Consequently many anti-smoking campaigns have developed around quit messages which contain pictorial

imagery that try to elicit an emotional response while still instructing on the hazards of tobacco smoking.

Graphic images and narratives that evoke visceral emotions such as fear, guilt and empathy have been demonstrated to be more effective in provoking quit responses and in preventing the uptake of tobacco smoking than positively framed messages such as encouragement and humour (9, 17, 18).

2.3 An alternative message for young smokers

Body image is an issue of concern for young people (19, 20). They place a high emphasis on acceptable body shape and employ a variety of health-related behaviours to achieve this, one of these being smoking because nicotine suppresses appetite (21). However, youthful-looking skin is also an important consideration for young people, and since damage to the skin is a side effect of smoking, this consideration should also be a motivator for them to quit smoking (22).

2.3.1 Cigarette smoking-associated changes in the skin

Cigarette smoking reduces capillary and arteriolar blood flow leading to oxygen deprivation causing wrinkle formation contributing to premature facial skin ageing (23). It has also been associated with the degeneration and break-up of the elastic fibres of connective tissue (24, 25), that is elastosis (26, 27, 28), therefore also contributing to premature skin wrinkling.

2.3.2 Cigarette smoking skin-ageing terms: 'cigarette skin', 'wrinkle score', 'smoker's face'

A variety of smoking skin-ageing terms have been coined. A meta-analysis by Grady and Ernster identified five studies that were published between 1965 and 1991 that evaluated the association of cigarette smoking and skin wrinkling [Table 2.1].

Table 2.1: Studies of cigarette smoking and facial wrinkling (Adapted from 29)

STUDY	SUBJECTS	SMOKING	WRINKLES	RESULTS	COMMENTS
Ippen and Ippen, 1965 (30)	224 white women, aged 35-84 years	Ever" vs. "never" smoker	"Cigarette skin"; pale with a greyish hue, wrinkled, especially on the cheeks, with thick skin between the wrinkles	RR+ = 4.1 *ǂ	No control for age or sun exposure; no information on blinding
Daniell, 1971 (31)	1,104 men and women, aged 30–70 years; 98% white	Smoker vs. non-smoker (smoker, smoked for at least five consecutive years at some time in life)	Facial wrinkles graded on a scale of 1–6 (1, minimally wrinkled; 6 severely wrinkled)	RR = 3.3* (comparing categories 1–3 and 4–6); also showed a duration (yearrs smoked) & dose(cigs/day) effect	Controlled for age and sun exposure; attempted blind study, but many subjects were patients or associates of the investigator
Allen *et al*., 1973 (34)	650 men and women (age not given); 79% white	Smoker vs. non-smoker (smoker, ≥ ½ pack per day current smoking)	Daniell's wrinkle categories 1–6	Among whites with <2 hours per day sun exposure, all non-smokers had wrinkle scores of ≤3 and all smokers of ≥4. Prominent wrinkling not	Data presented was not controlled for age or sun exposure. No information on blinding

				found among blacks	
Model, 1985 (36)	116 white men and women, aged 35–69 years	Smokers vs. non-smoker (smoker, smoked ≥10 cigarettes per week in last year and smoked ≥ 10 years)	"Smoker's face"; prominent facial wrinkling, gauntness of the facial features, greyish skin or plethora	"Smoker's face" present among 46% of smokers, 8% of former smokers and none of the non-smokers	Controlled for age and sun exposure; assessment of wrinkling before assessment of smoking status
Kadunce *et al.*, 1991 (37)	132 white men and women, aged 35–59 years	Pack-years of smoking	Daniell's wrinkle categories 1–6, evaluated on standardised photographs	Pack-years (RR): 0–0.9 (1.0); 0.9–49 (2.0); ≥50 (4.7*)	Controlled for age, sun exposure and skin pigmentation; blind assessment of wrinkles from photographs. Only 23 non-smokers included. Smokers and non-smokers from different populations (non-smokers from church groups, smokers from smoking cessation programs)

*$p < 0.05$
+ RR, relative risk
ǂ Calculated from data in the reference

In 1965, Ippen and Ippen (30) published the results of a study that recruited 224 Caucasian women including 'ever' and 'never' smokers, aged 35–84 years. The primary finding was a conclusive relationship between smoking and premature skin ageing. From their investigations they were able to:

i) define the term **'cigarette skin'** as pale, with a greyish hue, lacking local variations of pigmentation and excessive wrinkling, especially on the cheeks, with thick skin between the wrinkles;
ii) correlate the duration of cigarette consumption with the poorer facial skin quality;
iii) identify the main differences between 'cigarette skin' and' light-damaged skin', as differences in the colour and firmness of the skin, due to the different pathogenesis of these two types of skin damage (30).

A study by Daniell (31) published in 1971 recruited 1,104 men and women (98% white), including 'smokers' and 'non-smokers' aged 30–70 years) with the primary outcome being to develop a simple method of grading the severity of facial skin wrinkling associated with habitual cigarette smoking.

A **'wrinkle score'** was developed that assigned a grade from 1– 6 in ascending severity [see Table 2.2]. The wrinkle score assessed the severity of skin wrinkling in the "crow's foot" area, forehead and cheeks.

Table 2.2: Skin wrinkle grading (31)

Grade	Skin Appearance
I	Essentially unwrinkled. Two or three shallow wrinkles usually less than 1½ cm in length may be present in each crow's-foot area
II	Several wrinkles, each of which may be 3 cm long. The number of significant wrinkles on each side may be between two and six
III	Several prominent wrinkles on each side, 3 to 4 cm long. Many smaller wrinkles may be present as well. Increased wrinkling may be present in the forehead skin, but little wrinkling in the cheek areas
IV	Wrinkles extend from the crow's-foot area superiorly and inferiorly, usually 5 cm or more. If wrinkles are of unusual depth, they may be 4 cm long. Wrinkles extend over the cheek areas (zygomatic ridge). Men in this grade frequently exhibit prominent wrinkling of forehead and posterior nuchal region
V	Wrinkles extend from the crow's-foot area and are prominent over the cheeks and forehead
VI	Profound wrinkling extending over most of the face.

Daniell concluded that the most severe wrinkle category of people (in each age/sex group) was composed entirely of smokers with wrinkling influenced by two factors: duration of smoking and number of cigarettes smoked daily. He also found that smoking, and exposure to the sun, each separately caused wrinkling of the face and they had a considerably greater effect if combined (31). Subsequent studies also found that risk factors that contribute to wrinkle formation, such as tobacco smoking, age and sun exposure were independent of each other, with multiplicative effects observed if tobacco smoking was combined with excessive sun exposure (32, 33).

In 1973, Allen *et al.* (34) published the results of a study which examined 650 men and women (79% white; 21% black) 'smokers' and 'non-smokers'. (Allen *et al.* stated they included black patients in this study to effectively control for sunlight exposure). The study was undertaken to answer the three pertinent questions raised from Daniell's study:
"i) if smoking is the most important factor in producing wrinkling, why does it only occur in sun-exposed areas and not on all the integument?

ii) do blacks who smoke develop similar wrinkles?

iii) if smoking is the 'prime' cause of facial wrinkling, what is the mechanism by which it acts?" (34)

All patients were asked to complete a questionnaire (questions on their medical history, smoking history, past and present sun exposure, occupation, hobbies, weight change, country of origin) and underwent clinical and histological examinations for wrinkling in the "crow's foot" area and in the non-sun-exposed submental area. (Wrinkling was once again graded according to Daniell's skin wrinkling grading table [Table 2.2 (31)].

Allen *et al.* on the basis of all their examinations concluded that "*wrinkles in the 'crow's foot' area were shown to be caused by actinic exposure, not by cigarette smoking"* (34) because the black patients showed minimal changes of solar elastosis (i.e. wrinkles no greater than Grade 1 wrinkling – regardless of whether they smoked or were exposed to the sun) and the white smoking and non-smoking patients (with and without wrinkles) showed actinic elastosis changes in their histological preparations.

These findings contradicted the thesis of Daniell but this challenge was refuted by Weiss a few months later who published a letter to the editor in a journal (35) stating that the data presented by Allen *et al.* did not warrant this conclusion because even though blacks did not develop wrinkles the relationship between wrinkling and cigarette smoking could not be refuted in whites. Weiss also claimed that the use of their "control" was confusing (it did not properly control for all the different experimental sub-groups) and that the absence of submental wrinkling in any of the patients only proved that people do not wrinkle submentally. Therefore, Weiss stated that Allen *et al.* had failed to disprove Daniell's findings.

In 1985, Model coined the term **'smoker's face'** in the publication of a prospective survey (36) he conducted on 116 men and women (100% white, smokers and non-smokers) attending a general medical outpatient clinic at two hospitals. The aim of the survey was to test a hypothesis that middle-aged cigarette smokers could be differentiated from non-smokers by their facial features and the age group he assessed was 35–69 years.

The first part of the survey method involved a medical student asking a patient as they waited in the clinic room if they would like to participate in a survey. If the patient agreed to participate then the medical student asked the patient for the following information: age, dietary and smoking habits, alcohol intake, occupation, any recent changes in weight.

In the survey there were three smoking states defined:
1.) non-smoker: *one who smoked fewer than 10 cigarettes or less than 14g tobacco a week or had smoked for less than 10 years;*

2.) current smoker: *one who within the past year had smoked 10 or more cigarettes of 14g or more tobacco a week and had smoked for 10 years of more;*

3.) past smoker: *one who had not smoked within the past year but had smoked 10 or more cigarettes or 14g or more tobacco a week for 10 years or more before that.*

(36)

The second part of the study involved the patient entering the survey room where the physician, Model (not knowing the previous information gathered about the patient) would assess the patient's head and neck areas for wrinkles in daylight at a fixed distance of 1.5m and categorise the features of the patient's face. The assessment was done at this fixed distance so that Model would not be able to smell any tobacco odour or see any nicotine staining on the patient's fingers which could have biased his decision.

From this assessment, Model was able to divide the participants into two groups: those with a 'smoker's face' and those without a 'smoker's face'. He defined the term 'smoker's face' as the drastic and irreversible impact of smoking on physical appearance and it had to include, one or more of the following facial features criteria:

a) *"lines or wrinkles on the face, typically radiating at right angles from the upper and lower lips or corners of the eyes, deep lines on the cheeks, or numerous shallow lines on the cheeks and lower jaw.*
b) *a subtle gauntness of the facial features with prominence of the underlying bony contours.*
c) *an atrophic, slightly pigmented grey appearance of the skin.*
d) *a plethoric, slightly orange, purple, and red complexion different from the purply blue colour of cyanosis or the bloated appearance associated with the pseudo-Cushing's changes of alcoholism."* (36)

Information about the patient's exposure to sunlight over the years was also gathered by a subsequent postal survey and this information was categorised without knowledge of the main part of the survey. Participants were also divided into two social classes: non-manual and manual, according to their occupations. It was also noted that at the time of the survey, no patients were being treated for any dermatological disorders of the facial area.

An analysis of the 116 participants surveyed, showed 41 (35%) participants to be current cigarette smokers, 37 (32%) were past smokers and 38 (33%) were non-smokers. Model's assessments showed 'smoker's face' present in 19 (46%) current smokers, three (8%) past smokers and none (0%) of non-smokers. This association of

'smoker's face' with current cigarette smoking was shown to be highly significant ($p<0.001$).

Further analyses demonstrated neither social class, sun exposure, nor recent change in weight accounted for any relations between smoking habits and 'smoker's face'.

Therefore, Model stated that his survey also confirmed the findings of Ippen and Ippen and Daniell, that cigarette smoking causes recognisable wrinkling to the face.

A cross-sectional study conducted by Kadunce *et al.* (37) in 1991 recruited 132 male and female smokers (100% white) aged 35–59 years from a smoking cessation clinic and the community with the primary outcome being to demonstrate the correlation between premature wrinkling and increasing pack-years of cigarette smoking.

Data was collected by a self-administered questionnaire which quantified the participant's cigarette smoking and obtained information about possible confounding factors (such as facial skin pigmentation, sun exposure, age and sex). It was noted that no participants had ever had facial cosmetic surgery or undergone any pharmacotherapy treatment with tretinoin or sun-sensitising drugs.

The right temple of each participant's face was also photographed three times at a fixed distance and the single best photograph was then used to determine the degree of skin wrinkling based on a modified Daniell's skin wrinkling grading table (this modified table only categorised five grades of skin wrinkling now, with category 5 being the 'most wrinkled'). A logistic regression model, which controlled for the confounding variables of age, sex, sun exposure and pigmentation was developed to analyse the association of smoking with the development of excessive wrinkling as this model allowed smoking to be treated as a continuum of exposure, with heavy smokers being compared with mild smokers and non-smokers.

Results demonstrated a trend present for an association between cigarette smoking and wrinkling for both men and women, but only the trend for men was significant ($p<0.002$). Overall conclusions drawn from the Kadunce *et al.* study were:

- cigarette smoking is an independent risk factor for the development of wrinkles;

- excessive smoking is dose-dependent to smoking exposure;
- additive detrimental effects are likely from ageing and sun exposure. (37)

The evidence to date suggests facial wrinkle formation is a multifactorial condition influenced by a number of factors, such as age, genetic make-up, gene expression, sun exposure, environment toxicity (e.g. tobacco smoke), nutrition, steroids and mechanical forces (38). However, there is sufficient evidence to conclude that smoking is an independent risk factor for premature skin wrinkling and that there is an association between cigarette smoking and premature facial wrinkling (38-40) [Figure 2.1 (38)].

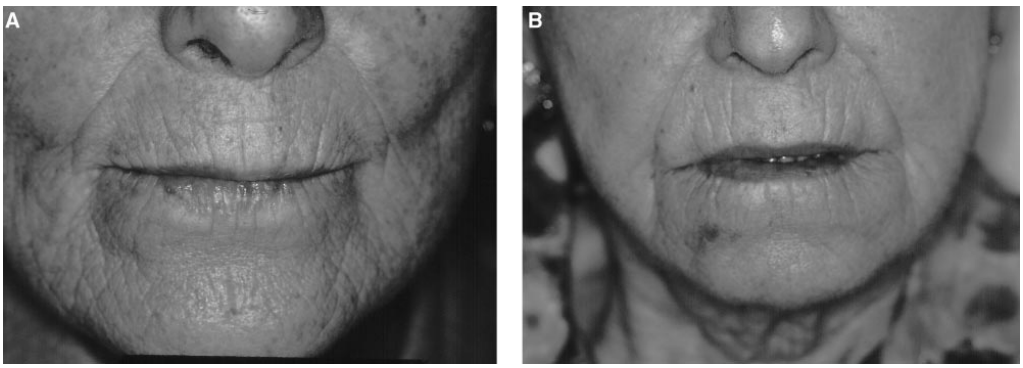

Figure 2.1: Perioral wrinkles of a female smoker (A) and female non-smoker (B), both around 60-years-old (38)

In 1995, Ernster *et al.* (39) conducted a cross-sectional study including a sample of 1,136 males and females aged 30–69 years, including never smokers [n=299], former smokers [n=551] and current smokers [n=286] to examine the association of smoking status with facial wrinkling. A questionnaire assessed smoking status, pack-years of smoking and potential confounding variables. Facial wrinkling was assessed by blinded standardised visual assessment (clinical examinations and a facial wrinkle score calculated). Multiple regression analyses of the relationship of pack years of smoking to facial wrinkle score were performed, controlling for confounding variables such as age, average sun exposure and body mass index, and they concluded that facial wrinkling was much more evident in current cigarette smokers compared to never smokers (estimated relative risks of: 2.3 [95% CI = 1.2, 4.2] for men and 3.1 [95% CI = 1.6, 5.9] for women).

In 1999, Demierre *et al.* (41) published the results of a telephone study conducted primarily to assess the public's awareness of the association between cigarette smoking and skin ageing. Telephone interviews were conducted in 678 randomly selected adult residents (46% male, 54% female) from non-seasonal dwelling units in Maine, USA. Results demonstrated that 54% of all respondents were aware of the association between cigarette smoking and skin ageing. Among the 678 participants, 162 (24%) of them were current smokers and after an adjustment for sex, age and education, they remained less likely to be aware of this association compared with former or never smokers.

2.3.3 Progression software (photo-ageing) research

In 1984 a Western Australian public health advertising campaign, "Not Just a Pretty Face", depicted a young, attractive woman smoking a cigarette while gradually morphing into a relatively unattractive older person [Figure 2.2 (42)]. The copy for this commercial was:

*"When you don't **smell** all that pretty*
*You don't **feel** all that pretty*
*And somehow you don't **look** all that pretty.*
*What good's a **pretty face** when you've got an ugly breath?"* (42)

20 years 30 years 40 years 50 years 60 years

Figure 2.2: HDWA advertisement "Pretty Face" created by John Bevins, Sydney, NSW (42)

Unlike other health-oriented anti-smoking messages, the Pretty Face advertisement addressed the social consequences of cigarette smoking by linking smoking to unattractive breath and appearance.

An investigation (42) was undertaken to assess the impact of "Pretty Face" on the attitudes of adolescents. A sample size of 215 students (103 male, 112 female; aged 10–15 years) were recruited from a large private Perth metropolitan school to view the advertisement and complete a five-page questionnaire. The authors concluded that the advertisement was highly successful in deterring girls from taking up smoking because of its powerful and direct message that "smoking makes you ugly". In 2003, a US 'Task Force for Tobacco-Free Women and Girls' research team published a 'Letter' (43) in *Tobacco Control* stating they were using a computer program, APRIL® Age Progression Software, that provided personalised, science-based illustrations of how smoking can affect facial appearance. The program had been developed as a result of an idea from an essay contest, where middle and high school students were asked to submit ideas for strategies for girls to reject tobacco. The APRIL® Age Progression Software program added approximately 30 years to an adolescent face in two versions: one as a non-smoker and another photo with the premature wrinkling and unhealthy skin tone associated with a pack-a-day smoker. Demonstrations involving middle and high school students were quick at five minutes each, requiring a digital photo of the person to be taken and then downloaded onto a computer and facial "landmarks" mapped, thereafter enabling subsequent animations to "morph" from the current photo to the future [Figure 2.3 (43)].

Figure 2.3: Computer simulation of ageing in a smoker and non-smoker (43)

It was noted that the intervention often evoked strong reactions from the participating students when they witnessed their own photos – there were shrieks, laughs and exclamations, but an opposing stunned silence from some participants was also

observed. The software's projection of future appearance was validated by many participants commenting how much their future photo resembled an older relative (43).

To measure the impact on current and future smoking intentions, surveys were completed by the students before and after the intervention and it was noted that the intervention affected current smokers and never smokers in different ways. Significant results were demonstrated among the responses from current smokers to the following survey questions:

i) "Do you think that you will smoke a cigarette anytime during the next year?" (43)

(86.7% answered 'yes' pre-intervention; 73.3% answered 'yes' post-intervention: p=0.000);

ii) "I think that becoming a smoker reflects poor judgement." (43)

(33.3% answered 'yes' pre-intervention; 43.5% answered 'yes' post-intervention: p=0.028).

Whereas, a significant attitudinal change was demonstrated among the never smokers in their responses to the following survey questions:

i) "Do you think that people risk harming themselves if they smoke one or less than one cigarette per day?" (43)

(79.2% answered 'yes' pre-intervention; 92.1% answered 'yes' post-intervention: P=0.001);

ii) "Does concern about your appearance affect the choices you make from day to day?" (43)

(68.4% answered 'yes' pre-intervention; 78.5% answered 'yes' post-intervention: P=0.043).

In 2005, Semer *et al.* (44) published a paper on an intervention which they designed and delivered to a group of 64 high school students (male and female students, aged 14 to 19 years) of which 37 were regular smokers. The primary objective of the study was to investigate the feasibility and acceptability of an intervention that used vanity and oral health issues associated with tobacco use to motivate the adolescent smokers to enter a school-based smoking cessation program. The intervention involved using a "special effects" computer program to "morph" digital photographs of the students. It used overlays on their facial photographs; the first overlay demonstrated facial wrinkling

associated with tobacco use; the second overlay simulated facial disfigurement associated with oral cancer from tobacco use. Overall, the intervention was considered feasible to deliver and favourably accepted by the adolescents. Post-intervention, 21 of the 37 (57%) regular smokers signed up for the school-based cessation program. From these signed-up regular smokers, 16 (76%) actually participated in the program, 8 (50%) completed all the treatment sessions and 4 (25%) reported they had quit smoking at the end of the program. These results supported the authors' hypothesis that when designing smoking cessation strategies for this particular adolescent demographic, not only do strategies have to possess an educative and informative format, but they must also be motivational (44).

Acknowledging the challenge of recruiting adolescents into smoking cessation programs, another study conducted in Switzerland in 2006–2007 (45) focused on vanity rather than health, using APRIL® Age Progression Software. During this period, a final study population of 845 participants (all females, aged 14 to 18 years) were photo-aged at 11 events (school events: high schools and vocational schools; public events: fairs, tobacco-related events and a party) and were asked to complete a pre- and post-intervention questionnaire. Of the study population, 378 (45%) reported they had never smoked, 206 (24%) reported they were currently smoking, 94 (11%) reported they were occasional smokers and 167 (20%) reported they had stopped smoking. The objectives of the study were to investigate whether the intervention had an impact on this specific 14–18 year age group and whether the images motivated them to quit smoking or to attend a smoking cessation course based on the previously validated Prochaska Scale, *'The Stages of Change' SOC* (46), which identifies pre-contemplators, contemplators and preparers.

From their results, the authors were able to demonstrate:

i) the intervention did have an impact as 24% of current smokers reported that the ageing images had increased their motivation to quit smoking; especially those in advanced motivational changes (8% pre-contemplation; 32% contemplation; 71% preparation);

ii) no participants were recruited for a smoking cessation course.

Overall, the authors concluded that photo-ageing had a promising impact informing the adolescents of the dangers of smoking and increasing their motivation to quit smoking, but other methodologies better suited for adolescents must be developed as recruiting them for smoking cessation courses may not be appropriate for this demographic age group.

In 2008 Burford *et al.* (47) conducted a pilot RCT which investigated the effectiveness of a photo-ageing intervention on smoking cessation rates and nicotine dependency and the feasibility of delivering such a complex intervention from a primary care setting, the community pharmacy. This study is reported as Chapter 3 of this thesis.

The most recent photo-ageing studies have been published in 2011 and include a qualitative study and RCT by Grogan *et al.* in the UK. In a qualitative study by Grogan *et al.* (48), 47 women aged 18–34 years were recruited from a 'stop smoking service' and photo-aged with the APRIL® Age Progression Software with the primary objective to investigate their engagement with the photo-ageing smoking cessation intervention by giving their accounts of their experiences as a result of seeing themselves photo-aged to any future age (to a maximum of 72 years age—the limit of the program) as a smoker and non-smoker. The key finding of the study was: women said they were afraid of visible ageing and seeing their own shocking future face as a smoker was definitely a motivating factor for quitting smoking (48).

In their RCT, Grogan *et al.* (49) recruited 70 female participants (aged 18–34 years), once again from a 'stop smoking service'. It was recorded whether the women had children or were currently pregnant – the rationale for this component of the study being this female age group has been identified as a public health priority (if they smoke during pregnancy, the result can be significant foetal damage).

The primary objective was to investigate if exposure to a photo-ageing smoking cessation intervention impacted on quit smoking cognitions, nicotine dependence, and self-reported and objectively assessed smoking in young women. The authors stated that this was the first RCT to be conducted with a photo-ageing intervention on women's cognitions and behaviour.

The 70 recruited participants were allocated at random to either the control group (where they received 'usual care' [i.e. exposure to a UK anti-smoking leaflet]) or the intervention group (where they received 'usual care' plus the photo-ageing intervention viewing smoking and non-smoking images of their own faces aged up to a max of 72 years of age, in two-year intervals). The researcher collecting the data was not blinded to group allocation.

Quit smoking cognitions, such as attitudes, subjective norms, perceived behavioural control and intention to quit smoking, were measured via positive reactions to quitting smoking based on the Theory of Planned Behaviour. Multiple items on five-point scales on the questionnaires completed by participants at three different points of time:
T1: baseline
T2: immediately after 'usual care' (and intervention)
T3: 4 weeks after receiving the intervention or 'usual care'.

At T1 and T3, participants also completed measures of nicotine dependence (using the Fagerström Test of Nicotine Dependence) and self-reported and objectively assessed smoking (breath carbon monoxide (CO) levels using a Smokerlyzer piCO+ CO monitor).

Key findings indicated:
i) The randomised allocation to the groups was deemed a success, as there were no statistically significant differences found between the groups at baseline ($p>.10$), thereby producing two groups matched on quit smoking cognitions and behaviour.

ii) The photo-ageing intervention produced immediate significant effects in the intervention group, increasing positive quit smoking attitudes, subjective norms, perceived behavioural control and intentions at the T2 stage. However, it was noted by the T3 stage (i.e. four weeks later), these effects were reduced, although the intervention group was still more positive than the control group about quitting and were still significant for attitude.

iii) The photo-ageing intervention revealed mixed results for the smoking measures:

• nicotine dependence (Fagerström) scores were lower in the intervention group compared with the control group, and this difference ***was*** statistically significant $p < 0.05$, with a medium effect size $\eta^2 = 0.09$;

• objectively assessed CO levels were lower in the intervention group compared with the control group, although this difference ***was not*** statistically significant and the effect size was small, $\eta^2 = 0.006$.

iv) As mentioned, the largest difference between the control and intervention groups was for the nicotine dependence smoking measure. Assessments using Mann-Whitney U tests conducted separately at T1 and T3 stage on total cigarettes smoked in last seven days revealed no significant difference between the groups at baseline $p = 0.13$, but at T3 the intervention group had smoked significantly fewer cigarettes compared to the control group $p<0.05$.

v) Parental or pregnancy status was taken into account in the analyses, but there were no substantive changes.

Although the authors stated their study was sufficiently powered to detect these effects on the key outcomes, they were also cogniscent of some limitations in their study and therefore, they encouraged the following future research to be done with this photo-ageing intervention:

• carry out further tests using objective measures;
• investigate effects over longer time periods;
• include other groups in this type of research (e.g. males);
• recruit samples from the general population;
• research the effect of interpersonal characteristics (e.g. body satisfaction) (49).

The most recent publication on photo-ageing interventions is a systematic review by Flett *et al.* (50) conducted to establish the effectiveness of physical appearance interventions in changing smoking perceptions, attitudes and behaviours. The authors searched 17 online databases locating 4356 articles in the 1980 to 2011 period, although only 11 articles were reviewed as they met the review criteria of investigating an

appearance intervention relating to changing smoking attitudes, intentions or behaviour [Table 2.3 below (50)].

Table 2.3: Brief study checklist (50)

Table 1 Brief study checklist

Study	Design	Participants	n	Outcome measures	Results
Semer *et al*,[18] (2005)	Cohort analytic	Female/male smokers and non-smokers	64	Smoking behaviours, intentions	Individuals reported that the intervention was effective. No statistical significant results.
Pirie *et al*,[19] (1992)	Cohort analytic	Female smokers	417	Weight, carbon monoxide ratings, smoking behaviours	Results are unclear due to various intervention components possibly having an impact. Statistical significant group differences.
Weiss *et al*,[20] (2010)	Cohort	Female students; non-smokers, ex-smokers and occasional smokers	845	Smoking behaviours, intentions, beauty perceptions	Increased motivations to quit smoking, however lack of engagement in smoking cessation course. Significant differences on stages of change variables.
Grogan *et al*,[21] (2011)	Randomised control trial	Female smokers	70	Carbon monoxide, smoking behaviours, theory of planned behaviour constructs, dependence	Increased intentions to quit smoking. Significant differences on theory of planned behaviour and nicotine dependence variables.
Burford *et al*,[22] (2009)	Randomised control trial	Female/male smokers	50	Dependence, smoking behaviours	Pilot study providing limited information regarding the outcomes measured. No statistically significant results.
Hysert *et al*,[23] (2008)	Cohort	Female/male smokers and non-smokers	792	Attitudes, smoking behaviour, diet, physical activity	Maintenance reported as individuals remembered the intervention, smoking behaviour differences. Statistically significant differences for progression to smoking.
Hysert *et al*,[24] (2003)	Cohort	Female/male smokers, non-smokers and ex-smokers	445	Self-image, intentions, perceptions	Statistically significant results including increased intentions to quit and positive attitudes.
Perkins *et al*,[25] (2001)	Cohort analytic	Female smokers	219	Carbon monoxide, depression, mood weight, dependence	Statistically significant differences between groups for increased smoking cessation rates.
Copeland *et al*,[26] (2006)	Cohort analytic	Female smokers	79	Carbon monoxide, weight, dependence, body concerns, situational factors	Support for tailored appearance interventions due to cessation rates, statistically significant differences between the two groups at a 3-month follow-up.
Kentala *et al*,[27] (1999)	Cohort analytic	Female/male smokers and non-smokers	2, 586	Smoking abstinence	Higher smoking cessation rates in control group, however not statistically significant.
Grogan *et al*,[28] (2010)	Qualitative	Female smokers	47	Semi-structured interviews and one focus group	Demonstrated effectiveness including increasing intentions to quit linked to personal susceptibility. No statistical outcomes as the study included only qualitative investigations.

A quantitative analysis was conducted using 'The McMaster Quality Assessment' which evaluated 10 studies (all except the qualitative Grogan *et al.* 2010 study). The assessment contained six quality ratings (selection bias, study design, blinding, data collection methods, withdrawals and dropouts) to compare the study to. The result was only one study, Grogan *et al.* 2011 was awarded with a global rating of {2} 'Moderate code', whilst the rest of the studies were awarded a global rating of {3} 'Weak code'.

The eleventh study, Grogan *et al.* 2010, which was a qualitative study was analysed using 'The Walsh and Downe Quality Assessment'. This assessment contained eight areas (scope and purpose, design, sampling strategy, analysis, interpretation, reflexivity, ethical dimensions and relevance/transferability) to analyse the study. In-depth information was gained from interviews and focus groups but as there were no statistical outcomes, the effectiveness of the intervention was inconclusive.

Overall, the authors of the systematic review concluded they were still undecided as to whether physical appearance interventions have an impact and therefore stated further well-designed studies are still needed in this complex combined area (50).

2.4 Expanding the role of the community pharmacist

Community pharmacists have an established role in the primary health care system (51) and have an ideal setting, the community pharmacy, from where to deliver primary health care (52). The pharmacist provides "reactive healthcare" to many consumers who frequent the pharmacy to seek smoking cessation advice and treatment options (53). There are many types of smoking cessation interventions, including behavioural therapy and pharmacological treatment options and they have varied success (54, 55). Therefore, with their professional training, pharmacists provide patients with comprehensive counselling and quit smoking support programs (56).

2.4.1 Effectiveness of community pharmacist quit smoking support programs

Community pharmacists are health care professionals who come into contact with large numbers of people and it is this front-line accessibility that places them in a good position to deliver brief interventions (57). As NRT is predominantly available as an OTC medication in Australia and many countries, smoking cessation is a particularly appropriate role for pharmacists to provide. Even though the oral nicotine dependence drugs, varenicline (Champix®) and bupropion (Zyban®) necessitate a consultation and prescription to be obtained first from the doctor, these medications have to be supplied through pharmacies and so the community pharmacist still has an opportunity in optimising health care for the patient, by providing expert smoking cessation counselling in conjunction with the dispensed medication (56).

Support for community pharmacy services was stated in a recent publication by Brown *et al.* who conducted a systematic review of services provided by pharmacies that promote healthy living (58). The research that contributed to the review was from the following geographical basis: UK (51.5%), US (20.4%), Australia/New Zealand (9.8%), Europe (7.7%) and Canada (7.2%) and the literature search covered the period January 1990–August 2011 inclusive. The authors concluded that good evidence exists to support the provision of services such as smoking cessation, cardiovascular disease

prevention, hypertension and diabetes but further evidence is still required to support the introduction of asthma and heart failure services.

With reference to the provision of smoking cessation services, the authors further concluded that community pharmacists can effectively deliver smoking cessation campaigns from their pharmacy. Evidence demonstrated that structured interventions together with NRT and counselling fared better in terms of cessation results than opportunistic interventions (58). Examples of these structured interventions are described in the following papers:

• Vial *et al.* study (59) published in 2002, compared the quit rates achieved by 102 smokers in a smoking cessation program. The program was initiated in hospitals and saw enrolled participant smokers (> 18 years) being randomised to either:

i) minimal intervention group (n=33) – where participants only received written materials and advice about quitting;
ii) hospital-based program (n = 35) – where participants received consultations, NRT and a follow-up program from a hospital outpatient clinic.
iii) community pharmacy-based program (n = 34) – where once again participants received consultations, NRT and a follow-up program by a community-based pharmacist.

Biochemical confirmation (CO measurements) to confirm abstinence from smoking were performed whenever possible, with continuous and point prevalence of abstinence assessed at 3, 6 and 12 months. At the final 12-month stage the quit rates were: 38% in the hospital group, 24% in the community pharmacy group and 4.6% in the minimal intervention group. The authors concluded that a structured smoking cessation intervention, either hospital-based or community pharmacy-based was superior to minimal intervention without nicotine patches. It was stated that community pharmacies were the ideal location to deliver smoking cessation programs because they were local settings which were easily accessible by patients. Delivering smoking cessation programs from community pharmacies also minimised the impact on hospital resources.

• The Maguire *et al.* study (60) in 2001 evaluated the PAS (Pharmacists' Action on Smoking) model. This model included: a structured community pharmacy-based smoking cessation counselling program, an information leaflet and a weekly follow-up for the first four weeks, and then monthly as needed. The objective was to evaluate whether higher quit rates would be demonstrated with the PAS intervention as compared to impromptu smoking cessation advice given by pharmacists. Pharmacists working in community pharmacies in Northern Ireland and London enrolled 484 smokers into a RCT and individually randomised them into the intervention group (n = 265) or the control group (n = 219). The primary outcome measure was self-reported smoking cessation and biochemical confirmation (cotinine validation) at the 12-month follow-up. Results indicated a statistical significant difference ($p<0.001$) as 38 (14.3%) smokers in the PAS intervention group were abstinent up to 12 months compared with six (2.7%) in the control group. The authors concluded that the community pharmacy-based PAS intervention could be an effective and workable model for pharmacies to adopt in the provision of smoking cessation services.

• The Dent *et al.* study (61) in 2009 assessed the effectiveness of a smoking cessation group program (a three-session 'face-to-face' group program conducted by the pharmacist) compared with a brief 5- to 10-minute standard telephone session by a pharmacist.

The RCT recruited 101 smokers and randomised them into the intervention program group (n = 50) or the control group (n = 51). The primary outcome of self-reported abstinence was biochemical confirmation (cotinine validation) at six months after the quit date. Using the ITT (Intention To Treat) approach, confirmed abstinence rates at the final six months were 28% for the intervention group and 11.8% for the control group which was a statistical significant result ($p<0.041$). The authors concluded that pharmacists are effective providers of smoking cessation interventions and recommended that pharmacists should be used more in this capacity as they could make significant impacts on smoking rates and therefore improve public health.

• The Sinclair *et al.* study (62) in 1998 evaluated a training workshop for pharmacists and pharmacy assistants to improve their counselling in the Stages of Change (SOC) smoking cessation model. This RCT recruited 62 pharmacies and randomised them into

an intervention pharmacy group (n = 32) and control pharmacy group (n = 30), with 31 and 29 pharmacies completing the trial respectively. All pharmacy staff (pharmacists and assistants) at the intervention pharmacies underwent the specialised two hour training of the 'Pharmacy Support Programme'. Customers who smoked were recruited to the study (n = 492) when they sought advice on stopping smoking during a 12-month period with 224 smokers recruited to the intervention pharmacy group and 268 smokers recruited to the control pharmacy group. The primary outcome measures were the perceptions of customers and pharmacy staff of the counselling received and self-reported customer quit rates at one, four and nine months follow-up. Results demonstrated that counselling training was found to be paramount to the success of the smoking cessation service, with adjustments made for potential confounders (such as sex, age, socioeconomic status, nicotine dependence, and type of NRT product used) as 85% of intervention customers were more likely to have discussed stopping smoking with pharmacy staff compared with 62% of control customers. This difference was statistically significant ($p<0.001$).

Another significant difference demonstrated was the quality of this discussion ($p = 0.048$), as 34% of intervention customers rated their discussion more highly than the 16% of control customers. The authors concluded that the specialised training intervention was associated with higher quality counselling with customers and a trend towards higher quit rates and this could potentially be an important contribution to national smoking cessation rates.

The importance of pharmacy provision of smoking cessation services was recognised by The Pharmacy Guild of Australia and as part of the 'Third Community Pharmacy Agreement', a project was funded in 2003 by the Australian Government Department of Health and Ageing on improving the quality, effectiveness and sustainability of smoking cessation services delivered through community pharmacies. A final report of the findings was prepared for the Pharmacy Guild of Australia and submitted by The University of South Australia, Division of Health Sciences (53).

Community pharmacies in the metropolitan and rural areas of South Australia were approached to participate in the project and out of the 230 pharmacies approached, 81 agreed to be in the project, although only 74 pharmacies completed the project from

July to December 2003 (37 pharmacies in a control group and 37 pharmacies in an intervention group).

Staff in the pharmacies were asked to complete three baseline questionnaires: staff questionnaire, self-audit of smoking cessation and pharmacy environment questionnaire. Then the pharmacies were randomly allocated into either a control or intervention group. Control pharmacies were asked to continue with their usual practice. Intervention pharmacies undertook a multi-faceted practice support program (including interactive workshop, mystery shopping with feedback, academic detailing visits, project officer support and provision of support materials).

The project set out to achieve three primary outcomes which were as follows:
"Outcome 1: *increase the identification, engagement and retention of consumers in pharmacy-based smoking cessation activities* (53, p5).
Outcome 2: *increase cessation rates in smokers participating in pharmacy-based smoking cessation activities* (53, p6).
Outcome 3: *demonstrate the potential value of pharmacy to the health system in a key primary health care and public health area.**"*** (53, p7).

The outcomes of the project were measured by:
Outcome 1: the participation of the intervention pharmacies and identification of pharmacy barriers by pharmacy staff (by questionnaires).
Outcome 2: comparison of quit smoking rates for recruited smokers who purchased NRT or received Bupropion (Zyban®) by (telephone follow-ups); referrals to the 'Quitline' program and pharmacy team support program (by telephone follow-ups); patient satisfaction with pharmacy staff in support service (by telephone interviews).
Outcome 3: a cost-effectiveness analysis of delivering these strategies.

Results for the first outcome demonstrated an overall high engagement of pharmacy staff (pharmacists and pharmacy assistants) of intervention pharmacies in the multi-faceted program as:
• 73% of intervention participants indicated the workshop aims had been achieved to a large extent or completely;

• 70% of intervention participants stated they had achieved good or great benefit from five of the seven major topic areas presented at the workshop;
• 50% of intervention participants stated their level of understanding and confidence was much greater or very much greater at the end of the session.

The mystery shopper visits revealed a significant shift in the provision of smoking cessation services by the intervention group compared to the control group. Results revealed:
• 70% of the intervention group discussed the importance of getting support from the Quitline (compared with 29% of the control group);
• 50% of the intervention group provided a Quit booklet (compared with 19% of the control group) and 46% of the intervention group provided a Quitline card (compared with 3% of the control group);
• 25% of the intervention group encouraged the mystery shopper to enrol in the Quitline program (compared with 5% of the control group).

Pharmacy barriers identified in the baseline survey by pharmacy staff were skills to assist patients to quit, knowledge about the printed resources, clearly defined roles and responsibilities for all staff, referral options, confidence, feedback, time, private consultation area and documentation system.

Due to low initial recruitment numbers and very high attrition rates, the results for the second outcome regarding quit smoking rates for recruited smokers who purchased a NRT product or received Bupropion (Zyban®) did not enable statistically meaningful comments about smoking cessation outcomes to be made. Results at the final follow-up (six months) showed quit rates for smokers recruited by intervention pharmacies to demonstrate a point prevalence quit rate using an intention to treat approach (ITT) of 12% (95% CI = 3-21). On the other hand, quit rates for smokers recruited by control pharmacies at the final follow-up (six months) represented a point prevalence quit rate using an ITT approach of 18% (95% CI = 5–31). The difference between the groups was postulated to be due in particular to the high drop-out rate of the intervention group.

Part of the project was that intervention pharmacy staff were encouraged to offer support programs to participants as a standard procedure when selling NRT or

Bupropion (Zyban®). Results for referrals to the 12-week 'Quitline' program and pharmacy team support programs demonstrated a total of 18 intervention group pharmacies (49%) recruiting 107 smokers into either the 'Quitline' program and/or their pharmacy team support program as compared to no referrals being received from the control group pharmacies during the same period.

Measuring patient satisfaction with pharmacy staff delivering smoking cessation support services in the project was not possible due to poor recruitment of smokers for follow-up. Therefore, the investigator team of the project sought permission from the funding body to undertake a supplementary investigation by interviewing smokers from the general community (n=151; 46% female, 54% male) about their perceptions and expectations of smoking services delivered by community pharmacy teams. These results demonstrated:

• 105 (70%) interviewees thought it would be very useful or extremely useful for people to discuss their quit attempts with pharmacy staff;

• 100 (66%) interviewees indicated that they would be interested in receiving certified smoking cessation counselling (one-on-one advice) and support from pharmacy staff (53).

(Results for the third outcome, cost-effectiveness of delivering implementation strategies are reported in the next section, 2.4.2.)

Overall, these six studies provide evidence for smoking cessation programs to be delivered through community pharmacies. The success of pharmacy support programs can be attributed to high-quality counselling delivered by pharmacists and pharmacy staff who have been trained in behaviour change methods and this intervention counselling when delivered alone or combined with NRT, has far better smoking cessation results than *ad hoc* counselling.

2.4.2 Cost-effectiveness of community pharmacist quit smoking support programs

There are only a limited number of cost-effectiveness analysis studies of community pharmacist quit smoking support programs. The definition of cost-effectiveness analysis being: *"a form of economic evaluation in which the measure of outcome is a simple uni-dimensional natural unit e.g. number of quitters"* (63, p108).

The report prepared for The Pharmacy Guild of Australia, as part of the 'Third Community Pharmacy Agreement' (53) mentioned in section 2.4.1, contained a cost-effectiveness study in relation to the three primary outcomes.

With reference to the first outcome, increasing identification, engagement and retention of consumers in pharmacy-based smoking cessation activities, the following are the cost-effectiveness calculations of relevance to the PAINT RCT:

i) smokers were referred by the intervention pharmacies (n = 37) into support programs (an overall recruitment rate of 0.6 smokers per pharmacy per month);

ii) primary costs incurred to implement the support program and therefore, sustain 0.6 smokers in support programs were AUD 1,385 per pharmacy per year (these primary costs included an initial and 'annual' refresher session plus two academic detailing visits per year);

iii) estimating for a five-year period, the cost would be AUD 3,105 per pharmacy. Therefore it was calculated that the cost per participant (or cost per smoker recruited into the support program) was AUD 86.

With reference to the second outcome, increasing cessation rates in smokers participating in pharmacy-based smoking cessation activities, the information presented in the study that was relevant to the PAINT RCT was the 'cost per quitter'.

A summary was calculated over a five-year time frame of the 'additional quitters' that would result if pharmacy staff enrolled customers into intensive support programs.

Based on a five-year average, at AUD 86 per smoker at a recruitment rate of 0.6 for a set-up of 37x pharmacies, the cost per quitter was calculated to be AUD1400.
(Please note these are 2003 values from the report).

Crealey *et al.* conducted a study over a two-year period in two pharmacies in Northern Ireland to determine the costs and effects associated with a community pharmacy-based smoking cessation program (64). The study examined the cost-effectiveness of the PAS model (the same model as described in the Maguire *et al.* study (60)).
The following outcomes were evaluated:
i) the costs involved in training pharmacists to deliver the PAS program;
ii) the cost-effectiveness of the PAS program (measured in terms of the additional life-years gained as a result of the intervention).

The fixed costs of delivering the PAS program (including PAS materials of manuals, locum fees, room hire, coordination of program and provision of training for staff) was approximately £55,000. Variable costs (including an average of one hour counselling time spent by pharmacists with patients, i.e. the consultancy rate for a community pharmacist) were calculated to be £30 per patient entering the program.

The cost-effectiveness of the PAS program: *"was accomplished by using data from a pilot study and by determining the difference between the percentage of patients who stop smoking if counselled under the PAS program and the percentage who would be expected to stop smoking without the pharmacist's intervention."* (64, p326).

The main economic analysis demonstrated that the PAS program was cost-effective, although it must be noted that the program was more cost-effective for men, as they are generally heavier smokers than women. Results showed the ranges for the costs per life-saved year to be:
men = £196.76 to £351.45;
women = £181.35 to £772.12.
(Please note these are 1997 values)

The authors concluded the implementation of the PAS model into community pharmacy settings compared favourably with other disease prevention programs and could have potential savings for the NHS (64).

Sinclair *et al.* conducted a RCT to assess the cost-effectiveness of an intensive pharmaceutical intervention in smoking cessation (63). They recruited 64 pharmacies in Scotland and evaluated the training of pharmacy staff based on the SOC model. The primary outcome was the number of quitters (continuous measure) at nine months and an estimate of the life years gained by smoking cessation.

The cost-effectiveness of the study showed the overall cost of delivering the intervention to be £14,915 and control costs to be £14,121. At nine months, the continuous abstinence rate was 12% for the intervention group and 7.4% for the control group. The cost-effectiveness ratios for the intervention were £300 per quitter which equated to £83 per life year gained (63).
(Please note these are 1995 values).

The authors concluded that higher smoking cessation rates were associated with the intensive pharmaceutical intervention and so this confirmed that pharmacy staff (pharmacists and pharmacy staff) trained in certified smoking cessation counselling techniques could make important contributions to optimising patient health and achieving national smoking cessation targets (63).

The three studies (Final Report for The Pharmacy Guild of Australia, Crealey *et al.*, Sinclair *et al.*) that have been reported in this cost-effectiveness section 2.4.2 are summarised in Table 2.4.

Table 2.4: Summary of pharmacy cost-effectiveness studies

Authors and date of publication	The Pharmacy Guild of Australia (2004)	Crealey *et al.* (1998)	Sinclair *et al.* (1999)
Country where research was conducted	Australia	Northern Ireland	Scotland
Cost per participant	AUD 86	£30	----
Cost per quitter	AUD 1440	----	£300
Cost per LYG (Life Year Gained)	----	Men: £196.76 – 351.45 Women: £181.35 – 1144.93	£83
Year of pricing	2003	1997	1995

2.4.3 Willingness To Pay (WTP) for community pharmacist delivered programs

The community pharmacy is a health care setting where the public can easily access the advice of a registered health practitioner at no charge and with no appointment. Pharmacists have always embraced their role as primary health care practitioners, but the extra time spent counselling and delivering brief interventions to customers/patients must be balanced with the viability of running a community pharmacy business. The lack of remuneration for professional services and the need for community pharmacies to change their existing models of practice has been highlighted and therefore pharmacists are keen to pursue paid professional services as this will aid the viability of their community pharmacy businesses (65).

Little is known about the value that customers place on paid pharmacist-provided services and to date, there are a limited number of economic studies conducted in the community pharmacy setting evaluating what customers would be Willing To Pay (WTP) for a professional service. A literature search revealed a small number of WTP studies conducted in community pharmacies in the following areas: diabetes (66), hypertension (67) and asthma (68), but no WTP studies were found in the smoking cessation area.

Hanna *et al.* (66) conducted a study from a sample of 130 diabetic patients recruited from 14 community pharmacies across Sydney, Australia to determine:

i) whether patients would be WTP for diabetes Disease State Management (DSM) services and how much they would be WTP for them;
ii) the relationships between WTP and the characteristics of patients (including clinical, socio, and demographic characteristics).

Patients completed self-administered questionnaires evaluating an intervention provided to patients. This intervention was a hypothetical pharmacist-provided diabetes DSM service (the service being consultations which would result in a 50% improvement in their diabetes control, lowering risk complications and optimising their health by improving their quality of life). The WTP was assessed by asking patients how much they would be WTP for initial and follow-up consultations. Patients were given a range

of amounts to choose from; AUD 0 to AUD 80 in $10 increments per 30 minute consultation and patients had to specify their maximum WTP.

Results suggested patients were WTP a median price of:

i) AUD 30 for a 50% improvement and AUD 40 for 100% improvement for the initial consultation;
ii) AUD 20 for 50% improvement and AUD 30 for 100% improvement for the final consultation.

Also, the authors found statistical significant relationships between WTP and the following clinical/socio/demographic characteristics of patients:

i) an increase in WTP if patients had an income greater than AUD 150,000;
ii) an increase in WTP as patients' perceptions of the pharmacist's abilities increased;
iii) an increase in WTP in patients with more frequent hospitalisations (i.e. two to four hospitalisations).

(Please note: these have been assumed as 2008 values as no date was provided).

Côté *et al.* (67) recruited 100 participants (aged between 34 and 80 years) taking anti-hypertensive medications from nine pharmacies in Quebec City, Canada to participate in a study to weigh the costs and benefits of a pharmacy-based health promotion program. The intervention they delivered was a program to improve blood pressure and WTP was one of the measures considered. This was done by asking the patients whether they would be WTP per month for the pharmacist to take their blood pressure regularly and give them medication advice, which would result in a quality of life improvement for them.

Results post-intervention found that only two participants would be WTP. This equated to a payment of CAN$0.54 per month after the intervention period.
(Please note these are 1998 values).

Naik-Panvelkar P *et al.* (68) conducted a study in community pharmacies in New South Wales, Australia with one of the objectives being to determine if patients would be WTP to receive a specialised asthma service from a community pharmacy. The intervention involved patients choosing between two hypothetical asthma service models with varying attributes (using discrete choice experiment questionnaires).

Results demonstrated that participants were WTP:

i) AUD 18.00 for a private area to be available in the pharmacy;
ii) AUD 44.50 for lung function testing;
iii) AUD 9.18 for an appointment with the pharmacist;
iv) AUD 22.80 to receive a comprehensive advice session on the disease state of asthma and the medications used to treat it.

A marginal WTP was calculated to be AUD 94.86 for a patient to receive an overall asthma service.
(Please note these are 2009 values).

The authors concluded that patients highly valued the asthma service and this result could be used to assist pharmacists and governments making decisions in the future regarding professionally paid services.

The three studies (Hanna *et al.*, Côté *et al.* and Naik-Panvelkar *et al.*) that have been reported in this WTP section 2.4.3 are summarised in Table 2.5.

Table 2.5: Summary of pharmacy WTP studies

Authors and date of publication	Hanna *et al.* (2010)	Côté *et al.* (2003)	Naik-Panvelkar *et al.* (2012)
Country where research was conducted	Australia	Canada	Australia
Area of clinical service provided	Diabetes	Hypertension	Asthma
WTP	Yes; for an initial consult: AUD 30 (50% improvement) AUD 40 (100% ") Yes; for a final consult: AUD 20 (50% improvement) AUD 30 (100% ")	No.	Yes; AUD 94.86
Year of pricing	2008 (assumption as no date provided)	1998	2009

2.5 References

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CHAPTER 3: PILOT PAINT STUDY

"Can a personalised smoking cessation intervention be delivered by community pharmacists in Western Australia? A pilot randomised controlled trial."

SUMMARY

Background

- A pilot study was sought to test the feasibility of a pharmacist delivering a complex intervention in a community pharmacy setting.
- The specific aims being to test the efficacy of a complex intervention to promote smoking cessation to young adult smokers and to explore the scope for a subsequent RCT.

Methods

- The pilot study recruited 50 participants from five community pharmacies (25 control group : 25 intervention group).
- All participants received the same smoking cessation advice; the intervention group also received the photo-ageing intervention.
- Three follow-up surveys were undertaken via telephone at one, two and three months.
- All quit attempts were self-reported.

Results

- There was a 38% attrition rate at the final three month follow-up.
- Six participants (four from the control group and two from the intervention group) made a self-reported quit attempt at the final three-month follow-up and all these participants came from the lowest smoking dependence category (0–2) at baseline. A Fisher's exact test suggested this difference between groups was not statistically significant (p=0.62).
- For participants with a greater smoking dependence score (FS 3+), there was a trend towards a greater proportion of the intervention group moving to a lower dependence by three months (83% intervention group vs. 38% control group, p=0.14).
- No participants moved from a lower to a higher dependence category at three months.

Conclusion

- It was feasible and practical for a pharmacist-researcher to deliver the complex photo-ageing intervention within a community pharmacy setting.
- There was a clear trend showing moderately dependent smokers moving to a lower dependence category.
- Based upon the pilot study results, it was proposed to continue this line of photo-ageing research by conducting a full RCT.

3.1 Introduction

The community pharmacy environment is dynamic, with pharmacists constantly adjusting the way they practice to try and maintain the business viability of their pharmacies (1, 2). There is evidence that customers in community pharmacies are being advised on a variety of health issues (3). There is a view that this health advice role may be further expanded in future (4).

Under the guidance of the MRC framework, this pilot study sought to test the feasibility of recruiting participants and delivering the intervention, following up participants, testing acceptability and the likely effect size.

It focused particularly on the potential of a powerful arousing message delivered by a respected health professional, the community pharmacist, to motivate young smokers to quit.

3.2 Objectives

The aim of the pilot feasibility study was to trial a smoking cessation intervention delivered within a community pharmacy setting. The specific aims were:

i) to test the efficacy of a complex intervention to promote smoking cessation based on personalised, vivid illustrations of 'smoker's face' on quit attempts and nicotine dependence among young smokers (18–30 years old);

ii) to explore the scope for the following elements of the subsequent RCT:

   a) recruitment of participants;
   b) delivering the intervention;
   c) follow-up of participants;
   d) testing acceptability; and
   e) likely effect size.

3.3 Outcomes Measured

Part One: Efficacy of the complex intervention:

i) quit attempts;

ii) nicotine dependence.

Part Two: Feasibility of delivering the intervention within a community pharmacy setting:

i) recruitment rates;

ii) acceptability to pharmacists of delivering the intervention on their premises.

3.4 Methods

Table 3.1:Research method summary for pilot PAINT study

	Part One: Community Pharmacies	**Part Two:** Participants (customers)
Pilot study design:		A pilot RCT.
Pilot setting:	Community pharmacies in Perth, WA	
Pilot study population:		Smokers aged 18 to 30 years-old.
Pilot sample size:	Five community pharmacies	50 participants: 25 for intervention group 25 for control group
Pilot sample size calculations:	N/A	Effect size: unknown. N=50 was selected as sufficient to detect a 'large' effect size (d=0.8), using an independent samples t-test (two-tailed), setting alpha=.05 and beta=.20, Power=80%.
Pilot sampling strategy:	Geographical distribution. (Due to modest response to advertisement in the Pharmaceutical Council of WA's newsletter "Rescript", a purposive sample of pharmacies was selected according to geographical distribution in the Perth CBD).	Random assignment. (Recruited participants of appropriate age were allocated to the control and intervention group on alternate weeks).
Eligibility criteria:	Community pharmacies within a 20km driving radius from Perth CBD. Pharmacist owners had to consent to participate: Pharmacy Information Sheet [Appendix 1] Pharmacy Consent Form [Appendix 2]	• 18 to 30-years-old • smokers • English speaking and able to give informed consent • no beards, moustaches or facial accessories that cannot be removed • contact availability for three months • not using NRT or taking drugs for nicotine dependence Customers had to consent to participate: Participant Information Sheet [Appendix 3] Participant Consent Form [Appendix 4]

3.4.1 The intervention

The APRIL® Age Progression Software is a normative-based 3D age progression software package [Appendix 5]. It creates a stream of aged images of faces from a standard digital photograph. The wrinkling/ageing algorithms are based upon research of more than 7,000 people of all ages, multiple ethnicities (Asian, South-east Asian, Caucasian, Hispanic, African) and lifestyle habits, as well as on published data regarding facial changes associated with ageing. The result is a colour, lifelike simulation of a person's face producing images of ageing with natural progression as a non-smoker and smoker.

In the pilot study, 'smoker's face' threat appeal simulations were created using a digital photograph taken of the participants and entered into APRIL® Age Progression Software, Version 2.4 Desktop edition on a laptop computer [Figure 3.1]. This software displayed three different applications: Smoking; Sun Exposure; Obesity. The pilot PAINT study only used the smoking application where the resulting aged images were adjusted to compare how a person would age as a smoker versus a non-smoker. The age progression software program has a finite range (i.e. it can only age up to a maximum age of 72 years). However, the optimum age on the program which demonstrates the premature skin wrinkling caused by smoking is 55 years. Therefore, the study only recruited participants to 30 years of age to allow a wide enough age range to effectively demonstrate the age progression.

Figure 3.1: APRIL® Age Progression Software, Version 2.4 Desktop edition

The creation of the simulations involved:

a) delineating a 'target' (smoker's and non-smoker's) face according to a predefined set of feature points;
b) distorting the delineations into a new configuration (based on lifestyle data from the faces of smokers and non-smokers, taking into account sex and race);
c) remapping textures (i.e., pixel intensities) into a newly generated image;
d) the initial resulting images displayed were a photo of the person (current age) as well as a photo-aged photo of them to any chosen age. It was a probability-based simulation of them in the future if they were to continue smoking [Figure 3.2] [Appendix 6].

Female current smoker, 25yrs Female photo-aged smoker, 65yrs

Figure 3.2: Current age photo and future photo-aged photo

The next step involved comparing this future photo-aged smoker's face with a future photo-aged non-smoker's face, in an effort to vividly demonstrate the additional facial wrinkling that smoking would have on their own future facial appearance [Figure 3.3].

Female photo-aged non-smoker, 65yrs Female photo-aged smoker 65yrs

Figure 3.3: Photo-aged non-smoker and photo-aged smoker photos

These created images [Figure 3.3] were then emailed to the participant's nominated email address within 24 hours of the participant receiving the intervention.

3.4.2 Data collection

Recruitment and data collection for the pilot study was undertaken part-time and occurred between February 2008 and October 2008 [Appendix 7]. Pharmacies were selected to cover a wide geographical region and different types of locations (some pharmacies were located inside a shopping centre and other pharmacies were located in a 'strip' of shops). This representation of pharmacies in the Perth metropolitan area was used to try and account for selection bias.

Customers presenting at the pharmacy for any service, including both prescriptions and OTC medications and those who appeared to be in the target age group were approached to participate in the study. Consenting participants (Selection criteria, Table 3.1) were randomised into two groups: a control group and an intervention group with equal numbers in each pharmacy. Allocation into control group and intervention group alternated weekly so that all participants recruited in any specific week received the same treatment at the time of recruitment. This was considered the most practical and least biased recruitment option suitable (because it would not have been practical to set

up and put away the intervention apparatus [photographic screen and lap-top] for every alternate person).

All participants were asked to fill out an identification (ID) page (demographic data) [Appendix 8] and a baseline questionnaire [Appendix 9]. The baseline questionnaire consisted of:

i) demographic data;

ii) questions from the Fagerström Scale [Appendix 10];

iii) questions concerning attitudes towards participants' appearance, health risks associated with smoking, perceived barriers to quitting smoking and pharmacy related questions.

Participants in the control group received standard smoking cessation advice from a pharmacist-researcher. This comprised of the researcher pharmacist showing a Pharmacy Self Care card on Smoking [Appendix 11] to the participant and discussing the health risks associated with smoking. This procedure from pre-screening to completion of recruitment took approximately five minutes.

Participants in the intervention group received from the pharmacist-researcher the same smoking cessation advice as the control group. In addition they were photographed and their images digitally aged, as a smoker and non-smoker, using APRIL® Age Progression Software and invited to view the age-processed images. This procedure from pre-screening to completion of post-intervention questionnaires took approximately 10 minutes. It was proposed that if participants became distressed or if they expressed an interest in smoking cessation, they would be counselled by the pharmacist-researcher but neither of these situations occurred in the pilot study.

3.4.3 Follow-up surveys

Follow-up surveys for the control group [Appendix 12] and intervention group [Appendix 13] were undertaken via telephone at one, two and three months after the intervention and took approximately three minutes to complete. The outcomes measured in these surveys were self-reported quit attempts and level of smoking dependence as assessed by the Fagerström smoking dependence scale [Appendix 10].

3.4.4 Data analysis

The baseline profile of the study participants was summarised using simple descriptive statistics (frequencies and percentages for sex; mean and standard deviation for age). The response rate at each of the follow-up surveys was documented as a percentage of the number of participants at recruitment.

The Fagerström scale was used to calculate a Fagerström Score [FS] of nicotine dependence. The Fagerström smoking dependence scale is based on responses to six questions and returns a whole number between 0 (very low dependence) and 10 (very high dependence). Then these scores are grouped into five categories [five-point ordinal scale] of smoking dependence, namely: 0–2 (very low), 3–4 (low), 5 (medium), 6–7 (high), 8–10 (very high).

The FS was calculated at each of the four surveys (baseline and three follow-up surveys). Missing data at each of the follow-up surveys was handled in two different ways:

i) they were excluded, so that tables of smoking dependence scores and changes in scores were based on observed data only (ACTUAL);
ii) a Last Observation Carried Forward (LOCF) strategy was used. In this approach, it was presumed that, if a person did not fill in the form, then their smoking dependence remained the same as their previous survey.

Changes in raw score from baseline to each survey were compared between the intervention and control groups by fitting a random effects regression model (equivalent to a repeated measures analysis of variance). P-values were attached to any difference between groups, as well as differences over the time period of the study. Change in the FS from baseline to the final survey was also calculated after reducing the score to the five-level ordinal scale. In this way, comparison of changes in broader smoking dependence level was compared (no change, or a reduction in dependence level) between intervention and control groups using the Chi-square statistic. The reason for performing this analysis was to investigate if any overall change in smoking dependence (from the regression model) occurred across all of these smoking dependence

categories, or only in one or two of these groups. The percentages of participants in each group (intervention or control) who had made an attempt to quit smoking were compared using the Chi-square statistic. Fisher's exact test was used instead of the Chi-square test if the numbers were too small for the Chi-square test to be valid.
Statistical analyses were carried out using the SAS version 9.2 statistical software program (SAS Institute Inc, Cary, NC, USA, 2008). For all statistical comparisons, a p-value < 0.05 was assumed to indicate a statistically significant association.

3.5 Results

3.5.1 PART I: Efficacy of the complex intervention

3.5.1.1 Response rate

Out of 83 possible recruits, 50 people consented to participate in the research. These 50 participants were recruited and assigned equally to the intervention and control groups. After recruitment, the participants were assessed at baseline and then followed up at monthly intervals to three months following recruitment. The response rates for each of the follow-up interviews are given below (see Table 3.2) and indicate that the attrition was greatest between enrolment and the first follow-up (26%), after which only a further six participants (12%) had dropped out by the three-month final follow-up. There appeared to be no significant difference in response rate between control and intervention groups (Chi-square test, p=0.97).

Table 3.2: Response rate of the pilot PAINT study

Timing	N (Control group)	N (Intervention group)
Baseline	25 (100%)	25 (100%)
1 Month	20 (80%)	17 (68%)
2 Months	17 (68%)	15 (60%)
3 Months	17 (68%)	14 (56%)

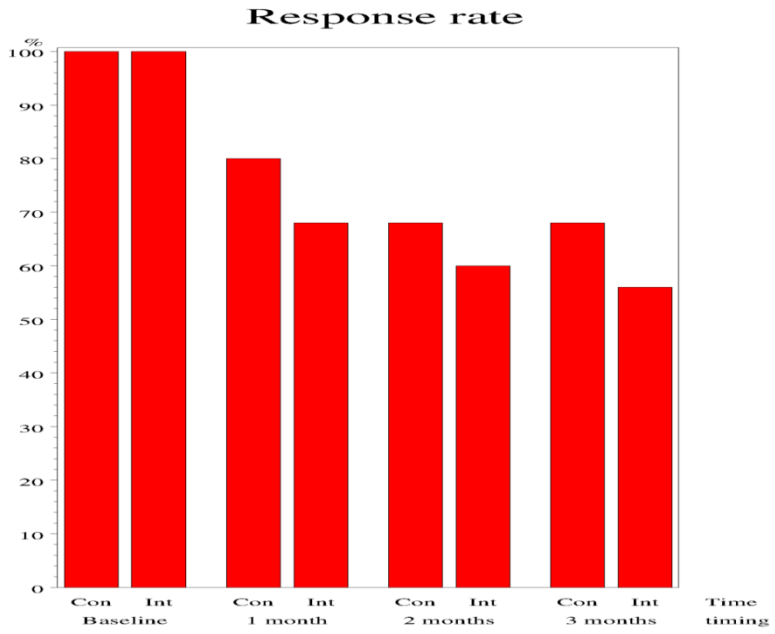

Figure 3.4: Response rate of the pilot PAINT study

3.5.1.2 Participant profile

The following Table 3.3 shows the demographic profile and baseline smoking habits of the study participants. There appeared to be a difference in level of education between groups, with a greater proportion of the intervention group having at least post-secondary school education. There also appeared to be a small (but not statistically significant) gender imbalance between groups, with a higher proportion of female participants in the intervention group (76% vs. 56%, p=0.14).

Table 3.3: Demographic and baseline smoking profile of study participants.

The p-values compare the responses of the two groups (based on the Chi-square test unless otherwise specified).

Variable	Control n (%)	Intervention n (%)	p-value
Gender			0.14
Male	11 (44)	6 (24)	
Female	14 (56)	19 (76)	
Age (Mean, SD)	24.3 (3.6)	24.0 (3.1)	0.80§
Education:†			0.0120*
Year 10 (school) or less	8 (32)	5 (20)	
Year 12	6 (24)	1 (4)	
TAFE/technical qualification	4 (16)	15 (60)	
Degree from university or college	5 (20)	4 (16)	
Cigarettes per day (last 30 days)			0.48*
1	1 (4)	5 (20)	
2–5	5 (20)	3 (12)	
6–10	6 (24)	7 (28)	
11–20	10 (40)	8 (32)	
21+	3 (12)	2 (8)	
Fagerström score (Mean, SD)	3.3 (2.8)	2.9 (2.4)	0.55§
Fagerström score			0.50*
0–2	11 (44)	11 (44)	
3–4	6 (24)	6 (24)	
5	1 (4)	4 (16)	
6–7	5 (20)	4 (16)	
8–10	2 (8)	0	

* Fisher's Exact test

§t-test (independent samples)

† Response to this variable contained two missing values (p-value is calculated on the basis of observed data only).

3.5.1.3 Quit attempts

Subjects who reported quitting smoking at the three-month follow-up survey were amongst those in the lowest smoking dependence group at baseline. There were no cases of quitting smoking at three months, amongst subjects who obtained a Fagerström dependency score of three or more at baseline. There were 22 participants in the 0–2 Fagerström group at baseline, of whom 17 provided follow-up data at three months. Of these 17 participants, 4/9 (44%) of the control group and 2/8 (25%) of the intervention group had made quit attempts at three months. A Fisher's exact test suggested this difference between groups was not statistically significant (p=0.62).

3.5.1.4 Assessment of nicotine dependence

Table 3.4 shows the pattern of smoking dependence at each follow-up. Note that quitters are excluded from calculation of the mean and median smoking dependence score. Hence these parameters relate only to subjects who are smoking at each time point.

Table 3.4: ACTUAL data (assessment of nicotine dependence)

Dependence	Baseline N (%)	1 Month N (%)	2 Months N (%)	3 Months N (%)
Quitter	0	0	1 (3.1)	6 (19.4)
0–2	22 (44.0)	21 (56.8)	19 (59.4)	15 (48.4)
3–4	12 (24.0)	6 (16.2)	6 (18.8)	6 (19.4)
5	5 (10.0)	4 (10.8)	0 (0.0)	1 (3.2)
6–7	9 (18.0)	5 (13.5)	5 (15.6)	2 (6.5)
8–10	2 (4.0)	1 (2.7)	1 (3.1)	1 (3.2)
Total	50	37	32	31
Median score	3	2	2	2
Mean [SD]	3.1 [2.6]	2.6 [2.4]	2.4 [2.5]	2.4 [(2.4]

Table 3.5: The equivalent ACTUAL data table

(Assessment of nicotine dependence) using the LOCF strategy

Dependence	Baseline N (%)	1 Month N (%)	2 Months N (%)	3 Months N (%)
Quitter	0	0	1 (2.0)	6 (12.0)
0–2	22 (44.0)	25 (50.0)	25 (50.0)	21 (42.0)
3–4	12 (24.0)	10 (20.0)	10 (20.0)	10 (20.0)
5	5 (10.0)	5 (10.0)	4 (8.0)	4 (8.0)
6–7	9 (18.0)	8 (16.0)	9 (18.0)	8 (16.0)
8–10	2 (4.0)	2 (4.0)	1 (2.0)	1 (2.0)
Total	50	50	50	50
Median score	3	2.5	2	3
Mean [SD]	3.1 [2.6]	2.9 [2.6]	2.8 [2.5]	3.0 [2.5]

3.5.1.5 Changes from baseline in Fagerström Score [FS] (continuous measure)

A repeated-measures ANOVA (implemented as a random effects regression model) was used to identify if there were any statistically significant changes from baseline in the Fagerström smoking dependence score. Records where the subject responded that they had quit smoking were excluded from analysis, so the figures in Table 3.6 are based on those subjects who were smoking at the time of each survey.

Comparison of the changes from baseline in FS (treated as a continuous variable) between the control and intervention groups showed that the intervention group tended towards lower dependence than the control group at each time point. While the small numbers meant that there was no significant difference over time in the dependence score for each group, overall there did appear to be a significant difference between control and intervention groups.

The analysis was repeated using the LOCF strategy, and similar results were obtained (Table 3.6). The analysis did not include adjustment for the predominance of more educated participants in the intervention group because it was not feasible to explore all possible associations of the small pilot trial. However, it was decided to include adjustment for gender in the repeated analysis because of the slight trend towards more

females in the intervention group. This analysis (not shown in tabular form) showed that gender did influence the change in FS score (females were less likely to change score). However, the adjusted trends and significance levels associated with the group (control or intervention) were similar to those shown in Table 3.6. Adjustment for gender generally led to the differences being of greater statistical significance. Note that this is to be expected, as inclusion of the statistically significant term for gender essentially reduces the residual standard deviation, making the trend for the group variable clearer (more statistically significant).

Table 3.6 shows the comparison of the changes from baseline in FS for the groups.

Table 3.6: Analysis of Fagerström smoking dependence score over time.

The table shows the raw (unadjusted) mean changes in score from baseline, but the p-values are calculated from a random effects regression model.

Group	Follow-up			p-value† (within group)	p-value‡ (between groups)
	1 month	2 months	3 months		
Control	-0.05	-0.41	-0.54	0.1537	0.0407
Intervention	-0.41	-0.57	-1.00	0.3409	
Control*	-0.04	-0.24	-0.29	0.4284	0.0363
Intervention*	-0.28	-0.42	-0.61	0.4452	

† p-values indicate if there is any significant change in score over time (to three months)

‡ p-values assess the significance of the difference between control and intervention groups (after adjustment for timing)

* indicates that the regression model was based on the LOCF method of estimating missing data

3.5.1.6 Changes from baseline in Fagerström Score [FS] (categorical score classification)

The change from baseline to three months in categorised FS is as given in the following table.

Table 3.7: ACTUAL data (changes from baseline in FS) categorical score classification

Baseline	Score at three months					
	Quit attempt	0-2	3-4	5	6-7	8-10
0–2	6	11	0	0	0	0
3–4	0	4	3	0	0	0
5	0	0	2	0	0	0
6–7	0	0	0	1	2	0
8–10	0	0	1	0	0	1

Table 3.8: The equivalent ACTUAL table (changes from baseline in FS) using the LOCF strategy

Baseline	Score at three months					
	Quit attempt	0-2	3-4	5	6-7	8-10
0–2	6	16	0	0	0	0
3–4	0	5	7	0	0	0
5	0	0	2	3	0	0
6–7	0	0	0	1	8	0
8–10	0	0	1	0	0	1

Note:

1) The six people who categorised themselves as non-smokers at three months ('Quitters') were all originally in the low dependence category (0–2 Fagerström). Nobody with higher dependence quit at three months.
2) No participants moved from a lower to a higher dependence at three months.
3) Of 14 participants who started the study with a moderate dependence

(FS 3+), six stayed in the same category and eight moved to a lower dependence category at three months (ACTUAL data – but a similar pattern for the LOCF data).

3.5.1.7 Moderate dependence group (FS 3+)

In the ACTUAL data, there were 28 participants who commenced the study with a FS of 3+, and 14 of these provided three-month follow-up data.

Table 3.9: ACTUAL data (moderate dependence group (FS3+))

Change in score at 3 months	Control	Intervention
Lower category	3 (38%)	5 (83%)
Same category	5 (62%)	1 (17%)

Of these 14 participants, 3/8 (38%) from the control group and 5/6 (83%) from the intervention group moved to a lower dependence category.

There was a trend in the predicted direction suggesting a difference between groups but a Fisher's exact test suggested it only approached statistical significance (p=.14). There was a similar trend for the LOCF data as shown in Table 3.10.

Table 3.10: The equivalent ACTUAL data table (moderate dependence group (FS3+)) using the LOCF strategy

Change in score at 3 months	Control	Intervention
Lower category	3 (21%)	6 (43%)
Same category	11 (79%)	8 (57%)

3.5.2 PART II: Delivering the intervention within a community pharmacy setting

The research method involved recruiting participants in community pharmacies who were waiting for their pharmacist to dispense their prescription or who were purchasing an OTC product.

The pharmacist-researcher had to be proactive in: the initial approach to potential recruits; to seek the person's attention; to assess their response and to be sensitive to cues that the person made to gauge whether further questions could be asked about their smoking status. When recruiting, it was as an advantage for the pharmacist-researcher to display a badge with their name and academic logo attached, as all potential participants were observed to take note of this detail in determining the credentials of the person recruiting to the study. Good communication skills were also essential in assisting the process.

Out of 83 possible recruits, 50 (60%) people consented to participate in the research with 33 (40%) people declining to be recruited stating reasons such as: "sorry, don't have time"; "don't want to participate"; "can't be bothered". Once participants had been recruited to the research, the three-month follow-up telephone calls also proved challenging. Although all participants readily stated their phone contact details (the overwhelming number of contact details ascribed a mobile phone number rather than a landline number), many were unwilling or unable to take calls. It was often necessary to call at least three times, on different days and at different times, to endeavour to make contact; 32% of participants had their mobiles set to message mode (a way of screening calls?) and did not respond to messages. Additionally, another 8% of mobile phone numbers appeared to be disconnected so no follow-up contact was possible. This amounted to a 38% attrition rate.

3.6 Discussion

3.6.1 PART I: Efficacy of the complex intervention

Only a small number of participants [six] had made quit attempts at three months, suggesting the effect size of the intervention was modest and the pilot study was underpowered to detect a significant effect in quit rates between the intervention and control groups.

All quit attempt participants came from the lowest smoking dependence category (0–2) at baseline. For participants who started out with a greater smoking dependence (FS 3+), there was a trend towards a greater proportion of the intervention group moving to a lower dependence by three months (83% intervention group vs 38% control group, p=0.14). Based on a difference in mean smoking dependency score of 0.7 at six months (extrapolating from the three-month results, and assuming a SD of 1.1), it was estimated that a sample size of 82 would be required to detect a difference of this magnitude with 80% power and Type I error = 0.05 (using the G*Power software). If allowances are made for a 50% attrition rate as observed in the pilot study, the required sample size would be doubled to 164. Therefore, for a subsequent full RCT, it was proposed to recruit 160 participants from eight community pharmacies to increase the power of the study.

The widely differing sex distributions of the intervention and control groups also pointed to a need to employ stratified sampling to ensure equal sex distributions.

3.6.2 PART II: Delivering the intervention within a community pharmacy setting

The pilot trial demonstrated that it was acceptable to the resident pharmacists for a pharmacist-researcher to deliver this intervention on their premises. As the time to deliver this intervention was unknown at the beginning of the pilot study, it was unreasonable to expect the resident pharmacists to deliver the intervention. At the conclusion of the pilot study it was also discovered, that for further research recruitment:

• wearing of a name badge is essential;

• the pharmacist must demonstrate good communication skills and an observant, sensitive attitude;

• obtaining, whenever possible, additional contact details apart from a mobile number for follow-up phone calls (e.g. home or work phone number) was necessary;

• establishing, at the initial interview, the best times for contacting the recruit for any future follow-up call (5).

3.7 Conclusion

The data demonstrated that it was feasible and practical for a pharmacist-researcher to deliver this complex intervention in a community pharmacy. There was a clear trend showing moderately dependent smokers moving to a lower dependence category. It was therefore deemed reasonable to proceed to a fully powered RCT with the following modifications:

- a larger sample size of participants [n=160] and pharmacies [n=8];
- a longer period of follow-up [six months];
- intervention participants to receive a copy of their photo-aged ‘smoker’s face’;
- to validate quit attempts with CO breath tests;
- to conduct an economic analysis of the intervention within pharmacy practice from a health sector perspective and community pharmacy perspective.

3.8 References

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CHAPTER 4: RCT PAINT STUDY

"Delivering a personalised smoking cessation intervention by community pharmacists in Western Australia.
A randomised controlled trial."

SUMMARY

Background

• Building on results of the pilot study, a full RCT was undertaken.

• The definitive study was to deliver a personalised smoking cessation intervention within a community pharmacy setting. The specific aims being to test the efficacy of the intervention and to conduct an economic analysis *(this analysis is discussed in the next chapter).*

Methods

• The RCT study recruited 160 participants from eight community pharmacies (80 control group: 80 intervention group).

• All participants received the same smoking cessation advice; the intervention group also received the photo-ageing intervention and their own photo to keep.

• Three follow-up surveys were undertaken via telephone at one, three and six months.

• All quit attempts were self-reported initially; then participants were asked to undertake a CO breath test to validate their smoking status.

Results

• There was a 24% attrition rate at the final six-month follow-up.

• Twenty-two (27.5%) participants self-reported a quit attempt when they were offered the photo-ageing intervention with smoking health information counselling rather than five (6.3%) participants who self-reported a quit attempt when the same counselling was delivered alone.

• Eleven (13.8%) confirmed participants made a quit attempt when they were offered the photo-ageing intervention with smoking cessation health information counselling rather than one (1.3%) confirmed, when the same counselling was delivered alone. This difference in biochemically confirmed quit rates was highly significant (p=0.0027).

Conclusion

• There was a significant difference in change in smoking dependence between groups (p<0.0001) with 11 (14%) participants of the control group moving to a lower category and 41 (51%) participants of the intervention group doing so.

4.1 Introduction

Building on results of the pilot study, a full RCT was proposed and undertaken (1). The definitive study delivered personalised photo-ageing smoking cessation images to a larger sample size from a greater number of community pharmacies. As in the pilot study, all subjects were given standard smoking cessation advice in the form of a leaflet. Subjects allocated to the control group received no further information, while those in the intervention group were photo-aged. Unlike the pilot study, participants in the intervention group received a paper copy of their photo-aged 'smoker's face'. The image was also attached in an email to the subject, if they provided their email address.

All the participants were followed-up for six months and at the conclusion of the study. Participants claiming to have made a quit attempt were invited to undertake a carbon monoxide (CO) breath test to validate their smoking status.

Customers' perceptions about the value of the intervention and its potential impact on future sales were also recorded. In addition, an economic analysis was undertaken from a health sector and community pharmacy perspective.

4.2 Objectives

The broad aim of the RCT was to deliver a personalised smoking cessation intervention within a community pharmacy setting. The specific aims were:

i) to test the efficacy of an intervention based on personalised, vivid illustrations of 'smoker's face' on quit attempts and nicotine dependence among young smokers (18–30 years old);

[These results are reported in this chapter]

ii) to conduct an economic analysis of the intervention within pharmacy practice from health sector and community pharmacy perspectives.

[These results are reported in Chapter 5]

4.3 Outcomes Measured

Part One: Efficacy of the intervention:

The primary outcome for the trial was 'quit attempts'. This was self-reported at each follow-up survey. At the end of the study, a smoking status was further confirmed using exhaled carbon monoxide (CO monitor).

The secondary outcome was level of smoking dependence as assessed by the Fagerström smoking dependence scale [Appendix 10].

[These outcomes are reported in this chapter]

Part Two: Cost-effectiveness of the intervention measured:

iii) from a health sector perspective in terms of the incremental cost per additional quitter and per additional lifetime quitter;

iv) the business viability of delivering the intervention in a community pharmacy.

[These outcomes are reported in Chapter 5]

4.4 Methods

Table 4.1: Research method summary for RCT PAINT study

	Part One: Community Pharmacies	Part Two: Participants (customers)
RCT Study Design:		A full RCT.
RCT Setting:	Community pharmacies in Perth, W.A.	.
RCT Study Population:		Smokers aged 18 to 30 years-old.
RCT Sample size:	8 community pharmacies	160 participants: 80 for intervention group 80 for control group
RCT Sample size calculations:	N/A	164 participants based on effect size of pilot study (probability of Type I error = 0.05, prob (type II error) = 0.2, so power=80%)
RCT Sampling strategy:	Geographical distribution.	Random assignment. (Recruited participants of appropriate age were allocated to the control and intervention group on alternate weeks)
Eligibility criteria:	Community pharmacies within a 20km driving radius from Perth CBD. Pharmacist owners had to consent to participate: Pharmacy Information Sheet [Appendix 1] Pharmacy Consent Form [Appendix 2]	• 18 to 30-years-old • smokers • English speaking and able to give informed consent • No beards, moustaches or facial accessories that cannot be removed • contact availability for six months • not using NRT or taking drugs for nicotine dependence Customers had to consent to participate: Participant Information Sheet [Appendix 3] Participant Consent Form [Appendix 4] Customers screened with: BDDQ [Appendix 14]

4.4.1 The intervention

The April® Age Progression Software (version 2.5 Desktop edition) was used. This was an upgraded version of the software used in the pilot feasibility study. The upgrade involved no modifications to the algorithms for photo-ageing. Therefore, the same intervention was delivered in the full RCT as was in the pilot study.

4.4.2 Data collection

4.4.2.1 Participants

Recruitment and data collection was undertaken part-time during the week and on week-ends at different times of the day and occurred from January 2010 to June 2011 [Appendix 15]. Customers who appeared to be in the target age group, were invited to participate in the study when they presented at the pharmacy for any service, including both prescriptions and OTC medications. The invitation to participate was completely impartial. Initially the pharmacist-researcher used their own judgement to scan for the customer's age before asking them if they were a smoker. Once this fact was established (i.e. if they were a smoker), they were then invited to participate in the research. No other selection biases were undertaken.

They were recruited and assigned by the pharmacist-researcher to the different arms of the study on alternate weeks to minimise contamination between intervention and control participants, as 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 recruitment target was 160 participants from eight pharmacies geographically distributed in the Perth metropolitan area, with 10 participants from each of the eight pharmacies to each treatment arm (intervention and control). This stratification by pharmacy was performed in an attempt to avoid any bias.

All participants were asked to complete a demographic profile (known as the ID page) [Appendix 8] and a baseline questionnaire [Appendix 9]. Participants in the control group received standard smoking cessation advice from the researcher pharmacist. This was delivered through a standard tool, the Pharmacy Self Care card on Smoking [Appendix 11]. The Pharmacy Self Care Card was selected because it is a small, concise health promotion card detailing the benefits of quitting smoking. The

information is set out in well-defined paragraphs which could quickly be outlined and discussed with the recruited participant. This procedure from pre-screening to completion of recruitment took approximately five minutes, as per the pilot study.

Participants in the intervention group received the same smoking cessation advice including the Pharmacy Self Care Card as the control group from the pharmacist. All participants were required to undertake the BDDQ (to screen participants for body dysmorphic disorder). This was done to screen out any subjects who may have been distressed by viewing photo-aged images showing disfigurement caused by nicotine. However, no participants warranted exclusion on this criterion. In addition, images were digitally aged, as a smoker and non-smoker, using April® Age Progression Software. Participants were invited to view the age-processed images. They were also asked to complete a WTP questionnaire [Appendix 16] so that a financial and cost-effectiveness analysis of the intervention and the service could be performed [results presented in Chapter 5]. This procedure from pre-screening to completion of post-intervention questionnaires took approximately 10 minutes. No participants became distressed and none expressed an interest in smoking cessation products. Each participant's digitally-aged colour photograph was then sent to their nominated email address within 24 hours of the intervention.

4.4.2.2 Follow-up surveys

Follow-up surveys for the control group [Appendix 12] and intervention group [Appendix 13] were undertaken via telephone at one, three and six-month intervals and took approximately three minutes to complete. The outcomes measured in these surveys were self-reported quit attempts and level of smoking dependence as assessed by the Fagerström smoking dependence scale [Appendix 10].

4.4.2.3 CO bio verification

At the final six-month follow-up, if any participant, either from the control or intervention group, stated they had quit smoking they were invited to undertake a CO breath test to validate their non-smoking status within 48 hours (2, 3). The CO monitor was a Pico+Smokerlyzer® [Appendix 17]. It was a portable and battery

operated monitor, manufactured by Bedfont Scientific Ltd, Kent, England) and it provided a CO level reading in parts per million (ppm).

4.4.3 Data analysis

The demographic and baseline smoking habit profiles of the recruited participants 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 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 baseline, one, three-month and six-month follow-up surveys. Data were analysed using SAS v9.2 software with $p<0.05$ taken to indicate a statistically significant association.

4.5 Results

Between January 2010 and December 2010, 1259 young adult pharmacy customers were screened for eligibility. Subsequently, 160 eligible participants were recruited: 80 to the control group and 80 to the intervention group (Figure 4.1).

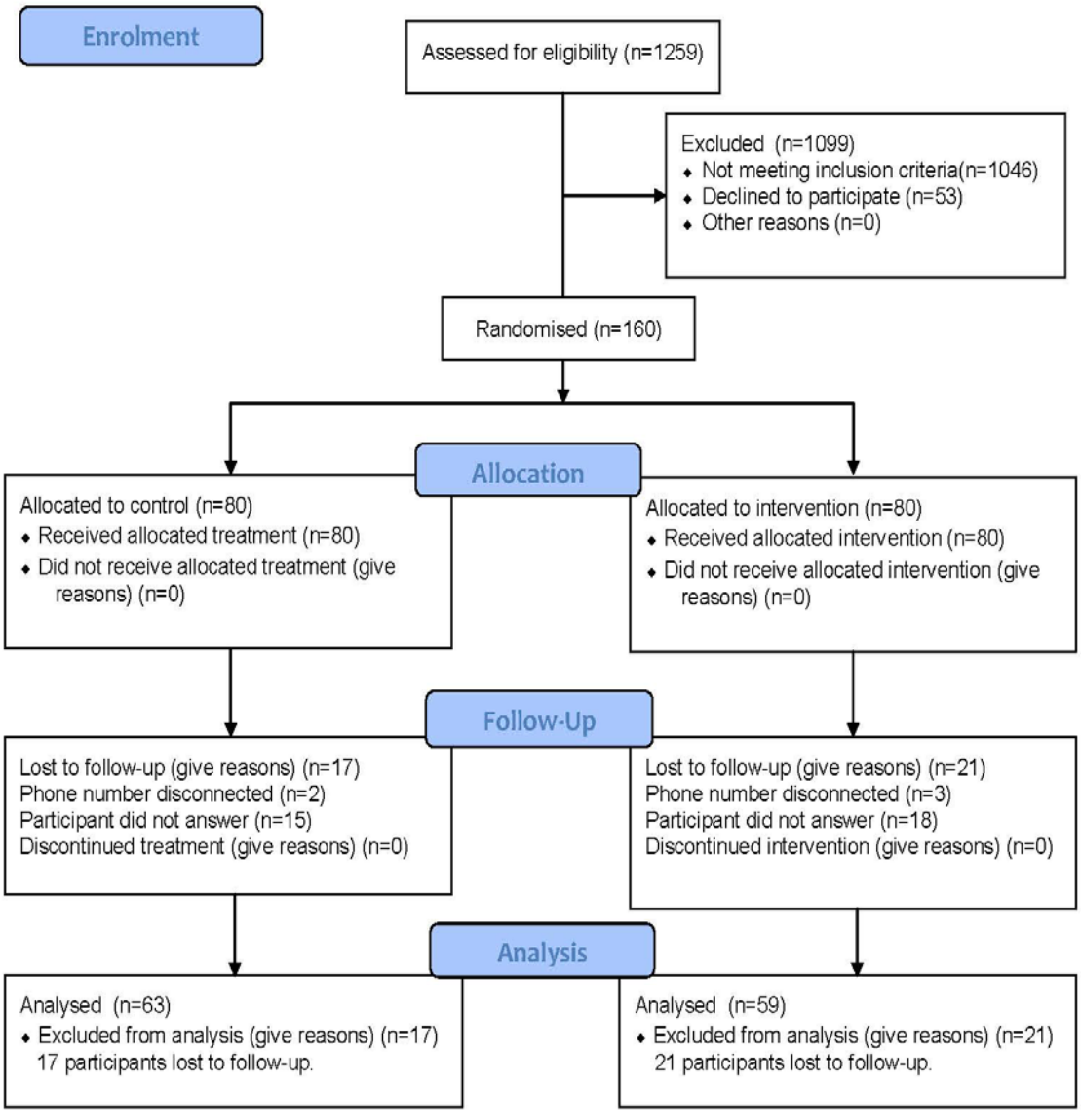

Figure 4.1: Profile of the PAINT RCT study

After recruitment the participants were assessed (baseline) and then followed up at one month, three months and six months. The response rates for each of the follow-up interviews are given below (see Table 4.2 and Figure 4.2) and indicate that the attrition rate was similar for both groups between enrolment and the first follow-up (control group 12% ; intervention group 11%).

Table 4.2: Response rate of the PAINT RCT study

Timing	N (Control group)	N (Intervention group)
Baseline	80 (100%)	80 (100%)
1 Month	70 (88%)	71 (89%)
3 Months	65 (81%)	64 (80%)
6 Months	63 (79%)	59 (74%)

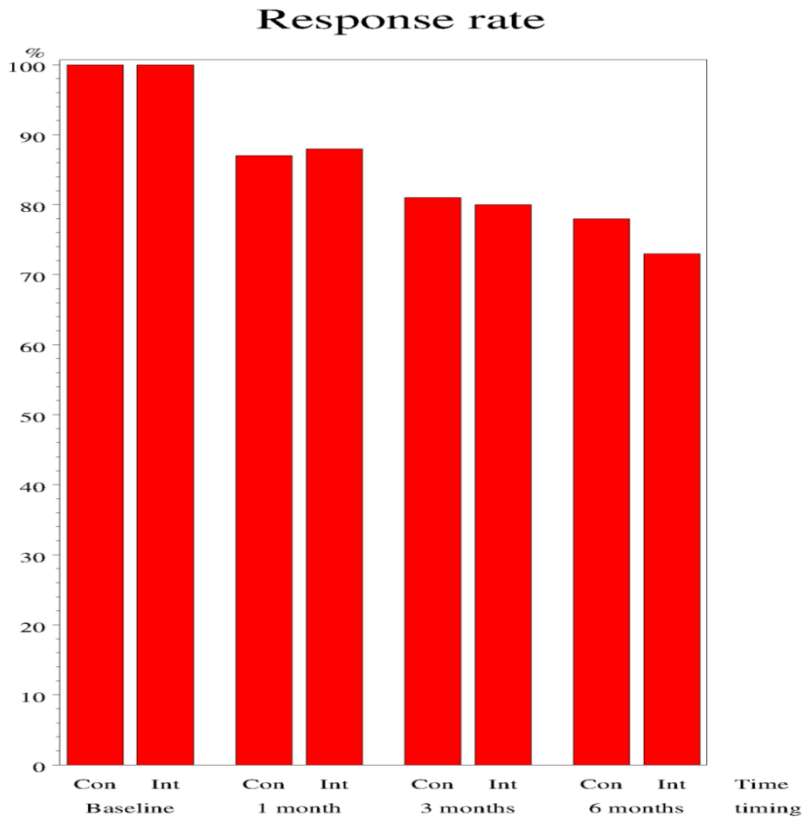

Figure 4.2: Response rate of the PAINT RCT study

4.5.1 Participant profile

The demographic and baseline smoking behaviour of recruited participants are shown and compared between groups (intervention vs. control) in Table 4.3 below. There were no statistical differences between control and intervention groups on the basis of demographic or smoking dependence variables at baseline.

Table 4.3: Demographic and baseline smoking profile of study participants.

Variable	Control group (N=80) n (%)	Intervention group (N=80) n (%)	p-value (χ^2 test)
Male	35 (44%)	25 (31%)	0.1025
Age: mean (SD)	25.1 (4.1)	24.2 (4.1))	0.1588ǂ
Education:			0.7060
Year 10 high school	15 (19%)	17 (21%)	
Year 12 high school	31 (39%)	29 (36%)	
TAFE/ technical qual	17 (22%)	22 (28%)	
Degree (uni/college)	16 (20%)	12 (15%)	
Cigarettes per day (last 30 days)			0.3476
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)	0.8228ǂ
Fagerström dependency score:			0.9232
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%)	

ǂ t-test

The p-value is based on the Chi-square statistic (unless otherwise marked), and compares the treatment groups.

4.5.2 Participants' attitudes towards self, and opinions about smoking

A number of questions in the baseline questionnaire were designed to gather the respondents' opinions of self-perceptions and attitudes towards their smoking behaviour (Table 4.4).

Table 4.4: Participants' attitudes towards self and opinions about smoking

The numbers shown are the number of people who either strongly agree or agree with each statement.

Variable	Control group (N=80) n (%)	Intervention group (N=80) n (%)	p-value
How I look is important to me	68 (85%)	74 (93%)	0.1333
I care about how people think I look	54 (68%)	66 (83%)	0.0285
I like the way my face looks	70 (88%)	68 (86%)	0.7909
Likelihood of smoking in future:			0.8137
Probably/definitely smoking	16 (20%)	15 (19%)	
Undecided	30 (38%)	27 (34%)	
Probably/definitely quit	34 (43%)	38 (48%)	
Opinion: health risk if smoking:			
Less than 1 per day	54 (69%)	44 (56%)	0.0800
1 per day	58 (73%)	58 (73%)	1.0000
2–5 per day	71 (89%)	69 (87%)	0.7843
6–10 per day	77 (97%)	78 (99%)	1.0000^
11–20 per day	77 (97%)	79 (100%)	0.4968^
21+ per day	78 (99%)	80 (100%)	0.4969
Concern for looks influences choices	48 (60%)	57 (71%)	0.1341
Smoking is related to facial wrinkles	68 (85%)	79 (99%)	**0.0015**

^ Fisher's exact test

Data confirmed that the groups were well matched. Groups were compared on Chi-square test or Fisher's exact tests as appropriate. There was no significant difference in the proportion of participants in each group who had made at least one attempt to quit smoking in the past (68% vs. 71%, p=0.73). However, there was a significant difference between the proportions who believed that smoking is related to facial wrinkles (p=0.0015), with the higher proportion in the intervention group.

4.5.3 Pattern of survey completion, and change in smoking behaviour at six months

Table 4.5 shows the pattern of responses to the follow-up calls and the smoking behaviour at the final six-month follow-up call (self-reported and confirmed by biochemical analysis). There was a significant difference in the proportion of participants self-reporting to have successfully quit smoking by the six-month follow-up call. Based on the conservative assumption that all participants who failed to complete the series of follow-up calls continued to smoke, results demonstrated that only five participants (6.3%) of the 80 control participants self-reported to be a non-smoker, compared to 22 (27.5%) of the intervention group. When all these self-reported non-smoking participants from either group were asked to undertake a CO breath test, only one person (1.3%) of the 80 control participants was a confirmed non-smoker, compared to 11 (13.8%) of the intervention group. This difference in biochemically confirmed quit rates was statistically significant (p=0.0027).

Table 4.5: Pattern of survey completion, and change in smoking behaviour at six months

Variable	Control group (N=80) n (%)	Intervention group (N=80) n (%)	p-value
Response to follow-up questionnaires			0.3780
All surveys completed	56 (70%)	48 (60%)	
Some missing data: Last survey:			
6 month			
3 month	6 (8%)	10 (13%)	
1 month	8 (10%)	14 (18%)	
No follow-up	3 (4%)	4 (5%)	
	7 (9%)	4 (5%)	
Quit smoking at 6 months:			
Self report (questionnaire)	5 (6.3%)	22 (27.5%)	**0.0003**
Confirmed (CO)	1 (1.3%)	11 (13.8%)	**0.0027**

4.5.4 Change from baseline to six-month follow-up, in the Fagerström score (grouped into five categories)

The Fagerström score was calculated for each participant at baseline and final six month follow-up. These were then grouped into the five broad dependence level categories, and changes in category were tabulated for each person (Table 4.6). In cases where the final six-month follow-up data was missing, it was presumed that the participant's smoking behaviour was unchanged from the latest follow-up call which they had returned. This strategy, called the "Last Observation Carried Forward" or LOCF strategy, is one method of dealing with missing data (4). There was a significant difference in change in smoking dependence between groups ($p<0.0001$), with 14% of the control group moving to a lower category, and 51% of the intervention group doing so.

Table 4.6: Change from baseline to six-month survey in the Fagerström score

Change	Control (N=80)	Intervention (N=80)	p-value
Lower category	11 (14%)	41 (51%)	**<0.0001**ǂ
No change	68 (85%)	39 (49%)	
Higher category	1 (1%)	0	

ǂ Fisher's exact test

4.5.5 Change from baseline in Fagerström score (using regression models)

A random effects regression model was used to model the change in Fagerström score from baseline, using all the available data from intermediate surveys at one and three months as well as the six-month data (Table 4.7). The model was applied both to the raw data and also to the data with missing scores inferred using the LOCF strategy. The results are very consistent, regardless of whether the missing data were estimated from the LOCF strategy or not. The control group did not experience a significant drop in Fagerström score over the study, while the dependence score of participants in the intervention group dropped by an average of approximately 1.6 points. The drop for the intervention group is statistically significant, and the difference in drops between control and intervention groups is also significant (final column of Table 4.7).

Table 4.7: Analysis of the change from baseline in Fagerström score

Group	Follow-up			p-value† (within group)	p-value‡ (between groups)
	1 month	3 months	6 months		
Control	-0.14	-0.38	-0.26	0.3613	<**0.0001**
Intervention	-0.83	-1.34	-1.88	**0.0023**	
Control*	-0.16	-0.35	-0.30	0.4161	<**0.0001**
Intervention*	-0.75	-1.23	-1.66	**0.0034**	

† p-values indicate if there is any significant change in the score over time (from months 1–6)

‡ p-values assess the significance of the difference between control and intervention groups (after adjusting for timing)

* indicates that the regression model was based on the LOCF method of estimating missing data

Although this was a RCT, and 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 purpose in doing this was to identify if these baseline measures were associated in any way with change in dependence score over the period of the study. For simplicity, 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 of change in score with age ($p=0.14$), sex ($p=0.72$) or baseline consumption ($p=0.49$). However, for the intervention group age ($p<0.0001$) and baseline consumption ($p<0.0001$) were significantly associated with the change in score while sex ($p=0.34$) was not associated. Data indicated that older participants were less likely to reduce their score than younger participants, inferring the intervention may have a greater effect on the younger participants.

Although the intervention was targeted at a relatively narrow age range of people predominantly in their 20s, there still appeared to be an age gradient with the intervention having a larger influence 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 ($p<0.0001$), independently of age. Participants smoking 6–10 cigarettes per day showed a trend towards a lowering in score ($p=0.068$), while light smokers (0–5 cigarettes per day) showed no change in score.

4.6 Discussion

Significantly more participants [11 confirmed = 13.8%] made a quit attempt when they were offered a personalised photo-aged photo with their smoking cessation health information counselling rather than when the same counselling was delivered alone [one confirmed = 1.3%].

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, as demonstrated by their movement to a lower nicotine dependence category [a significant drop demonstrated on the Fagerström scale ($p<0.0001$)].

Although previously Table 4.3 showed that there were no statistically significant differences between groups at baseline, there appeared a trend towards more females, and lighter smokers (smoking up to five cigarettes per day) in the intervention group.

In addition, the intervention group contained a larger proportion of participants responding to the question: "I care about how people think I look" (Table 4.4). A Logistic Regression model was used to identify the association between treatment group (intervention or control) and self-reported quitting, after adjustment for these potentially confounding variables. The p-value associated with the treatment group remained strongly significant after this adjustment (p=0.0026). A similar model, using 'confirmed quitting' as the dependent variable, showed an adjusted p-value for the treatment group of p=0.0285. 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% vs. 71%, p=0.73).

Table 4.7 shows an analysis of the change from baseline in FS. The drops shown in this table are from baseline, not from the previous observation. They represent a fairly linear drop in the FS over time and this could be attributed to the influence of the follow-ups, whereby this ongoing contact with the pharmacist-researcher could have prompted the participant to make a quit attempt. This could be considered to be a potential confounder.

The intervention was particularly effective in younger subjects. A main objective of non-smoking/quit-smoking campaigns in the past has been to stop people from starting to smoke, but this has been difficult. This intervention, appealing to the subject's perception of self-appearance, may have greater impetus to reduce or quit smoking amongst young people, than the health-oriented messages that have been used in the past.

4.7 Conclusion

The data support the primary hypothesis of this study that deploying a smoking cessation intervention illustrating personalised images of unavoidable detrimental effects of smoking in a community pharmacy setting would promote quit attempts or reduce nicotine dependency in young smokers.

4.8 References

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CHAPTER 5: ECONOMIC ANALYSIS OF PAINT RCT

SUMMARY

Background

- To date, health promotion activities that are delivered in community pharmacies do not attract fees.
- Studies that provide economic analyses on the costs and benefits of pharmacy-related professional services and on delivering them in the health system are needed.
- Therefore, an economic analysis of the photo-ageing intervention within pharmacy practice was conducted in the PAINT RCT.

Methods

- Data was collected from all intervention participants by asking them to complete a Willingness To Pay (WTP) questionnaire post intervention.
- Cost-effectiveness of the intervention was measured from a health sector perspective in terms of the incremental cost per additional quitter and per additional lifetime quitter and the business viability of delivering the intervention in a community pharmacy.

Results

- The intervention was highly cost-effective from a health sector perspective, achieving net total cost savings of AUD 1,778 after taking into account cost offsets of AUD 2,144 from a reduction in health care costs of quitters.
- The Incremental Cost-Effectiveness Ratio (ICER) was AUD 46 per additional quitter, or the equivalent of AUD 74 per additional lifetime quitter.
- From a community pharmacy perspective results demonstrated that participants were willing to pay a professional service delivery of AUD 20.25, which exceeded the mean cost per participant for delivering the service (AUD 5.79), therefore suggesting that the photo-ageing intervention would be a viable community pharmacy service even if it was not government funded or subsidised.

Conclusion

- Overall, from an economic point of view, this personalised photo-ageing smoking cessation intervention is relatively inexpensive and cost-effective to deliver.

5.1 Introduction

To date, health promotion activities that are delivered in community pharmacies do not attract fees but there is increasing discussion about the need to change and broaden the traditional role of pharmacy from solely dispensing medications to include the effective delivering of primary and preventative healthcare (1-4).

Studies that provide economic analyses on the costs and benefits of pharmacy-related professional services and on delivering them in the health system are needed and therefore, an economic analysis was conducted as part of the PAINT RCT. Two approaches were adopted for the analysis.

i) In the first approach, the cost-effectiveness of the photo-ageing intervention was evaluated from a health sector perspective. If the intervention was found to be cost-effective from this perspective, then an argument can be put forward that governments should consider the possibility of funding the implementation of the intervention.

ii) In the second approach, the cost-effectiveness of the photo-ageing intervention was evaluated from the perspective of community pharmacy on the assumption that governments do not fund the intervention. In this case, if the intervention was found to be financially viable for community pharmacies to deliver, then community pharmacies should consider providing it as a paid professional service.

5.2 Objective

To conduct an economic analysis of the intervention delivered in the PAINT RCT within pharmacy practice from:

i) a health sector; and
ii) community pharmacy perspective.

5.3 Outcomes measured

Cost-effectiveness of the intervention was measured:

v) from a health sector perspective in terms of the incremental cost per additional quitter and per additional lifetime quitter;

vi) the financial viability of delivering the intervention in a community pharmacy.

5.4 Methods

5.4.1 Data collection

Data collection was conducted by the pharmacist-researcher from January 2010 to December 2010. This involved asking all intervention participants to complete a questionnaire about their "Willingness To Pay" (WTP) for the digital ageing service and related questions [Appendix 16]. This questionnaire took approximately two minutes to complete.

5.4.2 Data analysis

Two perspectives were adopted: a health sector perspective and the perspective of a community pharmacy, the latter 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 (5) and tokens were costed based on market price (6). 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 (7). 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 (8). All costs were expressed in 2011 Australian dollars (AUD). The cost of the tokens was converted from US dollars to Australian dollars based on the average exchange rate in 2011 (9). The number of lifetime quitters was calculated assuming a long-term smoking relapse rate of 37% within 10 years (10). Smoking relapse after 10 years of abstinence has been found to be less than 1% per year (11).

To assess the robustness of the study results, a scenario sensitivity analysis with the 'best-case' and 'worst-case' scenario was performed (12). 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 5.1).

Table 5.1: 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 (9).

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.

5.5 Results

5.5.1 Health sector perspective

Total costs of implementing the intervention from a health sector perspective were AUD 463 or the equivalent of AUD 5.79 per participant (Table 5.2).

Table 5.2: Economic analysis of the 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) - cost per additional lifetime quitter (AUD)	 46 74	 41 64	 71 113
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) ($\overline{x} \pm SD$)	20.25 ± 15.32	-	-
Median willingness to pay for service (AUD) (mdn [IQR])	20.00 [10.00; 20.00]	-	-

With an additional 10 quitters 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.

5.5.2 Community pharmacy perspective

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 WTP was AUD 20.00 which was similar to the mean value. Ten respondents thought aspects of the service could be improved with recommendations by providing more information on methods to quit, offering a support program or showing the effects of smoking on major organs. 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.

5.6 Discussion

This analysis of the photo-ageing service suggested that the intervention was highly cost-effective from a health sector perspective, achieving net cost savings after taking into account cost offsets from a reduction in health care costs.

From the perspective of the community pharmacy, participants were willing to pay a professional service delivery fee that exceeded the calculated cost of delivering the intervention and furthermore were willing to promote the intervention to friends. Apart from an initial 'start-up' cost for the pharmacies to purchase a digital camera (maximum retail cost 200 AUD) to take photos of the participants, no other 'start-up'

costs were required. This suggested the photo-ageing service would be financially viable from the perspective of a community pharmacy even if it was not government funded or subsidised.

5.7 Conclusion

The results of the analysis presented in this chapter confirmed the secondary hypothesis of the study set out in Chapter 1, which stated that pharmacists delivering primary health care counselling in a proactive manner, would have no detrimental impact on the financial viability of the business. From an economic point of view, this personalised smoking cessation intervention was found to generate cost savings over a 10-year time frame and so represented a cost-effective intervention for governments to fund. If not government subsidised, the intervention could readily be adopted in community pharmacies as it was a financially viable service. The smoking cessation intervention targets young smokers who are at significant risk of adverse effects of smoking if they continue lifelong smoking.

5.8 References

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CHAPTER 6: GENERAL DISCUSSION

SUMMARY

Principal findings of the PAINT RCT:

• **Hypothesis 1 was confirmed** – that presenting a smoking cessation intervention based on personalised images of the detrimental effects of smoking could promote quit attempts or reduce nicotine dependency in young smokers in a community pharmacy setting.

• **Hypothesis 2 was confirmed** – that this type of intervention is cost-effective from a health sector perspective and financially viable to community pharmacies.

Models and theories relevant to the PAINT project:

• **The Normalisation Process Model (NPM)** is a recognised conceptual tool which identifies factors aiding or inhibiting the implementation of a complex intervention.

• Applying the NPM to the PAINT project helped identify elements which could be addressed, so that the intervention could be more successfully delivered within the community pharmacy setting.

• The **Stages Of Change (SOC) model** defines the motivational stages that a person can deploy to assist the goal of a 'healthier lifestyle' and is often used in the clinical area of smoking cessation.

• Participants exposed to the photo-ageing intervention in the PAINT RCT had an increase in motivational intension and were observed to 'move' through stages of the Stages of Change (SOC) behavioural model.

• **The Theory of Planned Behaviour (TPB)** has been validated as an appropriate model for smoking intentions as it can highly predict a smokers' intentions to quit based on three components: behavioural belief, normative belief and control belief.

• The PAINT RCT results support the TPB as the photo-ageing intervention increased the perceived risks of smoking to the young adult smoker, decreased the perceived social acceptability of smoking and increased the young smoker's self-belief and ability to make a quit-attempt.

• The human face is the most important 'social object' in the visual domain with **face recognition** being the process by which the human brain understands and interprets the face.

• **Face perception** enables us to assign individual characteristics of gender, age, skin colour and also make an assessment of the person from their facial appearance of their attractiveness, mood, intention, attentiveness and physical fitness.

• Human social interaction is governed by face perception with the three social aspects of face perception being: attraction, recognition and emotion. Physical attractiveness of a person is not only important to the person emotionally but it is also advantageous to be good looking.

• Conversely, facial disfigurement (either congenital or acquired) severely impacts on a person's psyche and ability to socially interact and therefore has long-term psychological and behavioural consequences.

• The importance of the face to the young adult smokers has therefore a firm theoretical basis. The photos were a key element of the intervention.

Study limitations:

• A key limitation of the PAINT RCT was that participants and pharmacist-researcher could not be blinded to the intervention.

• Another limitation was that the data was not analysed blind to the treatment group.

• Follow-up was six months with biochemical verification of smoking status. Follow-up to 12 months may have been preferable, but as the PAINT RCT was unfunded, only a six-month period was feasible. However, it was deemed, that any behaviour changes resulting from the photo-ageing would occur immediately post intervention (i.e. immediately after witnessing their future 'smokers' face'). Therefore, this resulted in the first six months.

• The study recruited participants only under the age of 30 (as this was identified as the primary target group for the intervention to work on; the age progression software has a finite 'ageing range', the maximum being 72 years).

Study strengths:

• The PAINT RCT was a fully powered trial recruiting males and females from the general public with a longer follow-up period of six months with biochemical verification of smoking status.

• The community pharmacies selected to take part in the RCT covered a geographical range around Perth (20km driving radius from Perth CBD) and recruited equal numbers of study participants for each treatment group.

• The PAINT RCT delivered a **personalised** smoking cessation intervention, which elicited an emotional response from the participant while still illustrating the hazards of tobacco smoking.

6.1 Principal Findings of the RCT

6.1.1 Hypothesis 1:

The RCT results confirm the first hypothesis of the PAINT project – that presenting a smoking cessation intervention based on personalised images of the detrimental effects of smoking could promote quit attempts or reduce nicotine dependency in young smokers in a community pharmacy setting.

The difference in confirmed quit attempts in the RCT was highly significant (p=0.003); i.e. more participants made a quit attempt when they were offered a personalised photo-aged photo with their smoking cessation health information counselling rather than when the smoking cessation health information counselling was delivered alone.

The data confirms the previous photo-ageing studies (1–3) that photo-ageing young smokers and showing them their own 'smoker's face' could have an impact on quit attempts.

Also, the participants in the PAINT RCT who did not make a quit attempt but who smoked more than 10 cigarettes per day, were likely to become less dependent on nicotine, as demonstrated by their movement to a lower nicotine dependence category.

This change in smoking dependency is represented in Figure 6.1. It shows the intervention group line descending away from the control group line from the first follow-up survey through to the third follow-up survey, exhibiting a Cohen's D = 0.5 (medium effect size). This movement can be attributed to the photo-ageing intervention.

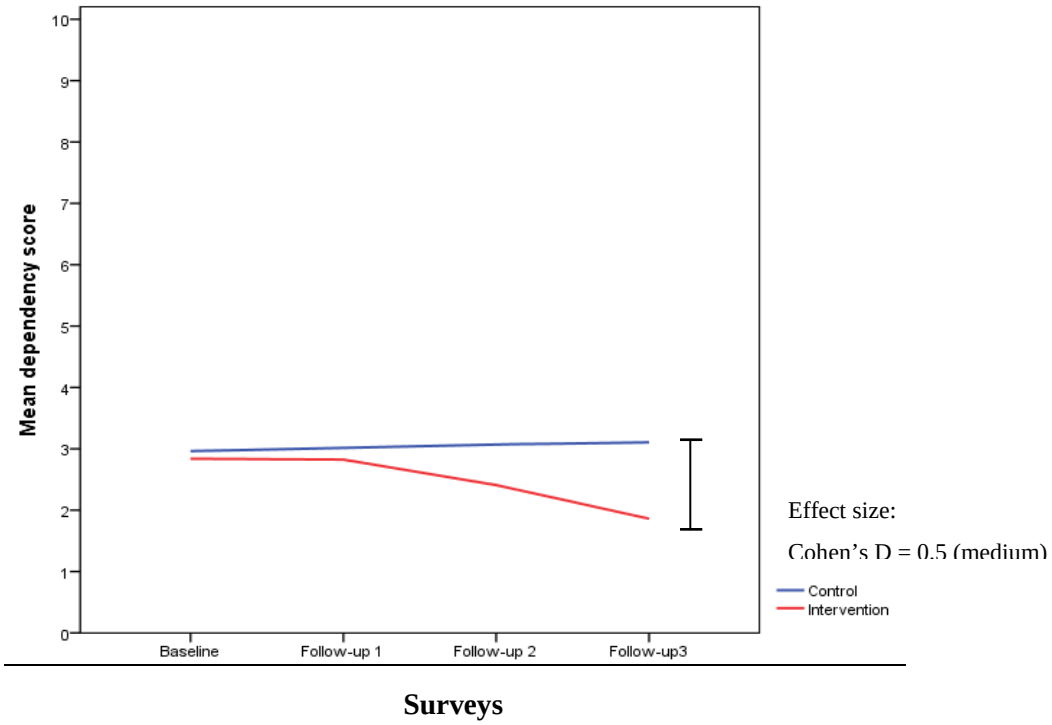

Figure 6.1: Overall mean of the total smoking dependence score

Figure 6.2 demonstrates this same movement to a lower nicotine dependence category of the intervention group over the six-month period (three follow-up surveys) in a bar graph format.

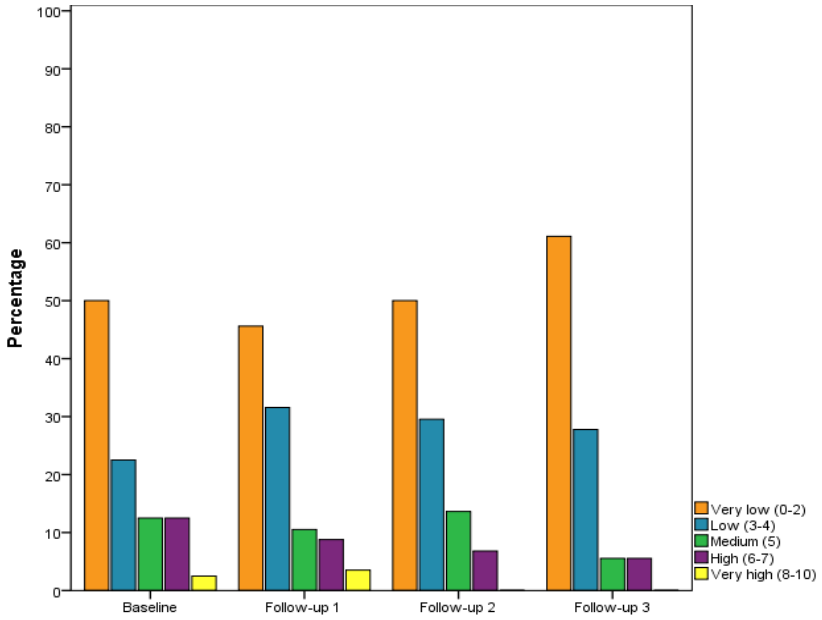

Figure 6.2: Nicotine dependence categories of the intervention group

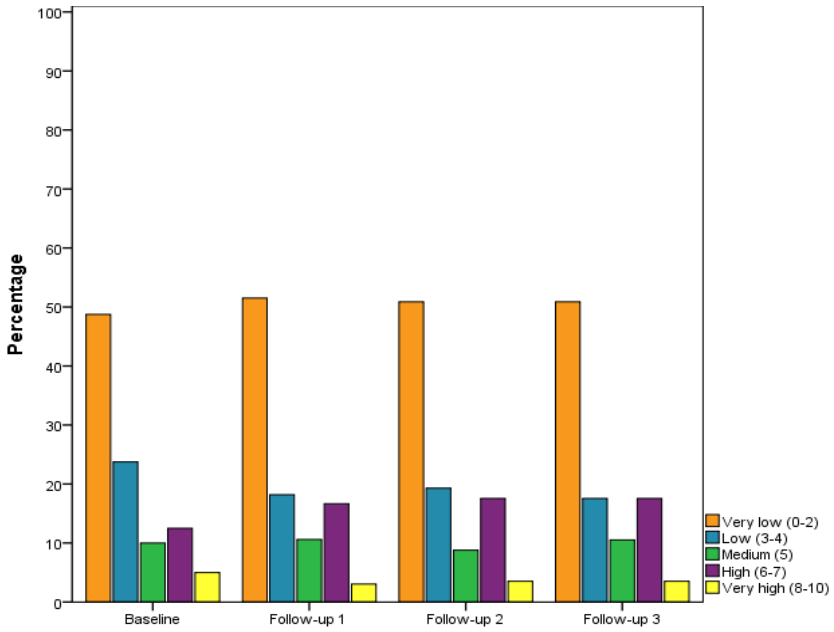

Figure 6.3: Nicotine dependence categories of the control group

The photo-ageing intervention was shown to have a larger influence on younger participants and this may have important implications when targeting anti-smoking messages to a demographic of young smokers; i.e. a personalised photo-ageing intervention is a potent motivating factor compared to a health message alone, because at this age, young people may not be concerned about their health, but appear to be concerned about their:

i) body image – as reported by Diedrichs *et al.* (4) and the results of the 'National survey of young Australians 2008' (5); and

ii) youthful looks – as concluded by Grogan *et al.* (6).

The PAINT RCT Baseline Questionnaire contained two questions on 'looks' from Pat Hysert's original questionnaire [Appendix 18]. The responses to these questions {question 8 and question 9} are graphed in Figure 6.4 and 6.5 respectively. Compared with males, females were generally more concerned about their looks (both to themselves, as well as how others perceived them).

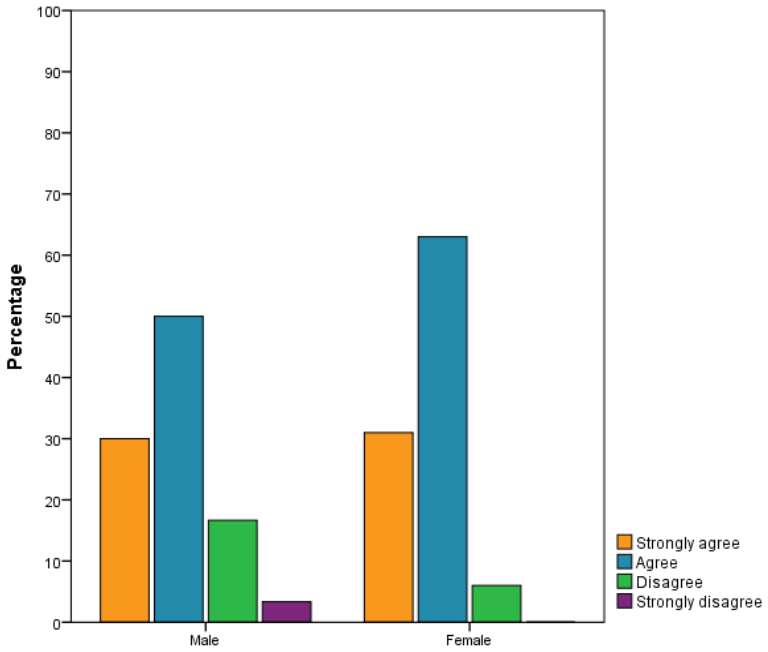

Figure 6.4: Responses to the question of "How I look is important to me" (Qu.8 from BQ)

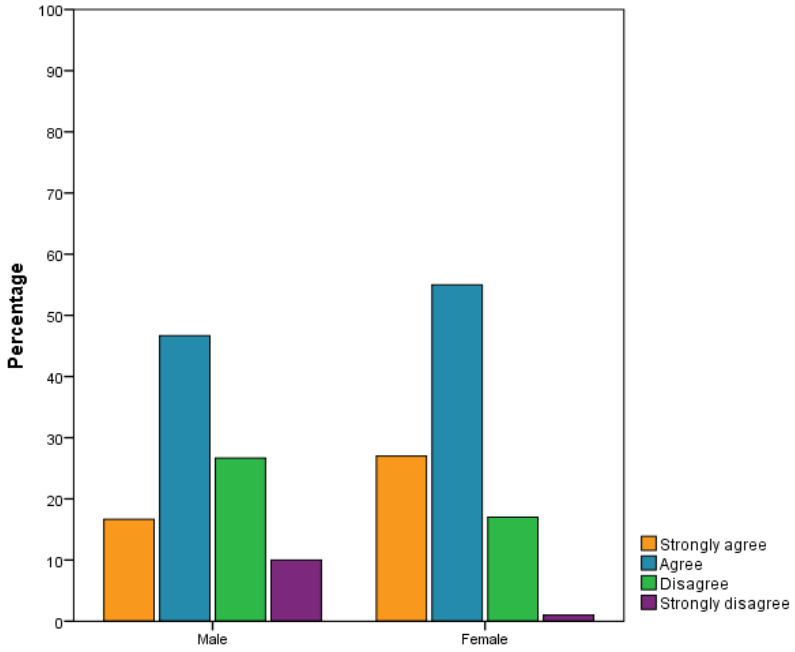

Figure 6.5: Responses to the question "I care about how people think I look" (Qu.9 from BQ)

The results from questions 8 and 9 reflect the findings of Grogan *et al.'s* qualitative study (7) where women stated they were afraid of visible ageing and that seeing their own shocking future face would definitely be a motivating factor for them to quit smoking. This suggests that prevention or smoking cessation programs targeting young female smokers should consider deploying the photo-ageing intervention.

6.1.2 Hypothesis 2:

The results of the economic analysis confirmed the second hypothesis – that this type of an intervention is cost-effective from a health sector perspective and financially viable to community pharmacies.

Table 6.1 compares the cost-effectiveness of the studies previously mentioned in Chapter 2.4 with the PAINT RCT. All figures are presented in Australian 2011 dollars (AUD) enabling the studies to be compared. The conversion to Australian dollars was based on purchasing power parities (8). The indexing of costs to 2011 values was based on AIHW's (Australian Institute of Health and Welfare) price indexes (9).

Table 6.1: Comparison of the cost-effectiveness of smoking cessation interventions delivered through community pharmacies

Study	The Pharmacy Guild of Australia	Crealey *et al.*	Sinclair *et al.*	**PAINT RCT**
Country where research was conducted	Australia	Northern Ireland	Scotland	Australia
Cost per participant	AUD 110.40	AUD 71.85	----	AUD 5.79
Cost per quitter	AUD 1,848.52	----	AUD 749.64	AUD 46.00
Cost per LYG (Life Year Gained)	----	Men: AUD 473.93 – 846.97 Women: AUD 437.24 – 2,759.52	AUD 208.23	AUD 74.00

When compared to the other pharmacy smoking cessation intervention studies, the cost of AUD 5.79 per participant of delivering the PAINT intervention demonstrates the personalised photo-ageing intervention to be relatively low cost if adopted in community pharmacies, more so than the personalised pharmacy smoking cessation intervention reported at AUD 110.40 cost per participant in the study by the Pharmacy Guild Of Australia and AUD 71.85 per participant for the PAS intervention reported by Crealey *et al.*

The PAINT results in Table 6.1 also have important implications for policymakers. With a cost per quitter of AUD 46.00 , the intervention is very cost-effective compared with the other two reported individualised smoking cessation programs, namely those implemented by the Pharmacy Guild of Australia (cost per quitter of AUD 1848.52) and Sinclair *et al.* (cost per quitter of AUD 749.64). Furthermore, if account is taken of cost offsets from a reduction in health care costs as a result of quitting smoking, the PAINT intervention has the potential to generate net total cost savings over the longer term.

Table 6.2 compares the pharmacy WTP studies previously mentioned in Chapter 2.4 with the PAINT RCT results also included. Once again, all figures have been presented in Australian 2011 dollars enabling the studies to be compared.

Table 6.2: Comparison of the willingness to pay for interventions delivered through community pharmacy

Study	Hanna *et al.*	Côté *et al.*	Naik-Panvelkar *et al.*	**PAINT RCT**
Country where research was conducted	Australia	Canada	Australia	
Area of clinical service provided	Diabetes	Hypertension	Asthma	
WTP	For an initial consult: AUD 32.36 (50% improvement) AUD 43.14 (100% ") For a final consult: AUD 21.57 (50% improvement) AUD 32.36 (100% ")	---	AUD 99.98	AUD 20.25

Table 6.2 demonstrates that clients would be willing to pay a mean price of AUD 20.25 for the PAINT service (comprising a photo-aged session plus specialised smoking cessation counselling by a pharmacist). This suggests a realistic service fee and is consistent with previous Australian pharmacy WTP studies, such as the Hanna *et al.* study in which the willingness to pay for the delivery of a diabetes disease state management service was examined (median price of AUD30/AUD40 for a 50%/100% improvement per 30 minute initial consultation; and AUD20/AUD30 for a 50%/100% improvement per 30 minute final consultation) and the Naik-Panvelkar *et al.* study in which the willingness to pay for delivering a specialised asthma service was evaluated

(price of AUD 100 for a private counselling area, lung function testing, pharmacist time, comprehensive advice on asthma and its medications). The mean amount of AUD 20.25 that participants indicated they were willing to pay for the digital ageing service exceeded the mean cost for delivering the service of AUD 5.79, which suggested the intervention would be financially viable for pharmacist to deliver even if not government funded. The other studies did not examine the financially viability by comparing the willingness to pay for services with the cost of delivering the service.

6.1.3 Relevant models and theories

The PAINT project (i.e. both the PAINT pilot study and RCT) aimed to test a complex intervention (photo-ageing) to promote smoking cessation among young adult smokers within a community pharmacy setting. The steps of this project as described clearly reflect the steps of the MRC framework. The theories and models that were relevant to the study and therefore used to assist in the evaluation of the intervention have been critiqued in the discussion section.

6.1.3.1 The Normalisation Process Model (NPM)

It is well known that acquiring new evidence-based knowledge alone about complex interventions is insufficient when translating research into practice (10). Authors Glasziou and Haynes devised a conceptual diagram "The research-to-practice pipeline" which illustrated this fact. The pipeline diagram showed different considerations to ponder, before research is translated into everyday practice (Figure 6.6).

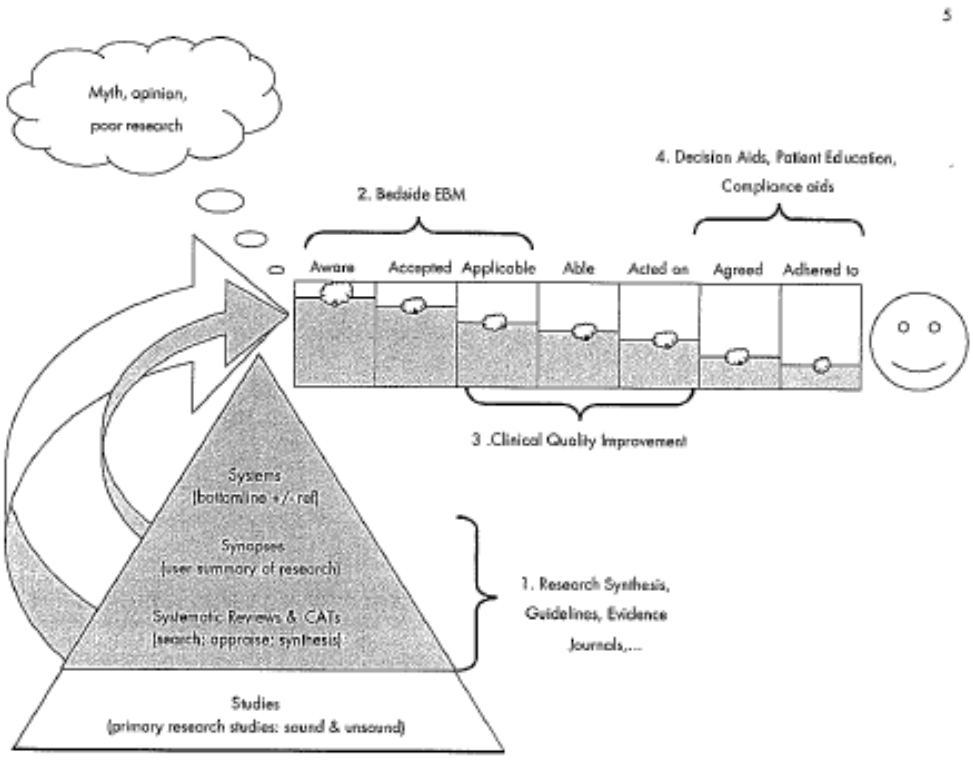

Figure 6.6: The research-to-practice pipeline diagram (10)

Glasziou and Haynes proposed that 'leakage' can occur at any ensuing stage of the pipeline which reduces the chance of the health care intervention being implemented and therefore they recommended reviewing limitations encountered in trials and devising strategies to address these limitations to optimise this transformation process (11).

This pipeline model can be applied to the pharmacy profession and it suggests that pharmacists have to be aware of research evidence; they have to accept the evidence and target the patients to whom it applies. Specifically to the PAINT project, the intervention had to be accessible and acceptable to professionals and to the target population. Finally, the intervention had to be successfully delivered in practice.

Complex interventions are routinely used in healthcare practice. Before they are implemented though, they need to be evaluated to establish if they will work in

everyday practice (12). The Normalisation Process Theory (NPT) is the theoretical framework assisting the evaluation in two ways:

i) it identifies the elements that aid or prevent the adoption of a complex intervention;
ii) an overall assessment can be made as to whether the complex intervention is likely to be successfully incorporated into everyday practice (13).

The NPM is the practical, evaluating tool devised from the NPT which detects these elements (14, 15). The NPM is illustrated in Figure 6.7 and it displays the relationships between the core concepts of the theory. These relationships are non-linear but dynamic and the overall message from the map is that it enables researchers to consider the factors that impact on the delivery of a complex intervention in practice. Therefore the map can be used by researchers to guide them in testing and implementing an intervention into everyday practice (13).

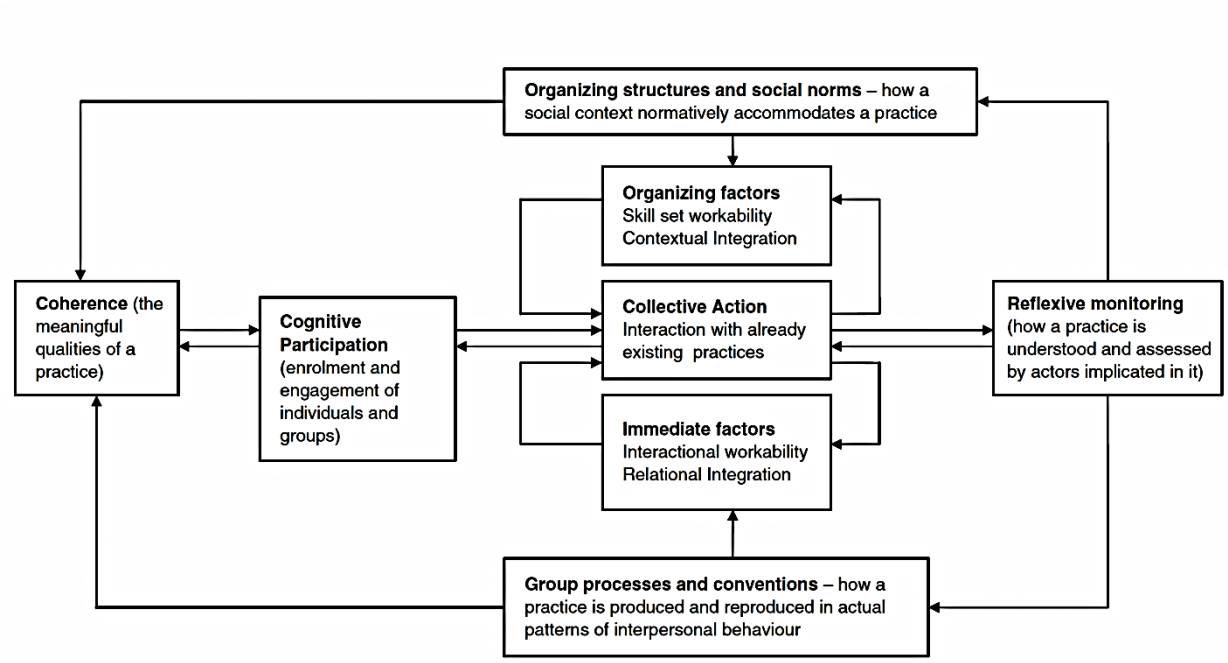

Figure 6.7: The Normalisation Process Model (13)

The PAINT project's main aim was to deliver a complex intervention (smoking cessation photo-ageing pictures) in a healthcare setting (community pharmacy) using the Medical Research Council's (MRC) guide for developing and evaluating such an intervention. As challenges to this process were envisaged, a tool had to be deployed to ensure the project's success. The NPM was the conceptual tool applied to the PAINT project.

The impact of delivering such a new, complex intervention in this setting had to be considered. Using the NPM model, elements (both aiding and preventing intervention delivery) were detected. Issues such as:
- the pharmacist would need new skills (how to use the photo-ageing software);
- the pharmacist would need to inform the staff and agree upon a process whereby the service would have minimal impact on the established routines in the pharmacy;
- the time spent by the pharmacist delivering the intervention would have to be minimal;
- the intervention would have to be delivered at a timely pace to participants who were either waiting for a prescription to be dispensed or entering the pharmacy to purchase an OTC product;
- all staff would have to be able to identify any pharmacy customers of interest who could receive the intervention;
- a suitable space for the set-up of the photo-ageing lap-top; what were the thoughts of all pharmacy staff regarding the intervention;
- what were the thoughts of other pharmacy customers regarding the intervention.

As the answers to certain issues were unknown (e.g. would the service have a minimal impact on the established routines in the pharmacy? What would be the total time spent by the pharmacist delivering the intervention?) it was decided that the intervention in the PAINT project would be delivered by a pharmacist-researcher and not by the resident pharmacists. The decision for a pharmacist-researcher to deliver the intervention was also supported by the fact that the PAINT project was not funded (meaning resident pharmacists would not have been remunerated at this stage for their extra work participating in the PAINT project).

All the elements identified using the NPM were addressed so that ultimately, the complex intervention (namely the photo-ageing intervention) was successfully delivered

within the existing professional practice (namely the community pharmacy) as part of a RCT.

The NPM has also aided the implementation processes of other complex interventions. Lovell *et al.* (16) used the NPM in the modelling phase when developing an intervention of a guided self-help primary care intervention for depression. They examined and evaluated the intervention before testing it in an exploratory RCT. In another study, Elwyn *et al.* (17) used the NPM to identify factors which would promote or inhibit the implementation of Decision Support Technologies (DSTs). DSTs (or decision aids) help patients and professionals in health care settings to make collaborative decisions. The authors concluded that the NPM proved to be a successful guiding framework.

6.1.3.2 The Stages Of Change (SOC)

The "Stages Of Change" (SOC) model was developed by Prochaska and DiClemente and a number of collaborators who sought to explain stages in behaviour change. They developed a model (applying it, expanding its scope, noting its limitations) in an effort to facilitate assessment (18).

The SOC can be aptly used to describe a wide variety of new behaviour change challenges, with smoking cessation being one of the most common clinical areas addressed (19, 20). The five different stages are: Pre-contemplation, Contemplation, Action, Maintenance and Termination (or Relapse) and they can be adapted to the self-change approach of an individual making an attempt to quit smoking (21).

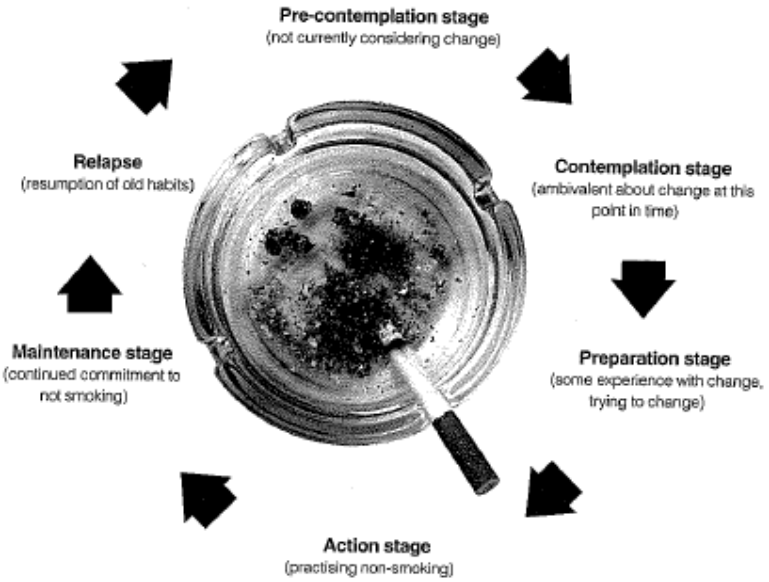

Figure 6.8: The Stages of Change [SOC] model (22)

The stages are represented in Figure 6.8. A smoker may repeat the 'stages of change' cycle a number of times before successfully quitting and evidence suggests that this is an important part of the skill-building process for successful long-term abstinence (22).

The relevance of the SOC model to support adolescents quitting was demonstrated in the PAINT project (both the pilot and RCT). Participants exposed to the photo-ageing intervention in both trials had an increase in motivational intension and were observed to 'move' through to a different stage. For example, the 'action' stage was demonstrated by high nicotine dependent smokers moving down to the moderate nicotine dependency category or by low nicotine dependent smokers making a quit attempt. (The Fagerström Scale [Appendix 10] was used to determine the participant's nicotine dependence category).

The SOC model depicts all the different motivational stages that a person can transcend through to the goal of a 'healthier lifestyle'. The SOC model was used to evaluate the 'intensive pharmaceutical intervention' delivered by pharmacy personnel in the Sinclair *et al.* study (23). Results of this study demonstrated that the intensive pharmaceutical

intervention was far more successful at attaining higher quit rates rather than standard pharmaceutical counselling.

Although the SOC model is widely recognized, accepted and used in the clinical area of smoking cessation, it was not used as a measure in this project. Delivering the photo-ageing intervention did result in participants making a move, from one stage to another, but a more extensive exposé of this model was beyond the scope of this thesis. This model has only been cited here for completeness.

6.1.3.3 The Theory of Planned Behaviour (TPB)

The Theory of Planned Behaviour (TPB) is a psychological theory proposed by Icek Ajzen about the link between attitudes and behaviour; it attempts to describe both the formation of a behavioural intention, and the self-regulatory process involved in translating these intentions into actions (24, 25). It is an extension of the Theory of Reasoned Action (TRA) [Figure 6.9] which proposed that attitude plus subjective norm increases motivation (intention) which in turn increases the chance of behavioural change.

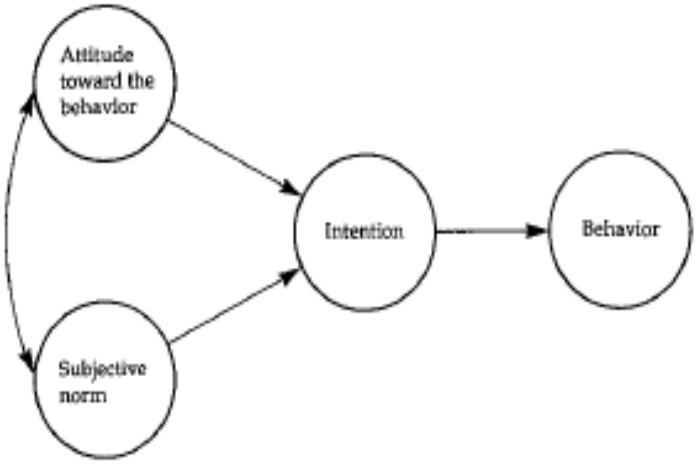

Figure 6.9: Theory of Reasoned Action [TRA] model (24)

Due to the limitations of the original TRA model in dealing with behaviours over which people have incomplete volitional control (i.e. the expectations a person has of success), Ajzen went on to develop the TPB [Figure 6.10] to include measures of control beliefs and perceived behavioural beliefs (26).

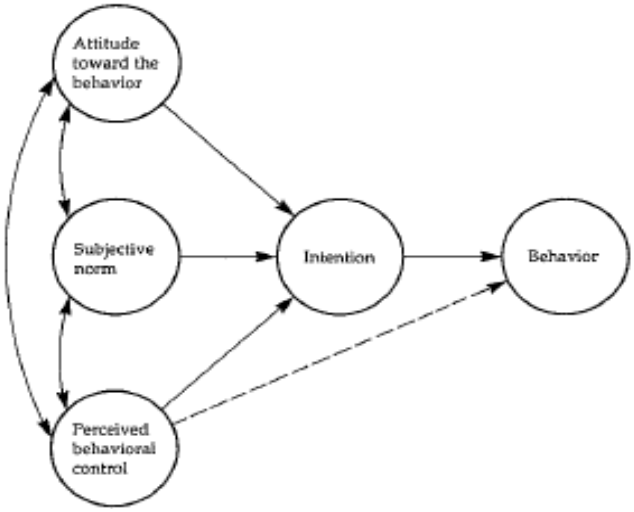

Figure 6.10: Theory of Planned Behaviour [TPB] model (24)

Several studies have validated the TPB as an appropriate model for smoking intentions (27-29) as it can highly predict a smoker's intentions to quit based on the three components:

i) behavioural belief (an individual's beliefs about the consequences of smoking);

ii) normative belief (perceived social expectations); and a

iii) control belief (perceived facilitators and barriers to quitting or continuing to smoke) (30).

Applying the Theory of Planned Behaviour (TPB) to smoking cessation research (i.e. linking attitudes to behaviour), means that smoking cessation messages could work by:

i) increasing the perceived risks of smoking;

ii) decreasing the perceived social acceptability of the behaviour;

iii) increasing the self-belief of a smokers' ability to quit (26).

Support for the TPB for comprehending smoking behaviour has been validated by previous smoking cessation behavioural studies (27-29) and the theory was also supported in the PAINT RCT. Results of the PAINT RCT demonstrated the photo-ageing intervention to increase the perceived risks of smoking to the smoker, as the smokers in the intervention group saw their own future smoker's face with increased facial wrinkling compared to a picture of them as a non-smoker at the same age.

The photo-ageing intervention also had the capability of decreasing the perceived social acceptability of smoking as results showed the intervention group smokers, who having witnessed their own future smoker's face realised that they would not look as beautiful in later life (this being an important issue for today's youth-orientated society).

Finally, the photo-ageing intervention increased the self-belief of a smoker's ability to make a quit attempt. This was clearly demonstrated with the statistically significant quit attempt results in the intervention group as smokers having witnessed their own future smoker's face were motivated into making a quit attempt.

6.1.3.4 Face perception

The human face is the most important 'social object' in the visual domain (31, 32). From an early age, humans can distinguish between different faces with evidence showing that newborns can even recognise their mother's face within the first few days (33). Face recognition is the process by which the human brain understands and interprets the face. Bruce and Young developed a theoretical face recognition model which shows the different components involved in recognising familiar faces and the aspects of face processing (34) [Figure 6.11].

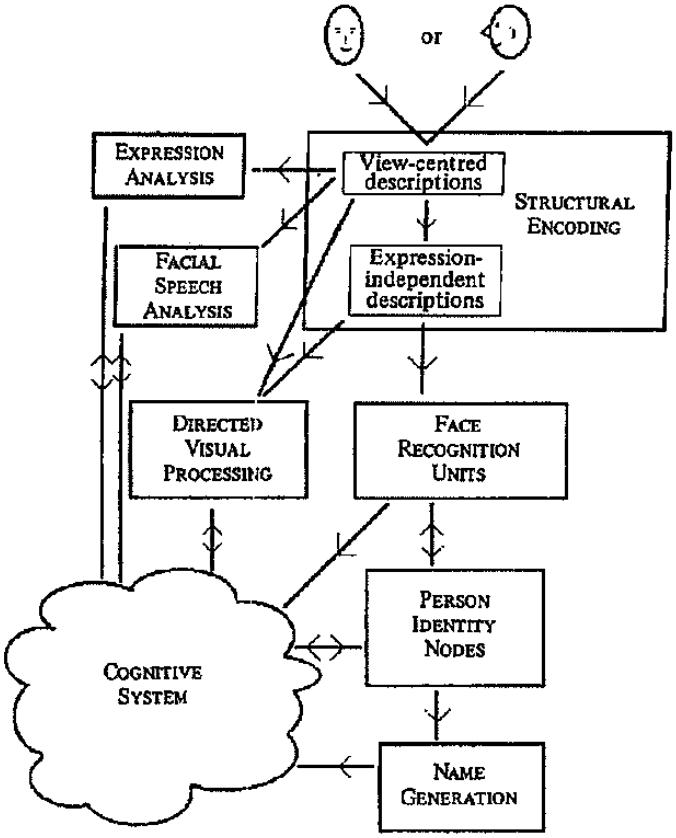

Figure 6.11: The face recognition model (34)

This theory suggests that the face is so distinctive that it is paramount to a person's identity (35). By perceiving a person's face, we can assign individual characteristics such as gender, age, skin colour and also make an assessment from their facial appearance of their attractiveness, mood, intention, attentiveness and physical fitness (32).

Human social interaction is governed by face perception with the three social aspects of face perception being: attraction, recognition and emotion (34). Studies have confirmed

that physical attractiveness or the visual aesthetic appeal of a person is not only important to the person emotionally but it is also advantageous to be good looking (36) as beauty has been associated with career success (37), health (38), wealth, popularity and happiness and therefore these attributes then influence the behaviour of the person (36). Conversely, facial disfigurement (either congenital or acquired) severely impacts on a person's psyche and ability to socially interact and therefore has long-term psychological and behavioural consequences (39, 40). Stress, anxiety, anguish and low self-esteem can be experienced, all of which have a negative impact on the mental health and functioning of the person (39).

The fundamental task of the PAINT project was to demonstrate to young adolescent smokers, photos of their future face: first of all, a photo of their future 'smoker's face' at the age of 55, compared with a photo of their future non-smoker's face at the age of 55. The photo-aged photos in the PAINT RCT resulted in being a very powerful and personal message to the young adolescent smokers who undertook the intervention because it demonstrated the damage to their own face. This supports the literature presented in Chapter 2 regarding the importance of the face in the visual domain (31, 32).

The face is not only a stabilised configuration of features with functions (eyes for looking, nose for smelling, mouths for breathing and ears for hearing) (32, 34) but it is a unique entity of communication capable of creating relationships (32). It is usually the first thing that another perceiver will interact with (35) and so therefore, humans place great emphasis on the aesthetic appeal of their face; some going to great lengths to justify the maintenance of their face (41) and others, even creating a new face for themselves (42).

The importance of the face (i.e. who you are, what you are, how old you are, what you look like and how others perceive you) to the adolescent smokers in the PAINT project was the motive behind them undertaking the challenge of seeing themselves photo-aged. Then, it was after they had witnessed their own photo-aged images, that the complex smoking cessation intervention released its powerful personalised health promotion message upon the adolescent smoker.

6.2 Study limitations

6.2.1 Strengths and weaknesses of the RCT study

The RCT design provides the strongest level of evidence for an interventional study of this type. The PAINT study was therefore designed as an RCT. The pharmacies selected to take part in the study were chosen to cover a geographical area around Perth (20km driving radius from Perth CBD). Apart from the pharmacies covering a wide geographical region, they also represented different types of locations (some pharmacies were located inside a shopping centre and other pharmacies were located in a 'strip' of shops). However, it must be noted that three from the eight recruited pharmacies were said to offer a smoking cessation service (encompassing a CO breath test plus counselling) to customers if requested. Therefore this had the potential for a clustering effect in pharmacies. An equal number of study participants were selected for each treatment group at each pharmacy, aiming to remove any potential biases (recruitment stratified by study site is a common strategy for multi-centre trials).

The invitation to participate in the research was completely impartial. Initially the pharmacist-researcher used their own judgement to scan for the customer's age before asking them if they were a smoker. Once this fact was established (i.e. if they were a smoker) they were then invited to participate in the research. No other selection biases were undertaken.

- **Blinding:**

A key limitation of the study though was that the participants and pharmacist-researcher could not be blinded to the intervention. It was decided that it was not reasonable to recruit participants to the control group when the photo-ageing hardware (camera and computer) were clearly visible. For this reason, the allocation to groups was not performed as eligible participants appeared, but according to the treatment being used at the pharmacy during that week. Another limitation was that the data could not be analysed blind to the treatment group.

- **Sample:**

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 it was decided to follow-up to six months with biochemical verification of tobacco use and cessation (43). 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 smoking status.

- **Follow-up:**

It was disappointing that so few participants in the control group agreed to CO verification. The possible reasons for this being that they continued to smoke or they were not as engaged in the project as the intervention group and were therefore less amenable to follow-up. This suggests further evidence that the photo-aged photos had a powerful emotional response in the intervention group.

Nevertheless the self-reported smoking status data was interesting and although quite likely to be prone to socially desirable responses (i.e. the ongoing follow-up contact with the pharmacist-researcher could have prompted the participants to make a quit attempt), the effect size was still substantial and on a par with other intervention trials.

- **Intervention:**

The study recruited participants only under the age of 30, as this was identified as the primary target group for the intervention to work on (because the software has a finite 'ageing range' and only 'age-progresses' to a maximum of 72 years). Intervention group participants seemed more likely to be affected by appeals to personal appearance than control group participants. Given that a sample size with 80% power and a type 1 error probability of 5% was achieved, it is reasonable to suppose that the smoking cessation achieved, could be attributed to the intervention.

While there appeared a trend towards more females and light smokers in the intervention group, this appeared not to detract from the very significant association between treatment group and quitting smoking (from the logistic regression analysis).

- **Interventionist:**

The PAINT project required a pharmacist to deliver the photo-ageing intervention, but as the time taken to deliver the intervention was unknown, it was decided that the intervention would be delivered by a pharmacist-researcher so as to minimise the impact on the established routines in the pharmacy. Another factor supporting this decision

was the fact that the PAINT project was unfunded, meaning that the resident pharmacists would not have been remunerated for their extra work participating in the PAINT project.

6.2.2 Strengths and weaknesses of the RCT study in relation to other studies

Many successful individualised smoking cessation interventions have been implemented in the last few decades including:

- brief counselling delivered by health professionals (doctors, pharmacists, nurses and social workers) including one-to-one consultations to group support behaviour therapy (44–46) with support from services such as Quit-lines (47, 48). With the advent of digital technology, quit messages can now be delivered by mobile telephone, email, text messaging and online social networks (48).
- pharmacotherapy including NRT (Nicotine Replacement Therapy) products such as nicotine patches, nicotine gum, nasal sprays and oral doses, bupropion and varenicline (44-46, 48).

However, even though these are individualised interventions they do not contain any element which could elicit an emotional response such as photo-ageing while still illustrating the hazards of tobacco smoking.

To date, there have only been a few personalised photo-ageing studies conducted (3, 7, 49), but all these studies have only recruited females, and only one of these studies was a RCT conducted in the UK which recruited its 70 participants from a sample of women smokers which had been referred to the “Quit for a New Life” free Stop Smoking Service (3).

In comparison to these previously conducted photo-ageing studies, the PAINT study was an appropriately powered trial which recruited males and females from the general public with a longer follow-up period of six months with biochemical verification of smoking status.

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CHAPTER 7: CONCLUSIONS & RECOMMENDATIONS

7.1 Conclusions

The PAINT project explored the feasibility of a pharmacist delivering a complex photo-ageing smoking cessation intervention to young adult smokers who entered the pharmacy and it was guided by the MRC's framework for design and evaluation of complex interventions to improve health.

The PAINT RCT was an appropriately powered trial, containing a sample (N=160) of males and females from the general public with a follow-up period of six months including biochemical verification of smoking status.

It explored the effect of the intervention and data demonstrated a significant increase in the number of smokers who made a quit attempt and also, a significant result in participants decreasing their nicotine dependence.

These findings indicated that the photo-ageing intervention was effective in motivating and promoting smoking cessation in young adult smokers which suggests that it might be a promising smoking cessation approach for young adult smokers.

The PAINT project also confirmed that the photo-ageing intervention was highly cost-effective from a health sector perspective and financially viable from the perspective of a community pharmacy even if it was not government funded or subsidised.

It was delivered by a pharmacist, a highly-trained health care professional who, over the years, has established a role in practising ***'reactive healthcare counselling'*** by delivering smoking cessation pharmacotherapies and other forms of cessation assistance from the community pharmacy setting.

The PAINT project demonstrated that it was feasible and practical for a pharmacist to successfully deliver the photo-ageing smoking cessation intervention in a ***'proactive healthcare counselling'*** manner therefore supporting the pharmacist's role as a health promotion agent [Figure 7.1].

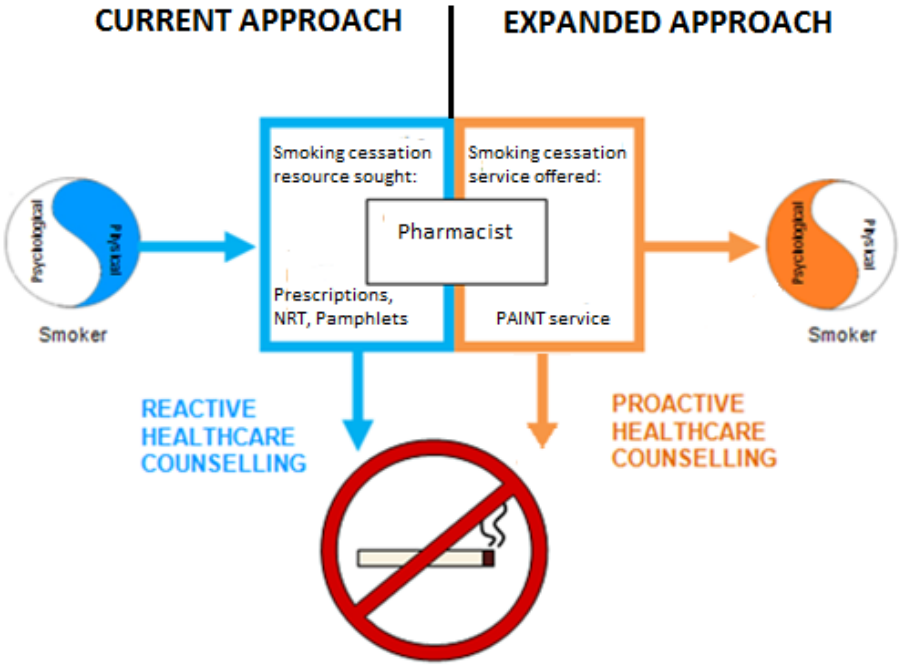

Figure 7.1: Current and expanded approach of health care counselling by a community pharmacist

The left side of Figure 7.1 shows a pharmacist delivering the current approach, **reactive health care counselling** to smokers who enter the pharmacy to purchase Nicotine Replacement Therapy (NRT) or to have a bupropion (Zyban®) or varenicline (Champix®) prescription dispensed.

The right side of Figure 7.1 shows the expanded approach, **proactive health care counselling** being delivered by the pharmacist. When applicable, pharmacists can appeal to the 'psychological side' (i.e. the vanity side) of young adult smokers who present at the pharmacy, by offering them the PAINT service. This is a combination of standard smoking cessation advice and photo-aged photo. This service offers an additional smoking cessation intervention.

As well as exploring the effect of the intervention, an economic analysis of the intervention was conducted from a health sector and community pharmacy perspective. Overall, results suggested the intervention to be highly cost-effective from both perspectives. It achieved net total cost savings of AUD 1,778 from a health sector perspective, after taking into account cost offsets of AUD 2,144 from a reduction in healthcare costs of quitters. The ICER was AUD 46 per additional quitter, or the equivalent of AUD 74 per additional lifetime quitter.

It was also calculated to be a 'viable' service from the perspective of a community pharmacy, as participants stated they would be WTP a professional service delivery of AUD 20.25, which exceeded the mean cost per participant for delivering the service (AUD 5.79). The implications for pharmacies to implement this service would involve:

- training the pharmacist to deliver this personalised smoking cessation package (combining standard smoking cessation counselling plus photo-aged photos of the smoker as a future smoker and non-smoker);
- purchase of a standard digital camera and online 'tokens' of the progression software;
- advertising the photo-ageing smoking cessation service;
- locating a suitable space in the pharmacy (first to take a photo of the client and secondly, to counsel them);
- deciding what fee to charge for the service;
- deciding what target group – e.g. any client? women smokers? > 18 years only?
- deciding if there would be a follow-up;
- offering smoking cessation treatments (eg. NRT) in conjunction with the photo-ageing service.

At the outset, it was decided that it was not practical or possible for the resident pharmacist to deliver the intervention in the PAINT RCT because the time taken to deliver the intervention was an unknown. At the conclusion of the RCT it was evident from the calculations that on average, it took 10 minutes to photo-age and counsel a client, which suggests that it could be feasible for resident pharmacists to invest this time in delivering the PAINT service to young adult smokers, especially if they were to charge a professional health service fee.

7.2 Recommendations for future research

1.) The PAINT project trialled a proactive health care format with an associated economic analysis which concluded that pharmacy clients would be WTP (median cost AUD 20) for a professional smoking cessation service delivered by a pharmacist (consisting of photo-aged photos accompanied with smoking cessation advice).

Therefore, the first recommendation is:

R1: Introduce the PAINT service as a paid professional service in certain community pharmacies specialising in smoking cessation in Western Australia (WA). Trained pharmacists could deliver the PAINT service opportunistically to young adult smokers.

2.) The PAINT project has implications for government and policy makers as it could be feasible to deliver the photo-ageing smoking cessation service in government hospitals. For example, asthma educators on respiratory wards could combine their health care counselling by also offering the photo-ageing service in an effort to motivate young adolescent smoking asthmatics to quit.

Therefore, the second recommendation is:

R2: The PAINT service should be implemented in WA hospitals or primary care facilities especially in relevant health services (e.g. asthma clinics).

3.) Technology has been a significant development in the delivery of anti-smoking messages and examples such as the Internet, social networking sites and smart phones, have the potential to reach huge populations at a mass and individual level, particularly younger people.

Technological interventions have particular appeal to teenagers and young adults, as they have been exposed to computer technology to a greater extent than older people. The PAINT project explored delivering an individualised technological intervention to promote smoking cessation to young adults between the ages of 18–30 years of age and the RCT results demonstrated that overall, the intervention had a larger influence on the younger participants.

Therefore, the third recommendation is:

R3: Smoking cessation photo-ageing research should be conducted to include the younger demographic group of 13–17 years of age.

4.) With the increasing use of technology in health promotion, could a similar personalised photographic intervention be developed and used to target other health-related problems such as obesity and excessive sun exposure, both being significant health issues in Australia?

Therefore, the fourth recommendation is:

R4: Photo-ageing research should be conducted in other health-related areas such as obesity and excessive sun-exposure.

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APPENDICES

Appendix 1: Pharmacy Information Sheet

School of Pharmacy

Community Pharmacy
PAINT (Photo-Ageing INTervention) Project

PHARMACY INFORMATION SHEET

Doctor of Philosophy candidate researcher: Ms Oksana Burford (Pharmacist)
Supervisor: Professor Moyez Jiwa

This study is being carried out by Curtin University researchers from the School of Pharmacy and is a research study about smoking in young adults called "Photo-Ageing Intervention for smoking cessation in Community Pharmacy". The PhD candidate will conduct the entire research study within your pharmacy.

BACKGROUND:
Smoking is a worldwide problem and despite declining rates of daily smoking, tobacco still contributes significantly to Australia's disease burden. Smoking changes a person's facial appearance as they age and they develop a typical "smoker's face". Community pharmacists are ideally placed to deliver smoking cessation interventions aimed at improving the health of their clients.

Also, despite ample research surrounding tobacco there seems to be a lack of research about smoking cessation in young people. For this reason we are targeting young adults, age 18 to 30 years old, to test a smoking cessation intervention in a community pharmacy setting. As this is a randomised control trial, half the participants will receive standard smoking cessation advice lasting approximately 2 minutes (Cessation advice type 1) and the other half will receive the same standard smoking cessation advice plus have a photo taken of them and then the photo will be aged using modern computing techniques to show them their "smoker's face". This will take approximately 6 minutes (Cessation advice Type 2).

WE WILL BE RECRUITING PHARMACY CLIENTS / CUSTOMERS IF:
- they are 18 to 30 years old
- they smoke
- they speak English and are able to give informed consent
- they don't have a beard, moustache or facial accessories that can't be removed
- they are available for contact for the next 12 months, to receive 4 follow-up phone calls.

RISKS / DISCOMFORTS OF THIS RESEARCH:
There are no known risks associated with your client's participation, though some clients may be surprised when they see their 'aged progressed' images. If they experience any distress they will be counselled by the researcher (pharmacist) straight away.

CONFIDENTIALITY:
The information that you and your clients provide will be kept separate from all personal details, and only the PhD candidate researcher and Supervisor will have access to this. If the results of the study are published, identities will not be disclosed in any way. Information will be collected using questionnaires and follow-up telephone calls. All information collected will be secured in a locked filing cabinet at Curtin University of Technology for a minimum of five years and anything on a computer will be protected and virus protection software. Following this time period the information will be destroyed, and treated as confidential waste. Names and addresses will be stored separately and will only be used for further contact of information. You, the pharmacy staff and pharmacy clients will not be identifiable in any articles, reports or letters written in connection with this study.

CONSENT TO PARTICIPATE:
Your involvement in the research is entirely voluntary. You have the right to withdraw at any stage without it affecting your rights or the researcher's responsibilities. When you have signed the consent form we will assume that you have agreed to participate and allow your data to be used in this research study.

FURTHER INFORMATION:
This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 01/2008). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266-2784 or by emailing hrec@curtin.edu.au

If you would like further information about the study, please feel free to contact the Supervisor Professor Moyez Jiwa by email: M.Jiwa@curtin.edu.au

THANKYOU VERY MUCH FOR YOUR INVOLVEMENT IN THIS RESEARCH. YOUR PARTICIPATION IS GREATLY APPRECIATED.

Appendix 2: Pharmacy Consent Form

School of Pharmacy

PHARMACY CONSENT FORM

Community Pharmacy PAINT Project

Doctor of Philosophy candidate researcher: Ms Oksana Burford

Supervisor: Professor Moyez Jiwa

- I understand the purpose and procedures of the study.
- I have been provided with the pharmacy information sheet, and I have had the opportunity to ask questions.
- I understand that involvement in this study is voluntary and I can withdraw the pharmacy at any time without problem.
- I understand that no personal information like names and addresses will be identifiable in any articles, reports or letters written in connection with this study and that all information will be securely stored for 5 years before being destroyed.
- I agree to the pharmacy participating in the study outlined to me.

Name of Pharmacist	Signature of Pharmacist	Date

Name of PhD candidate researcher	Signature of Researcher	Date

Appendix 3: Participant Information Sheet

School of Pharmacy

Community Pharmacy
PAINT (Photo-Ageing INTervention) Project

PARTICIPANT INFORMATION SHEET

We are inviting you to participate in a research study about smoking in young adults called "Photo-Ageing Intervention for smoking cessation in Community Pharmacy".

This study is being carried out by Oksana Burford, PhD candidate from the School of Pharmacy.

BACKGROUND:
In this research project we are testing a variety of ways of helping people to stop smoking. It has not been proved whether any particular way of advising people about the dangers of cigarette smoking is better than any other. In this project you will be offered one of two different smoking cessation packages.

YOU ARE ELIGIBLE TO PARTICIPATE IF:
- you are 18 to 30 years old
- you are a smoker
- you speak English and are able to give informed consent
- you don't have a beard, moustache or facial accessories that can't be removed
- you will be available for contact for the next 12 months, to receive 4 follow-up phone calls.

RISKS / DISCOMFORTS OF THIS RESEARCH:
There are no known risks associated with your participation, though some participants may be concerned about the consequences of smoking as relayed to them in the session. If you experience any distress please indicate this to the pharmacist straight away.

CONFIDENTIALITY:
The information you provide will be kept separate from your personal details, and only the Researcher and Supervisor will have access to this. If the results of the study are published, your identity will not be disclosed in any way. Information will be collected

using questionnaires and telephone interviews. This information will be grouped to protect your privacy and identity. All information collected will be secured in a locked filing cabinet at Curtin University of Technology for a minimum of five years and anything on a computer will be protected and virus protection software. Following this time period the information will be destroyed, and treated as confidential waste. Your name and address will be stored separately and will only be used to contact you for further information or feedback. You will not be identifiable in any articles, reports or letters written in connection with this study.

CONSENT TO PARTICIPATE:
Your involvement in the research is entirely voluntary. You have the right to withdraw at any stage without it affecting your rights or my responsibilities. When you have signed the consent form we will assume that you have agreed to participate and allow your data to be used in this research study.

FURTHER INFORMATION:
This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 01/2008). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au

If you would like further information about the study, please feel free to contact the Supervisor, Professor Moyez Jiwa by email: M.Jiwa@curtin.edu.au

THANK YOU VERY MUCH FOR YOUR INVOLVEMENT IN THIS RESEARCH.
YOUR PARTICIPATION IS GREATLY APPRECIATED.

Appendix 4: Participant Consent Form

School of Pharmacy

PARTICIPANT CONSENT FORM

Community Pharmacy PAINT Project

Doctor of Philosophy candidate researcher: Oksana Burford

Supervisor: Professor Moyez Jiwa

- I understand the purpose and procedures of the study.
- I have been provided with the participant information sheet, and have had the opportunity to ask questions.
- I understand that the procedure itself may not benefit me.
- I understand that my involvement is voluntary and I can withdraw at any time without problem.
- I understand that no personal information like my name and address will be identifiable in any articles, reports or letters written in connection with this study and that all information will be securely stored for 5 years before being destroyed.
- I agree to participate in the study outlined to me.

Name of Participant	Signature of Participant	Date

Name of Researcher	Signature of Researcher	Date

Appendix 5: APRIL® Age Progression Software Details

APRIL®
age progression software

Deirdre Hogan
Sales Manager

dhogan@aprilage.com

Aprilage Development Inc.
461 King Street West
Toronto, ON M5V 1K7 Canada
t. 416 599-2673 x458 f. 416 599-1212
www.aprilage.com

age-me.com

Deirdre Hogan
Managing Director

EMEGA Imaging Limited
6 Northbrook Road
Dublin 6
Ireland

T: +353 1 495 9258
F: +353 1 495 9299
M: +353 87 915 2627
Skype: deirdehogan

dhogan@age-me.com
www.age-me.com

Appendix 6: Image Talent Release Form

Curtin University

Approval form for the use of "talent" in images

I give approval for my image to be used by Curtin University for the purpose of the marketing and promotional activities of Curtin's education programs and core activities only for a maximum period of 3 years.

I acknowledge and agree that I can withdraw my approval at any time by the giving of written notice to Curtin addressed to the Director of Corporate Communications.

Curtin use only:

Organisational unit: .....

Responsible staff member: .....

Date: ..... Extension: .....

Initiating project: .....

.....

Image reference number(s): .....

.....

Talent description (i.e. clothes, hair, glasses, etc): .....

.....

Photographer: .....

Appendix 7: Ethics Committee Approval for Data Collection in WA

memorandum

To	Professor Moyez Jiwa WACCPC
From	A/Professor Stephan Millett, Chairperson, Human Research Ethics Committee
Subject	Protocol Approval **HR 01/2008**
Date	8 February 2008
Copy	Dr Owen Carter, Oksana Burford Graduate Studies Officer, Faculty of Health Sciences

Curtin University of Technology
Office of Research and Development
Human Research Ethics Committee
TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*Can a personalised smoking cessation intervention be delivered by community pharmacists in Western Australia? A pilot randomised control trial.*" Your application has been reviewed by the HREC and is **approved** subject to the conditions detailed below:

1) Please amend the third advertising pamphlet - third dot point - to read 'interesting and engaging".
2) Please spell out the acronym PAINT on the information sheet.
3) Please include the following in the information sheet:

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 01/2008). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au

Please forward the amended copy and a covering letter outlining the changes to the Ethics Office for final approval.

Please note the following:

- You are authorised to commence your research as stated in your proposal when a response is received and approved by the Executive Officer
- The approval number for your project is **HR 01/2008.** *Please quote this number in any future correspondence.*
- Approval of this project is for a period of twelve months **05-02-2008** to **05-02-2009**. To renew this approval a completed Form B must be submitted before the expiry date **05-02-2009.**
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Divisional Graduate Studies Committee.
- The following standard statement **must be** included in the information sheet to participants:

  This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 01/2008). If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

- It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

Regards,

A/Professor Stephan Millett
Chairperson
Human Research Ethics Committee

Appendix 8: ID Page

ID PAGE

ID NO: _____

First Name: _____

Age: _____ (yrs)

Gender: MALE ☐ FEMALE ☐

Main language spoken at home? _____

Highest level of education that you have completed?

i) Primary school
ii) Year 10 high school
iii) Year 12 high school
iv) TAFE or technical qualifications
v) Degree from university / College of Advanced Education / Other ?

Contact details:

Home ph: _____

Mobile: _____

Email: _____

Appendix 9: Baseline Questionnaire

BASELINE QUESTIONNAIRE ID No:_____

1. How soon after you wake up, do you smoke your first cigarette?
   1. After 60 minutes
   2. 31- 60 minutes
   3. 6 – 30 minutes
   4. Under 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   1. NO
   2. YES

3. Which cigarette would you most hate to give up?
   1. First cigarette in the morning
   2. Any other cigarette

4. How many cigarettes per day do you smoke?
   1. 10 or less
   2. 11 - 20
   3. 21 - 30
   4. 31 or more

5. Do you smoke more in the first hours after waking than during the rest of the day?
   1. NO
   2. YES

6. Do you smoke even if you are so ill, that you're in bed most of the day?
   1. NO
   2. YES

7. During the past 30 days, how many cigarettes did you smoke per day?
   1. Less than 1 cigarette per day
   2. 1 cigarette per day
   3. 2 – 5 cigarettes per day
   4. 6 – 10 cigarettes per day
   5. 11 – 20 cigarettes per day
   6. More than 20 cigarettes per day

8. "How I look is very important to me"
   1. Strongly agree
   2. Agree
   3. Disagree
   4. Strongly disagree

9. "I care about how people think I look"
   1. Strongly agree
   2. Agree
   3. Disagree
   4. Strongly disagree

10. "Overall, I like the way my face looks"
    1. Strongly agree
    2. Agree
    3. Disagree
    4. Strongly disagree

11. How likely is it that you will be smoking in the future?
    1. I definitely will be smoking
    2. I probably will be smoking
    3. I might or might not be smoking
    4. I probably won't be smoking
    5. I definitely won't be smoking

12. Do you think young people risk harming themselves if they smoke……..
(In this question, please circle NO or YES for EACH option)

1.	Less than 1 cigarette per day	NO	YES
2.	1 cigarette per day	NO	YES
3.	2 – 5 cigarettes per day	NO	YES
4.	6 – 10 cigarettes per day	NO	YES
5.	11 – 20 cigarettes per day	NO	YES
6.	More than 20 cigarettes per day	NO	YES

13. Does concern for your appearance affect the choices you make from day-to-day?
    1. Definitely yes
    2. Probably yes
    3. Probably not
    4. Definitely not

14. Is smoking related to getting facial wrinkles?
    1. NO
    2. YES

---

15. How important are EACH of the following reasons for you not to smoke in the future?

	1.Very Important	2.Important	3.neither	4. Not important	5. Not at all important
Physical fitness	☐	☐	☐	☐	☐
Bad breath	☐	☐	☐	☐	☐
Smelly hair	☐	☐	☐	☐	☐
Smelly clothes	☐	☐	☐	☐	☐
Bad skin	☐	☐	☐	☐	☐
Cost	☐	☐	☐	☐	☐
Future Health	☐	☐	☐	☐	☐

---

16. Do you agree or disagree.....

	1.Agree	2.Mostly agree	3.Neither	4.Mostly Disagree	5. Disagree
Smokers know how to enjoy life more than non-smokers	☐	☐	☐	☐	☐
I would prefer to date people who don't smoke	☐	☐	☐	☐	☐
The harmful effects of cigarettes have been exaggerated	☐	☐	☐	☐	☐
I think that becoming a smoker reflects poor judgement	☐	☐	☐	☐	☐
I personally don't mind being around people who are smoking	☐	☐	☐	☐	☐
Smoking is a dirty habit	☐	☐	☐	☐	☐
I strongly dislike being near people who are smoking	☐	☐	☐	☐	☐

17. What percentage of your friends smoke? _____%

18. What percentage of your immediate family (parents; siblings) smoke? _____%

19. What percentage of the general population do you think smoke? _____ %

20. How many quit attempts in the past have you made? _____ and using what method(s)? _____

21. Would you ask your community pharmacist for advice on.....

	1.Agree	2.Mostly Agree	3.Neither	4. Mostly Disagree	5.Disagree
a cough	☐	☐	☐	☐	☐
breathlessness	☐	☐	☐	☐	☐
fever	☐	☐	☐	☐	☐
bad breath	☐	☐	☐	☐	☐
facial wrinkling	☐	☐	☐	☐	☐

Appendix 10: Fagerström Scale

Fagerstrom Scale

How Addicted Are You to Nicotine?

Did you know there's a scale that can tell you just how addicted you are to nicotine? By answering a series of short questions you can have mathematical proof of just how bad your addiction to nicotine is.

Why not take the test and find out for yourself?

1. How soon after you wake up do you smoke your first cigarette?
   * After 60 minutes (0)
   * After 31 - 60 minutes (1)
   * After 6 - 30 minutes (2)
   * In less than 5 minutes (3)
2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   * No (0)
   * Yes (1)
3. Which cigarette would you most hate to give up?
   * First in the morning (1)
   * Any other (0)
4. How many cigarettes per day do you smoke?
   * 10 or less (0)
   * 11 - 20 (1)
   * 21 - 30 (2)
   * 31 or more (3)
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?
   * No (0)
   * Yes (1)
6. Do you smoke even if you are so ill that you are in bed most of the day?
   * No (0)
   * Yes (1)

Scores:

0 - 2 = Very low dependence

3 - 4 = Low dependence

5 = medium dependence

6 - 7 = High dependence

8 - 10 = Very high dependence

If nothing else, it's interesting to the put the addiction to numbers and see how you score.

Appendix 11: Pharmacy Self Care Card

General Health 0109 – 2006

Pharmacy Self Care Health Information

Smoking

Pharmaceutical Society of Australia

Smoking damages nearly every organ in your body. One in two lifetime smokers will die from their smoking. Quitting at any age will give you immediate benefits and reduce your chances of getting smoking-related illnesses. With planning and determination you can quit and stay a non-smoker.

Health effects of smoking

Tobacco smoke is toxic and contains more than 4,000 chemicals. Harmful ones include:

- **Nicotine** – an addictive drug that can make quitting difficult, but not impossible. It also affects heart rate and blood pressure and reduces blood flow to hands and feet.
- **Carbon monoxide** – replaces some of the oxygen normally carried in your blood, which means muscles, heart and brain get less oxygen.
- **Tar** – contains many cancer-causing chemicals. Lower tar or 'light' cigarettes are not any better: despite seeming less harsh, they still give you as much toxic chemicals as regular cigarettes.

Smoking:

- Increases the risks of developing cancer, heart disease, stroke and lung disease
- Clogs your arteries and increases the risk of peripheral vascular disease
- Increases your risk of mouth and throat cancer, and periodontitis (a disease affecting the gums and jawbone)
- Reduces fertility in women. It can also lead to erection problems (e.g., impotence) in men and miscarriage or complications in pregnancy and labour
- Interferes with your immune system, making you more susceptible to infections
- Can cause or contribute to many other health problems – e.g., blindness, osteoporosis.

Harm to others

Tobacco smoke in the air comes from both the burning end of a cigarette and from the smoke breathed out by a smoker. Smoke in the air is breathed in not only by the smoker, but also by family members, friends and co-workers.

This 'passive' smoking' can cause heart disease, and lung cancer, and increase breathing problems in non-smokers living or working with smokers. Children exposed to passive smoking are more likely to suffer from health problems including pneumonia, asthma, meningococcal disease, middle-ear infections, coughs and chest infections. Smoking by the mother puts the baby at a higher risk of sudden infant death syndrome (SIDS or 'cot death').

Why stop smoking?

It's important to be clear about your reasons for smoking and for quitting. Some good reasons to quit include:

- Your breathing will improve within days.
- Food will smell and taste better within days.

- You can save money – about $3600 per year for a pack-a-day habit.
- The condition of your heart, lungs, circulation and immune system will improve.
- You will find it easier to exercise and be active.
- Your general health and resistance to infection will be better and you are likely to have less sick days.
- You can be a positive example

Pharmacy Self Care is a program of the Pharmaceutical Society of Australia

for children and others.

Before you quit

Before you quit, consult your doctor if you:

- Are taking any medicines, as chemicals in cigarette smoke change the way some medicines work
- Have suffered from depression, anxiety or other mental illness, as stopping smoking can be stressful.

Where to get help

Stopping smoking involves more than overcoming the physical addiction to nicotine. Having more support when quitting helps you stay quit.

Various quitting methods, support groups and products are available to help you stop smoking and stay quit.

- Quitline 137 848 (13 QUIT) – for the cost of a local call – offers a free Quit pack, expert information and advice, courses, coaching, and support.
- The Quit Coach (www.thequitcoach.org.au) is a free, interactive web site.
- Nicotine replacement therapy (NRT) can reduce nicotine craving and withdrawal symptoms. It is available from pharmacies, without a prescription, as chewing gum, skin patches, inhalers, sublingual tablets or lozenges. People who use NRT are twice as likely to stay quit as those who try to use willpower alone. NRT is most useful for people who smoke more than 10 cigarettes per day – ask a pharmacist for advice.
- A non-nicotine medication called bupropion can be prescribed by a doctor to help you stop smoking.

Quitting and staying quit

- Smokers who make a 'quitting plan' before they quit, set a quit date and follow their plan are more successful than those who do not.
- Know when and why you smoke. Once you decide to quit, plan to avoid situations in which you are tempted to smoke – e.g. being with others who are smoking, coffee breaks, drinking alcohol, stressful or frustrating situations.
- When you get the urge to smoke, remember the 4Ds – do something else, delay, deep breathe, drink water.
- Having one cigarette does not have to mean the end of your quit attempt. A slip up is a setback, not a defeat.
- Call the Quitline 137 848 (13 QUIT) for further information and support.

Other fact cards of interest

- *Nicotine Replacement Therapy*
- *Staying a Non-smoker*
- *Relaxation techniques*
- *Weight & Health*
- *Exercise and the Heart.*

A doctor – listed under 'Medical Practitioners' in the yellow pages of the phone book

The Quitline – phone 137 848 for information and a free Quit pack or visit www.quit.org.au

Other Quit web sites:
www.quitnow.info.au
www.quittas.org.au
www.actcancer.org
www.quitsa.org.au
www.health.nsw.gov.au
www.qldcancer.com.au

The state or territory **Cancer Council** – listed under 'Cancer' in the phone book

A Self Care pharmacy – to locate, telephone 1300 369 772 and ask for the Pharmacy Self Care Field Officer

Pharmacists are medicine experts. Ask a pharmacist for advice when choosing a medicine.

Your **Self Care** Pharmacist

Sponsored by

Quitline 137848

93-23449-00556

Appendix 12: Follow-up Questionnaire [Control group]

FUQC: _____ **ID No:** _____

Are you still a smoker? Yes ☐ Go to Qu.1 No ☐ Go to Qu.8

---

1. How soon after you wake up, do you smoke your first cigarette?
1. After 60 minutes
2. 31- 60 minutes
3. 6 – 30 minutes
4. Under 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?
1. NO
2. YES

3. Which cigarette would you most hate to give up?
1. First cigarette in the morning
2. Any other cigarette

4. How many cigarettes per day do you smoke?
1. 10 or less
2. 11 - 20
3. 21 - 30
4. 31 or more

5. Do you smoke more in the first hours after waking than during the rest of the day?
1. NO
2. YES

6. Do you smoke even if you are so ill, that you're in bed most of the day?
1. NO
2. YES

7. During the past 30 days, how many cigarettes did you smoke per day?
1. Less than 1 cigarette per day
2. 1 cigarette per day
3. 2 – 5 cigarettes per day
4. 6 – 10 cigarettes per day
5. 11 – 20 cigarettes per day
6. More than 20 cigarettes per day -------- GO TO Qu.11

---

8. How long has it been since you quit? _____

9. On a scale from one to ten, how confident are you that you have quit for good?
(1 – not confident at all → 10 – very confident) _____

10. What made you decide to attempt quit smoking? _____

11. How important are EACH of the following reasons for you not to smoke in the future?

	1.Very Important	2. Important	3.Neither	4. Not important	5.Not at all important
Physical fitness	☐	☐	☐	☐	☐
Bad breath	☐	☐	☐	☐	☐
Smelly hair	☐	☐	☐	☐	☐
Smelly clothes	☐	☐	☐	☐	☐
Bad skin	☐	☐	☐	☐	☐
Cost	☐	☐	☐	☐	☐
Future Health	☐	☐	☐	☐	☐

12. Would you ask your community pharmacist for advice on……..

	1. Agree	2. Mostly Agree	3. Neither	4. Mostly Disagree	5 Disagree
a cough	☐	☐	☐	☐	☐
breathlessness	☐	☐	☐	☐	☐
fever	☐	☐	☐	☐	☐
bad breath	☐	☐	☐	☐	☐
facial wrinkling	☐	☐	☐	☐	☐

Appendix 13: Follow-up Questionnaire [Intervention group]

FUQI: _____ **ID No: _____**

Have you kept the photo-aged photo of yourself?

Yes ☐ No ☐

Where did you put it? _____ What did you do with it?

Have you shown it to anyone? _____ _____

Who? _____

Are you still a smoker? Yes ☐ No ☐

Go to Qu.1 Go to Qu.8

---

1. How soon after you wake up, do you smoke your first cigarette?
1. After 60 minutes
2. 31- 60 minutes
3. 6 – 30 minutes
4. Under 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?
1. NO
2. YES

3. Which cigarette would you most hate to give up?
1. First cigarette in the morning
2. Any other cigarette

4. How many cigarettes per day do you smoke?
1. 10 or less
2. 11 - 20
3. 21 - 30
4. 31 or more

5. Do you smoke more in the first hours after waking than during the rest of the day?
1. NO
2. YES

6. Do you smoke even if you are so ill, that you're in bed most of the day?
1. NO
2. YES

7. During the past 30 days, how many cigarettes did you smoke per day?
1. Less than 1 cigarette per day
2. 1 cigarette per day
3. 2 – 5 cigarettes per day
4. 6 – 10 cigarettes per day
5. 11 – 20 cigarettes per day
6. More than 20 cigarettes per day → Go to Qu.11

---

8. How long has it been since you quit? _____

9. On a scale from one to ten, how confident are you that you have quit for good?
(1 – not confident at all ⟶ 10 – very confident) _____

10. What made you decide to attempt quit smoking? _____

---

11. How important are EACH of the following reasons for you not to smoke in the future?

	1. Very Important	2.Important	3.Neither	4.Not important	5.Not at all important
Physical fitness	☐	☐	☐	☐	☐
Bad breath	☐	☐	☐	☐	☐
Smelly hair	☐	☐	☐	☐	☐
Smelly clothes	☐	☐	☐	☐	☐
Bad skin	☐	☐	☐	☐	☐
Cost	☐	☐	☐	☐	☐
Future Health	☐	☐	☐	☐	☐

---

12. Would you ask your community pharmacist for advice on……..

	1. Agree	2. Mostly Agree	3. Neither	4.Mostly Disagree	5. Disagree
a cough	☐	☐	☐	☐	☐
breathlessness	☐	☐	☐	☐	☐
fever	☐	☐	☐	☐	☐
bad breath	☐	☐	☐	☐	☐
facial wrinkling	☐	☐	☐	☐	☐

Appendix 14: HREC Form B: Progress Report/Application for Renewal

Curtin University

Curtin HREC Form B

PROGRESS REPORT
or APPLICATION FOR RENEWAL

The Form B is to be completed and returned to *the Secretary, Human Research Ethics Committee, c/- Office of Research & Development.*

If any of the points below apply prior to the expiry date, this form should be submitted to the Committee at that time. An application for renewal may be made with a Form B three years running, after which a 'new' application form, providing comprehensive details, must be submitted.

Approval Number:	HR 01/2008	Expiry Date 5/2/2012
PROJECT TITLE:	Delivering a personalised smoking cessation intervention by community pharmacists in Western Australia. A randomised controlled trial.	

1A	Has this project been completed?	YES☒	NO☐
1B	OR Do you wish to apply for a renewal of the project?	YES☐	NO☒
If YES please state the expected completion date.			
If NO please state why, eg abandoned/withdrawn/no funding etc. All data collection was completed by June 2011.			
2	Has this project been modified or changed in any manner that varies from the approved proposal?	YES☐	NO☒
If yes, please provide details_____ *(Attach additional comments on a separate sheet of paper if necessary)*			
3	Have any ethically related issues emerged in regard to this project since you received Ethics' Committee approval? (e.g. breach of confidentiality, harm caused, inadequate consent or disputes on these).	YES☐	NO☒
If yes, please provide details *(Attach additional comments on a separate sheet of paper if necessary)*			
4	Have any ethically related issues in regard to this project been brought to your attention by others? (i.e. study respondents, organisations that have given consent, colleagues, the general community etc).	YES☐	NO☒
If yes, please provide details _____ *(Attach additional comments on a separate sheet of paper if necessary)*			

Investigator:	Moyez Jiwa	Signature:	
Co-Investigator:	Oksana Burford	Signature:	
School/Department:	School of Pharmacy		
Head of Enrolling Area:	Jeff Hughes	Signature:	
Date:	2/2/2012		

Office Use Only
APPROVED: _____ DATE: ____/____/____
Executive Officer

Appendix 15: Body Dysmorphic Disorder Questionnaire

Body Dysmorphic Disorder Questionnaire (BDDQ)

Name _____

This questionnaire assesses concerns about physical appearance. Please read each question carefully and circle the answer that best describes your experience. Also write in answers where indicated.

1. Are you very concerned about the appearance of some part(s) of your body that you consider especially unattractive? Yes No

   If yes: Do these concerns preoccupy you? That is, you think about them a lot and wish you could think about them less? Yes No

   If yes: What are they? _____

   Examples of areas of concern include: your skin (e.g., acne, scars, wrinkles, paleness, redness); hair (e.g., hair loss or thinning); the shape or size of your nose, mouth, jaw, lips, stomach, hips, etc.; or defects of your hands, genitals, breasts, or any other body part.

   If yes: What specifically bothers you about the appearance of these body part(s)? (Explain in detail):

(NOTE: If you answered "No" to either of the above questions, you are finished with this questionnaire. Otherwise please continue.)

2. Is your main concern with your appearance that you aren't thin enough or that you might become too fat? Yes No

3. What effect has your preoccupation with your appearance had on your life?

   - Has your defect(s) caused you a lot of distress or emotional pain? Yes No
   - Has it significantly interfered with your social life? Yes No

   If yes: How? _____

   - Has your defect(s) significantly interfered with your school work, your job, or your ability to function in your role (e.g., as a homemaker)? Yes No

   If yes: How? _____

   - Are there things you avoid because of your defect(s)? Yes No

   If yes: What are they? _____

   - Have the lives or normal routines of your family or friends been affected by your appearance concerns? Yes No

   If yes: How? _____

4. How much time do you spend thinking about your defect(s) per day on average? (add up all the time you spend) (circle one)

   (a) Less than 1 hour a day
   (b) 1–3 hours a day
   (c) More than 3 hours a day

Appendix 16: Willing to Pay Questionnaire

QUESTIONNAIRE

1. What would you be willing to pay for providing you with this photo-ageing service?

$ _____

2. Are there any aspects of this service that could be improved?

_____

_____

_____

3. As a result of this photo-ageing service, would you be more likely to use this pharmacy to purchase future smoking cessation therapies such as nicotine patches, nicotine gum etc.?

Please circle your answer **YES** **NO**

4. As a result of this photo-ageing service, would you be more likely to use this pharmacy more generally for other purchases?

Please circle your answer **YES** **NO**

5. Do you think any of your friends would be willing to pay for this service?

Please circle your answer **YES** **NO**

6. Would you recommend this photo-ageing service to friends of yours that are smokers?

Please circle your answer **YES** **NO**

If YES, how many friends? _____

Appendix 17: Pico+ Smokerlyzer® CO Monitor

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piCO+ Smokerlyzer®

Operating Manual

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Bedfont Scientific Ltd
105 Laker Road, Rochester Airport Industrial Estate,
Rochester, Kent, ME1 3QX England
Tel: +44 (0)1634 673720. Fax: +44 (0)1634 673721
Email: ask@bedfont.com
www.bedfont.com

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Appendix 18: "At Face Value – 2" Questionnaire

At Face Value -- 2

ID# _____

Do you agree or disagree...

1. **"How I look is very important to me."** (Circle only one answer)

   a. Strongly Agree
   b. Agree
   c. Disagree
   d. Strongly Disagree

2. **"I care about how people think I look."** (Circle only one answer)

   a. Strongly Agree
   b. Agree
   c. Disagree
   d. Strongly Disagree

3. **"Overall, I like the way my face looks."** (Circle only one answer)

   a. Strongly Agree
   b. Agree
   c. Disagree
   d. Strongly Disagree

Do you agree or disagree...

4. **(Circle one choice for each question)**

		Agree	Mostly Agree	Neither	Mostly Disagree	Disagree
a.	Smokers know how to enjoy life more than non-smokers	1	2	3	4	5
b.	I would prefer to date people who don't smoke	1	2	3	4	5
c.	The harmful effects of cigarettes have been exaggerated	1	2	3	4	5
d.	I think that becoming a smoker reflects poor judgment	1	2	3	4	5
e.	I personally don't mind being around people who are smoking	1	2	3	4	5
f.	Smoking is a dirty habit	1	2	3	4	5
g.	I strongly dislike being near people who are smoking	1	2	3	4	5

5. **Do you think that you will try a cigarette soon?** (Circle only one answer)

   a. I have already tried smoking cigarettes
   b. Yes
   c. No

6. **Do you think that you will smoke a cigarette anytime during the next year?** (Circle only one answer)

   a. Definitely yes
   b. Probably yes
   c. Probably not
   d. Definitely not

7. **If one of your best friends offered you a cigarette, would you smoke it?** (Circle only one answer)

   a. Definitely yes
   b. Probably yes
   c. Probably not
   d. Definitely not

8. **Do you think young people risk harming themselves if they smoke...** (Circle yes or no for each question)

   a. Less than 1 cigarette per day Yes No
   b. 1 cigarette per day Yes No
   c. 2 to 5 cigarettes per day Yes No
   d. 6 to 10 cigarettes per day Yes No
   e. 11 to 20 cigarettes per day Yes No
   f. More than 20 cigarettes per day Yes No

9. **Does concern for your appearance affect the choices you make from day-to-day?** (Circle only one answer)

   a. Definitely yes
   b. Probably yes
   c. Probably not
   d. Definitely not

10. **Do you think young people who smoke cigarettes have more friends?** (Circle only one answer)

    a. Definitely yes
    b. Probably yes
    c. Probably not
    d. Definitely not

OVER →

11. In your opinion, which word or phrase most closely describes <u>most kids your age who smoke</u>. (Circle one choice for <u>each</u> pair)

a.	Not Cool	Cool
b.	Foolish	Wise
c.	Wimpy	Tough
d.	Dumb	Smart
e.	Cowardly	Brave
f.	Not Popular	Popular
g.	Bad at schoolwork	Good at schoolwork
h.	Plain-looking	Good-Looking
i.	Usually disobey	Usually obey
j.	Like to be alone	Like to be with a group
k.	Uninterested in dating	Interested in dating
l.	Drink alcohol	Don't drink alcohol
m.	Try to act big	Act your own age

Do you agree or disagree...

12. Tobacco companies... (Circle agree or disagree for <u>each</u> question)

a.	Want young people to smoke	Agree	Disagree
b.	Are honest about the health effects of their tobacco products	Agree	Disagree
c.	Target their advertising to teenagers less than 18 years of age	Agree	Disagree