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Photoageing Intervention (PAINT): A proposal for a randomised controlled trial in Australian Primary Care

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Abstract

The adverse health impacts of tobacco smoking are a drain on national resources. This study will test an intervention to promote smoking cessation among young adults aged 18-30years. The intervention will be delivered within two settings in Australian health care; community pharmacies and general practice. The new study builds on the pilot data, reported here, which inform the feasibility, recruitment strategy, outcome measure, effect size and attrition rate. The new study is a randomised controlled trial with 200 clients recruited from general practice and community pharmacies in Western Australia.

Health risks associated with smoking

The prevalence of smoking is a major challenge in health care. Tobacco smoking 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, leading to death or disability and drain on national resources. Most long-term smokers will die prematurely, half of these in middle age, as smoking reduces the life expectancy of a heavy smoker by approximately seven years and increases the remaining life years in poor health (1,2). Even light smokers who only consume between one to four cigarettes per day triple their long-term risk of dying of cardiovascular disease or lung cancer (3). The most recent estimate for the prevalence of smoking in Australia suggests that 17.4% aged 14 years and over smoke tobacco on a daily basis, equating to approximately 2.8 million people and in Western Australia in 2005 31.5% of school children aged 12-17 years had smoked at least part of a cigarette in their lifetime (4,5). 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 (6).

Traditional quit messages

Advertising by tobacco companies is designed to have a strong emotional impact because this then increases the chances of the product being bought. (7,8) Individuals must be encouraged to change behaviour and this encouragement needs strong emotional arousal. (9) Therefore, information that deepens the experience of fear or guilt seems to be particularly effective in initiating behaviour change. (7,10,11,12) There would be few Australians now who could claim ignorance of the detrimental health effects of smoking. However health promotion research shows that, in isolation, knowledge about the hazards of smoking is insufficient to deter smoking behaviours (13). Most adolescents are naturally curious about smoking and experimentation is strongly predicted where smoking is prevalent within their own environment and access to cigarettes is facilitated by parents, siblings or friends who smoke. 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 (14).

An alternative message for young smokers

“Smoker’s Face” is the medical term used to describe the drastic and irreversible impact of smoking on physical appearance. Smoking dries out the skin and reduces blood circulation leading to oxygen deprivation causing wrinkle formation contributing to premature skin ageing. (15).

In 1984 a West Australian advertising campaign, “Not Just a Pretty Face”, depicted a young, attractive woman smoking a

cigarette while gradually morphing into a relatively unattractive older person. Two evaluations of this campaign concluded that the advertisement was highly successful in deterring girls from taking up smoking because its powerful and direct message that smoking makes you ugly. (16,17) Unfortunately, following generations have not been exposed to the 1984 "Not Just a Pretty Face" campaign and have only had exposure to repetitive graphic and visceral images of the harmful effects of smoking, such as those used in the National Tobacco Campaign (1997-2003) and on cigarette packets (2006-2007). These images have proven to be effective in deterring adolescents from initiating smoking (18) however, those that are already smoking seem to be resistant and do not heed these messages.

Adolescents who have initiated smoking don't necessarily consider themselves at high risk of developing health problems because they associate such risks with long-term smokers and they intend to give up the habit sooner rather than later. They believe that the long-term effects of smoking can be almost entirely avoided by quitting before they get 'too old' and even if they still continue to smoke, there's no certainty that they will become sick as they all know of a relative who smoked heavily and "still lived to a ripe old age". (14) Some of these 'treatment resistant' smokers are even asthmatics who despite recommendations to quit are impervious to quit campaigns. (19)

In a Norwegian study carried out among young smokers, 59% women indicated that concerns about their own physical appearance would contribute to thoughts of quitting (20) and in another survey, about 25% of extant smokers would quit if they knew that smoking increased facial ageing and premature wrinkling. (21)

Many health care professionals are nonplussed that smokers continue to smoke given the widespread information that is available to them. There is clearly a present challenge within the health community to find strategies to overcome these entrenched resistances to the quit smoking messages. Within this context, premature ageing is a real fear to today's youth-oriented society and emphasising the link of smoking to the detrimental effects on skin and physical appearance can be an effective motivator to either prevent many adolescents from taking up smoking or to motivate them towards the intention to quit. (22)

Expanding the role of the community pharmacist

Community pharmacists are trusted health care professionals whose role is established in the management of minor illness (23) . In addition their training and the availability of NRT (Nicotine Replacement Therapy) make pharmacists well placed to deliver smoking cessation interventions. In recent years pharmacists may have diminished the emphasis on health care services by expanding their business into the retail sector (24). Pharmacists need to differentiate their businesses by creating a benefit to customers, so that these customers perceive this being of greater value to them than they can get by spending money elsewhere. Smoking cessation saves lives, measurably reduces healthcare costs and improves well-being and life expectancies pharmacists should not only promote smoking cessation therapy, but take a pro-active role in advising their clients of the benefits of smoking cessation (25).

The role of the general practitioner

In Australia there are over 100 million consultations with general practitioners annually (26). Each consultation is an opportunity to promote smoking cessation. However it has been shown that there is only a limited increase in the motivation to quit using the tools and techniques available in practice (27). Only 46% of divisions of general practice actively offer smoking cessation advice therefore there is considerable scope to develop more effective strategies to engage the patient effectively in health promotion activity (28).

Objectives

The aim of this study is to test the efficacy of an intervention based on personalised, vivid illustrations of 'smoker's face' on quit attempts or 'state of change' progression attitudes among young smokers (18-30 years old).

Methods

Participants will be recruited when they present at a community pharmacy for any service or enrol on a smoking cessation clinic organised by a Division of general practice.
Eligibility criteria:

i) 18-30 yrs old (self-report);
ii) Smokers (self-report);
iii) Able to give consent;
iv) Available for follow up for 12 months (self-report);
v) No beards, moustaches or facial accessories that can't be removed
vi) No body dysmorphia (clients will be screened for BDD using the diagnostic instrument: BDDQ - Body Dysmorphic Disorder Questionnaire) (29);

They will be randomised into two groups - a control group and an intervention group with equal number of participants in each. Allocation into control group and intervention group will alternate weekly (most feasible and least bias option suitable for the different settings) so that all clients recruited in any specific week will receive the same intervention. All participants will be asked to complete a baseline questionnaire.

The intervention:

The APRIL® Age Progression Software is the only statistically-based 3D age progression software now available. The software creates a stream of aged images of faces from a standard digital photograph. The wrinkling/aging algorithms are based upon research of more than 7,000 people of all ages, ethnicities and lifestyle habits, as well as on published data regarding facial changes associated with aging. Additionally, the resulting aged

images can be adjusted to compare how a person will age as a smoker verses a nonsmoker; if he or she adds excessive weight; or if they experience a high degree of unprotected sun exposure. See demonstration video accompanying this report.

Control Group

Participants will receive standard smoking cessation advice by a pharmacist or smoking cessation clinic officer. In pharmacy this comprises the Pharmacy Self Care card on Smoking (a health information card from the Pharmacy Self Care program of the Pharmaceutical Society of Australia) and counselling. In general practice this will be the 5A's approach to smoking cessation (30). They will be asked to complete the Baseline questionnaire consisting of demographic data and the Fagerstrom scale. This procedure from pre-screening to completion of Baseline questionnaire is estimated to take 5 minutes. Follow-up surveys will be undertaken via telephone at 1 month, 3 months, 6 months and 12 months later and will take 5 minutes each to complete.

Intervention Group

Participants will receive the same smoking cessation advice as the control group from the pharmacist General practitioners or smoking cessation clinic team. They will also be asked to complete the Baseline questionnaire. Then they will be photographed and their images digitally aged, as a smoker and non-smoker, using APRIL® age software and invited to view the age-processed images. This procedure from pre-screening to completion of post-intervention questionnaire will take 10 minutes. If participants become distressed or should they express an interest in smoking cessation, they will be counselled by the relevant health practitioner. A photo (ie. a coloured printed photocopy) of their photo-aged face will be posted to them, to their nominated address within a week of the intervention. Follow-up surveys will be undertaken via telephone at 1 month, 3 months, 6 months, and 12 months later and will take 5 minutes each to complete.

The 'Smoker's Face' Personal Threat-Appeal Simulations

The 'smoker's face' threat appeal simulations will be created using a digital photograph taken of participants and inputted to APRIL® Age Progression Software on a laptop computer.

The creation of the simulations involves:

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 health data from the faces of smokers and non-smokers, taking into account of gender and race);
c) remapping textures (ie. pixel intensities) into the newly generated simulation.

The result is a colour, lifelike simulation of a person's face if he or she were to continue or become a smoker compared to a non-smoker's normally aged face.

The simulations will be presented on a laptop computer with a 15.2 inch monitor with a screen resolution of 1152x760 (85Hz), set to millions of colours.

Outcomes measure

The effect of the intervention will be measured using quit attempts and the Fagerstrom Scale as a measure of nicotine dependence (31).

Sample size

Sample sizes have been calculated on the basis of a pilot study with 50 subjects, 25 in the intervention group and 25 in the control group .There were 17 (34%) male subjects, and 33 (66%) Female. Of the control group, 11/25 (44%) were male, while only 6/25 (24%) of the intervention group were male. The responses to 6 questions were used to calculate the Fagerstrom score – a number between zero and 10 indicating the level of dependence on smoking. Higher scores indicate greater nicotine dependence. Previous studies using this scale have divided subjects into 5 groups (scores: 0-2, 3-4, 5, 6-7, 8-10). Those subjects who had stopped smoking at the time of questionnaire were allocated a Fagerstrom score of -1 in order to distinguish them from very low-dependence smokers. We assumed that those participants who did not complete a follow up survey in our pilot study had the same smoking dependence as their previous survey. Six subjects were classified as 'Quitters' at 3 months, and they all came from the lowest smoking dependence category (0-2) at baseline. For these subjects, there was no significant difference between treatment allocation groups (p=0.29). For subjects who started out with a greater smoking dependence (Fagerstrom score 3+), there was a trend towards a greater proportion of the Intervention group moving to a lower dependence by 3 months (p=0.11). From the effect size seen in the 'mean smoking dependency scores' of the control and intervention groups, a sample size of 200 was calculated which would be required for a definitive RCT in each setting with 80% power and 5% significance. This would allow for a 50% attrition rate.

Data analysis

The quantitative research data will be analysed using SPSS Statistics v17 software. The profile of the subjects under study will be summarised using descriptive statistics (means and Standard deviations for continuous variables, and proportions for categorical variables). Univariate group comparisons will be performed using Chi-square tests (categorical variables), and t-tests (continuous variables). Multivariate analyses of continuous variables will be performed using Analysis of Variance (possibly a repeated measures analysis for endpoints measured at several time points through the study). Multivariate Logistic regression may be used to analyse the binary endpoint variables (for example: very low dependence vs other), in order to compare treatment groups after adjustment for other factors. If the continuous variables exhibit excessive skewness, non-parametric methods may be used in preference to the Analysis of Variance.

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