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Smoking cessation intervention for young adults using multimedia mobile phones: development and effectiveness

Robyn Whittaker

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

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2011
Abstract

Tobacco smoking is the most important single preventable cause of disease in New Zealand and a leading global health problem. Despite overall reductions, young adults and particularly young Māori (the indigenous population of New Zealand) continue to have high rates of smoking. Novel cessation support strategies that appeal to young people are required. Mobile phones have rapidly become integrated into daily life and are starting to be used for health purposes. Mobile phones offer the potential to deliver health interventions directly to people at appropriate times in a proactive manner. The aim of this thesis was to determine whether multimedia mobile phones could be effective in delivering smoking cessation support, particularly for young adults.

A systematic review was conducted on studies of mobile phone-based smoking cessation interventions. Only two studies of mobile phone-delivered interventions met the inclusion criteria, one of these being a pilot study (n=200). The meta-analysis demonstrated a short-term increase in self-reported point prevalence abstinence (no smoking within past seven days) for text message-based interventions compared with control groups (RR 2.18, 95% CI 1.80-2.65). As yet there is no evidence of long-term benefits of mobile phone-only interventions. A further two studies on a mobile phone and internet programme were analysed separately demonstrating a long-term increase in repeated point prevalence abstinence (RR 2.03, 95% CI 1.40, 2.94). A major methodological issue evident in previous research was the challenge of conducting trials in young adults, both in terms of recruitment and retention during follow-up.

A multimedia mobile phone cessation intervention was developed with social cognitive theory as a basis for using role models to provide observational learning. Video messages from role models included their use of effective techniques for smoking cessation, in order to enhance self-efficacy for
quitting. Almost 250 young people had input into an extensive development phase and a pilot study. Some of the findings from this phase included the importance of confidentiality, flexibility, cost, and the use of peers who understand the issues. Feedback from participants endorsed the use of video role modelling messages, and included the need for a choice of role models who must be perceived by participants to be ‘real’ and credible as smokers. Feedback on the content of the videos included the need for the message to be believable and not overly negative.

A randomised controlled trial of the effectiveness of the intervention was undertaken. Recruitment was slower than anticipated and had to be terminated before reaching the target sample size due to funding considerations. In all, 226 participants were randomised. At six months, cessation rates were high in both groups: 26% of the intervention group (29/110) and 28% of the control group (32/116) (p=0.7) had quit (five or less cigarettes since quit date) using an intention to treat analysis. In a responders-only analysis, excluding those lost to follow-up, 39% and 36% had quit in the intervention and control groups respectively (p=0.2). These results were added to the previous meta-analysis of studies with mobile phone-only interventions, with a non-statistically significant increase in long term continuous abstinence with mobile phone interventions (RR 1.21, 95% CI 0.94-1.57, I²=65%).

Feedback from the intervention group participants indicated that watching someone like them go through the quitting process was helpful (88%) and that they felt supported to quit (86%). Three-quarters stated that getting messages at the right times was helpful. In those who had relapsed at six months, their confidence in quitting next time had increased (from 58.7% to 62.0%) compared to a decrease in the control group (66.9% to 62.2%). A small qualitative sub-study (n=10) endorsed the theme of support provided by watching someone like them go through the quitting process and by feeling that they were not quitting alone. It was important to this group that they could select a role model they could relate to. Those who did not successfully quit this time reported feeling more confident to quit again in the future having learnt what would be required to be successful.
Conclusions: It is difficult to draw conclusions about the effectiveness of this intervention as the trial was under-powered to detect an effect. Due to high quit rates in both groups it is possible that the control programme, of infrequent general health video messages plus the setting of a quit date, was as effective as the intensive theory-based content of the intervention. This is the first video messaging mobile phone intervention to be described in the literature. It demonstrates that it is feasible to deliver rich content via video messages directly to people. It also demonstrates the acceptability of multimedia mobile phone health interventions to at least a proportion of the population, although there are still issues with attracting young adults to smoking cessation programmes. The use of multimedia mobile phone technology has been slow to be adopted in New Zealand, which may have affected recruitment. As this technology becomes more commonplace there are likely to be future opportunities to investigate such novel interventions. Those working in this area may learn from the input of young adults into the intervention design and the feedback from participants on what was helpful.
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Dr Ralph Maddison
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Dr Hayden McRobbie
Dr Simon Denny
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Mai Media Ltd

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<tr>
<td>3G</td>
<td>third generation mobile communications network technology</td>
</tr>
<tr>
<td>ABC</td>
<td>New Zealand smoking cessation guidelines mnemonic (Ask about smoking, give Brief advice, and provide Cessation support or referral)</td>
</tr>
<tr>
<td>ACTRN</td>
<td>Australian New Zealand Clinical Trials Registry</td>
</tr>
<tr>
<td>CAD</td>
<td>Centre for Academic Development, University of Auckland</td>
</tr>
<tr>
<td>CCFPR</td>
<td>Centre for Child and Family Policy Research, University of Auckland</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control, USA</td>
</tr>
<tr>
<td>cf</td>
<td>compared with</td>
</tr>
<tr>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>CO</td>
<td>carbon monoxide</td>
</tr>
<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CTRU</td>
<td>Clinical Trials Research Unit, University of Auckland</td>
</tr>
<tr>
<td>FTND</td>
<td>Fagerstrom test of nicotine dependence</td>
</tr>
<tr>
<td>GYTS</td>
<td>Global Youth Tobacco Survey</td>
</tr>
<tr>
<td>HONC</td>
<td>Hooked on Nicotine Checklist (a measure of nicotine dependence)</td>
</tr>
<tr>
<td>HSC</td>
<td>previously known as the Health Sponsorship Council of New Zealand</td>
</tr>
<tr>
<td>html</td>
<td>hypertext markup language (language for webpages)</td>
</tr>
<tr>
<td>ICT</td>
<td>information and communications technology</td>
</tr>
<tr>
<td>IT</td>
<td>information technology</td>
</tr>
<tr>
<td>ITT</td>
<td>intention to treat (analysis)</td>
</tr>
<tr>
<td>IVRS</td>
<td>interactive voice response system</td>
</tr>
<tr>
<td>m-Health</td>
<td>mobile health</td>
</tr>
<tr>
<td>MMS</td>
<td>multimedia message service</td>
</tr>
<tr>
<td>MPSS</td>
<td>mood and physical symptoms scale (for nicotine withdrawal symptoms)</td>
</tr>
<tr>
<td>NRT</td>
<td>nicotine replacement therapy</td>
</tr>
<tr>
<td>NZ</td>
<td>New Zealand</td>
</tr>
<tr>
<td>NZDep</td>
<td>New Zealand deprivation index</td>
</tr>
<tr>
<td>NZTUS</td>
<td>New Zealand Tobacco Use Survey</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>OR</td>
<td>odds ratio</td>
</tr>
<tr>
<td>OS</td>
<td>(computer) operating system</td>
</tr>
<tr>
<td>PIS</td>
<td>participant information sheet</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>---------</td>
<td>------------</td>
</tr>
<tr>
<td>QD</td>
<td>quit date</td>
</tr>
<tr>
<td>RA</td>
<td>research assistant</td>
</tr>
<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
</tr>
<tr>
<td>RR</td>
<td>relative risk</td>
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<tr>
<td>SCT</td>
<td>social cognitive theory</td>
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<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>Shortcode</td>
<td>4-digit number that replaces a mobile phone number</td>
</tr>
<tr>
<td>Smartphone</td>
<td>a mobile phone that also has functions of a computer (operating system, applications and email/internet access)</td>
</tr>
<tr>
<td>SMS</td>
<td>short message service/text messaging</td>
</tr>
<tr>
<td>STOMP</td>
<td>Stop smoking by mobile phone (CTRU’s text message cessation intervention)</td>
</tr>
<tr>
<td>STUB IT</td>
<td>the final video message mobile phone intervention</td>
</tr>
<tr>
<td>ttfc</td>
<td>time to first cigarette (after waking)</td>
</tr>
<tr>
<td>Txt</td>
<td>text message</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>URL</td>
<td>website address</td>
</tr>
<tr>
<td>US/USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>WAP</td>
<td>wireless application protocol</td>
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1 Introduction

“The future of health is mobile”

Dr Jay Bernhardt, Centers for Disease Control (CDC), 2009

Tobacco smoking is the most important single preventable cause of disease globally. (1) In New Zealand, tobacco smoking causes approximately 5000 deaths, or 18% of all deaths, each year. (2) Tobacco smoking also accounts for one quarter of the ethnic disparity between Māori (the indigenous population of New Zealand) and non-Māori in life expectancy in this country. (3) The adverse health effects of tobacco smoking became widespread knowledge in the 1960s and 1970s and reductions in the prevalence of tobacco smoking followed. During the 1980s New Zealand established a multifaceted tobacco control programme that included media campaigns and taxation. This was reflected in the fastest rate of decline in consumption of tobacco amongst Organisation for Economic Cooperation and Development (OECD) countries from 1985-1990. (4) Unfortunately the rate of decline has levelled off in more recent years (5) and other OECD countries now have lower smoking prevalence rates than New Zealand. (6-8)

The reductions in smoking prevalence in New Zealand have not been equally distributed, with a slower decline in smoking amongst Māori. (9) The current tobacco smoking prevalence rate for the New Zealand population (aged 15 years and over) is 23% but remains at 45% for Māori. Smoking prevalence rates amongst young adults (between 18 and 25 years) also appear more resistant to change than rates in older age groups. (9) Today’s young adults have grown up with the health promotion messages and understand the adverse health effects of smoking. However, despite professing the desire to quit, (10) most will go on to smoke for many years. (11) Young adults tend not to use smoking cessation support services (10, 12) and there is little evidence of effective smoking cessation interventions for young adults. (13) There are likely to be other factors that encourage smoking or discourage quitting for young
adults, predominantly social and lifestyle factors, alongside addiction to nicotine.(14-16) Further research is required to determine how to accommodate these social and lifestyle factors into innovative approaches to support young adults to quit.

Mobile phones are well integrated into the daily lives of young adults. Mobile communications networks have only been around since the 1980s, and text messaging since the 1990s, but the uptake of this particular technology has been more rapid than with previous technological developments.(17) The increase in mobile phone usage over the same period as the decline in smoking led some to speculate that mobile phones may substitute for smoking in young people.(18) Unfortunately this has proved not to be true and high usage of mobile phones may even be associated with behaviours such as tobacco smoking in adolescents.(19, 20)

Health services are starting to recognise the benefits of using mobile phones to improve communication with their clients and thereby increase the efficiency and effectiveness of their services. This includes sending reminders for appointments,(21, 22) reminders to improve adherence to medications,(23, 24) report test results,(25, 26) and collect data between visits for those with long-term conditions.(27, 28) Mobile phones are also being used to deliver healthy behaviour change support programmes directly to individuals.(29, 30) These include programmes to support weight loss,(31) increase physical activity,(32) and manage diet for people with diabetes.(33) Smoking cessation interventions have also been delivered via mobile phone with some improvement in quit rates. (34-36)

Early indications are that mobile phones are a good way to support people trying to quit smoking, as messages can be delivered directly to the individual wherever they may be. There is no requirement for a participant to attend a clinic or ‘log on’ to a website. Programmes are therefore proactive rather than reactive. Messages can be timely, sent at usual smoking times, or saved and viewed at the most appropriate times by the recipient. Messages can be tailored
to individual characteristics but set up in advance to be sent automatically. In this way, programmes are personal and yet require little input from scarce health person resources. Ongoing support can continue to be provided for as long as required at little extra cost.

One of the limitations of mobile phone programmes to date is the limit on information that can be included in a text message. This may also limit the appeal of, and engagement with, the programme for young technologically advanced people. New mobile phone handset and network technologies allow multi-media content on mobile phones, such as photographs, graphics, audio, video, and internet sites. It is possible that a health programme delivered via multimedia content would be more appealing and more engaging for young adults, and result in greater improvements in quit rates, than simple text messages were able to achieve.

1.1 Objectives of the thesis
The aim of this thesis was to determine whether multimedia mobile phones could be effective in delivering smoking cessation support, particularly for young adults. This was achieved by conducting a systematic review of the literature on mobile phones in smoking cessation, developing a theory-based smoking cessation intervention using multimedia mobile phones, and testing the effectiveness of the intervention in a randomised controlled trial.

1.2 Structure of the thesis
This chapter introduces the topic and thesis. Chapter 2 summarises the background literature in order to establish the context for this body of work. This includes the importance of tobacco smoking on health, effective smoking cessation support methods, and smoking prevalence and cessation in young adults. The use of mobile phones in health services and to support healthy behaviour change is also reviewed. Chapter 3 presents a systematic review and meta-analysis of the literature on the effectiveness of mobile phone smoking cessation programmes.
Chapter 4 describes the theory and process used to develop a multi-media mobile phone smoking cessation intervention for young adults. Chapter 5 presents the methods and results of a randomised controlled trial of the multimedia mobile phone smoking cessation intervention. This chapter also includes an update of the meta-analysis presented in Chapter 3 after results of the randomised controlled trial are included. Chapter 6 describes a qualitative sub-study undertaken with a sample of participants in the randomised controlled trial to inform interpretation of the findings and future intervention development. Chapter 7 presents a discussion of the findings of all the research in this thesis and draws some conclusions on implications for future practice and research.
2 Background Literature Review

2.1 Introduction
This literature review summarises the literature about the importance of tobacco smoking, the prevalence of tobacco smoking in New Zealand, smoking cessation interventions found to be effective internationally, and the current smoking cessation support services that are available in New Zealand. The review then focuses on young adults and their tobacco smoking, interest in stopping smoking, use of cessation services and support, and reported requirements in youth-targeted cessation support. The second part of this review examines the use of mobile phones in health services (m-Health), the specific use of mobile phones for behaviour change support, and the limitations of using mobile phones in health services.

2.2 The importance of tobacco smoking as an issue
Tobacco smoking is the most important single preventable cause of disease globally and in New Zealand.(1, 2) In 2000, 4.83 million premature deaths (estimate range 3.94-5.93 million) globally were estimated to be due to tobacco smoking, occurring equally in industrialised countries (2.43 million) and in developing countries (2.41 million).(1) The leading causes of death were cardiovascular diseases (1.69 million deaths, 35% of all smoking-attributable deaths), chronic obstructive pulmonary disease (COPD; 0.97 million deaths), and lung cancer (0.85 million deaths).(1) Twenty-two per cent of all deaths from cancer in adults and 11% of all cardiovascular disease deaths worldwide were considered to be attributable to smoking.(1) To date a large proportion of the tobacco-related deaths have occurred in industrialised countries,(1) but it has been predicted that due to changes in smoking prevalence rates there will be dramatic increases in tobacco-related deaths in developing countries.(37, 38)
The economic burden of tobacco-induced diseases is huge. In the United States of America (US) it has been estimated that during 2001-2004 the total economic burden of tobacco smoking was approximately US$193 billion per year in direct health care costs and lost productivity. (39) Funding for tobacco prevention and control programmes around the same time was US$595 million per year - approximately 325 times less than the smoking-related costs. (39) These costs were not equally distributed with African-Americans bearing a disproportionate burden of costs and years of life lost. (40)

In New Zealand, tobacco smoking has been estimated to cause 18% of all deaths (using 1997 data). (2) Of the estimated 5000 tobacco-related deaths in New Zealand each year, the majority (4600) are due to active smoking but approximately 400 are due to passive exposure to someone else’s tobacco smoke. (2) Three-quarters of all these deaths are due to lung cancer, COPD and cardiovascular diseases. (5) The average New Zealand smoker has been estimated to lose 5.2 years of life. (3)

Tobacco smoking is also important as a key factor in health disparities in New Zealand. (3) At least one third of the socioeconomic deprivation gradient in life expectancy, and approximately one quarter of the ethnic disparity in life expectancy is accounted for by tobacco smoking. (3) The New Zealand population consists of several large ethnicity groupings: Māori (the indigenous population, 14%), New Zealand Europeans (65%), people from the Pacific Islands (predominantly Samoa, Cook Islands, Tonga, Nuie, Fiji, Tokelau 7%), and Asian people (including those from many countries predominantly China, India, Korea, Phillipines, Japan, Sri Lanka, Cambodia, 9%) (Table 2.1). (41)
Table 2-1: The ethnic composition and life expectancy of the New Zealand population

<table>
<thead>
<tr>
<th>Ethnic group</th>
<th>n</th>
<th>%</th>
<th>Life expectancy at birth male/female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Māori</td>
<td>565,329</td>
<td>14</td>
<td>70.4/75.1 years</td>
</tr>
<tr>
<td>New Zealand European</td>
<td>2,609,589</td>
<td>65</td>
<td>Non-Māori</td>
</tr>
<tr>
<td>Pacific Islands</td>
<td>265,974</td>
<td>7</td>
<td>79.0/83.0 years</td>
</tr>
<tr>
<td>Asian</td>
<td>354,549</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4,027,947</td>
<td>100</td>
<td>78.0/82.2 years</td>
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</tbody>
</table>


Māori in particular suffer the burden of tobacco induced diseases. Deaths due to cardiovascular disease have been reported as twice as high, at 139.8/100,000 person-years (age-sex standardised rates, 2000-2004) in Māori and 61.2/100,000 in non-Māori (rate ratio 2.29 95% confidence interval (CI) 2.21-2.36).(42) Deaths due to respiratory disease were three times higher (33.8/100,000 versus 13.1/100,000, rate ratio 2.59 95% CI 2.42-2.76) than in non-Māori.(42) Deaths from lung cancer were also three times higher at 36.8/100,000 in Māori and 11.4/100,000 in non-Māori (rate ratio 3.23 95% CI 3.03-3.45).(42)

2.2.1 The prevalence of tobacco smoking in New Zealand

The New Zealand Tobacco Use Survey in 2008 reported an overall ‘current smoking’ prevalence rate of 23% in those aged 15 years and over. Tobacco smoking prevalence rates were highest in Māori (45.4%) followed by Pacific people (31.4%), European/Other (21.3%), and Asian groups (5.2%).(5) Those in the most deprived neighbourhood areas (NZDep2006 Index, Quintile 5) were 1.5 times as likely to be current smokers (39.4% of males and 37% of
females) as those living in the least deprived areas (Quintile 1: 15.3% of males and 12.9% of females).(5)

Repeated surveys have demonstrated a gradual reducing prevalence of smoking over time since 1983.(9) In recent years the reduction has fallen behind other similar countries, with the US reporting 20.6% in 2008,(6) Canada 19% in 2007,(7) and Australia 19% in 2007.(8)

2.2.2 Tobacco smoking cessation

The benefits of stopping tobacco smoking are well known. Doll’s seminal research on British doctors showed that those who stopped smoking before the age of 35 years returned to almost the same risk of tobacco-related diseases as non-smokers.(43) However stopping smoking at any age reduces the risk compared with current smokers.(43) Reducing smoking prevalence is a priority of the New Zealand Health Strategy, the Cancer Control Strategy, and the Ministry of Health’s 5-year plan for tobacco control (‘Clearing the Smoke’). Smoking cessation was one of six government target areas in the Ministry of Health’s 2009 Statement of Intent (“better help for smokers to quit”).(44)

A multitude of studies and reviews have been published on effective methods to assist those who wish to quit smoking. Effective cessation support methods include brief advice to quit from a health professional,(45) individual counselling,(46) group counselling,(47) telephone counselling help-lines,(48) and self-help materials.(49) Effective pharmacological support includes nicotine replacement therapies (NRTs),(50) varenicline,(51) nortriptyline and bupropion.(52) Many countries, including New Zealand, have attempted to bring this evidence together into practice guidelines.(53, 54) As well as advising health professionals on the effective methods, these guidelines tend to reinforce similar central principles such as:
1. The need for a coordinated approach so that all parts of the health care system consistently ask about and document the smoking status of their population and offer available cessation support services or methods to those who wish to quit
2. The effectiveness of combining cessation support methods, particularly pharmacological support plus counselling
3. The common need for repeated intervention and multiple attempts before people successfully quit
4. The need for a comprehensive tobacco control programme so that people are repeatedly encouraged to quit with a variety of readily available and accessible methods

However, despite the evidence of effective cessation methods, many quit attempts are still made without any form of cessation support. Even with effective cessation support, quit rates remain low (e.g. 17% smoking cessation at six months with any nicotine replacement therapies(50)). Although the chances of quitting using these methods is increased by between 1.4 to 2.1 times compared with no support.

2.2.3 Tobacco smoking cessation support available in New Zealand

New Zealand guidelines recommend that all health professionals undertake the ‘ABC’ of smoking cessation – ‘Ask’ about smoking status, give ‘Brief’ advice to stop smoking, and refer to (or provide) ‘Cessation’ support.(53) National cessation services are provided by a charitable trust organisation (The Quit Group) in the form of a free-phone counselling service (Quitline), subsidised NRT, online ordering of NRT, online blogs, and more recently a text message service (txt2quit). Primary care practices offer opportunistic brief advice and referral. Individual cessation counselling services are available in most hospitals, in some primary care practices, from private counsellors, and by a network of Māori smoking cessation services (Aukati kaipaipa). Health workers can undertake training in cessation and become ‘quit card
providers’ in order to provide their clients with vouchers for subsidised NRT ($5 per quit card) from any pharmacy. A private internet-based cessation service has been developed by a New Zealand general practitioner and is available at a cost to the general public.(55) Pharmaceutical companies also make available internet/email/text support programmes for those prescribed some pharmacological cessation therapies.

Several pharmacological options are available in New Zealand. NRT patches, gum and lozenges are subsidised and available from a quit card provider, Quitline, or on prescription from a doctor. Nortriptyline and buproprion are also subsidised but are only available on prescription from a doctor. Varenicline also requires a prescription and is not subsidised.

2.2.4 Tobacco smoking cessation attempts in New Zealand

In a 2008 survey of 5132 respondents from a nationally representative sample (New Zealand Tobacco Use Survey, NZTUS 2008), it was estimated that 19,600 New Zealanders (15-64 years of age) had successfully quit smoking in the previous 6-12 months.(10) In this survey, 78.5% of those who smoked said they would not smoke if they had their life over again.(10) One third of current smokers (32.5%) said they had ‘quit’ for at least 24 hours in the past 12 months. However, only one-third (34.3%) of those who had recently attempted to quit had used any cessation support or advice in that attempt. Of those who did use support, the most common methods were NRT (19.5%), followed by Quitline (12.8%) and assistance from their general practitioner (6.2%).(10)

Also during 2008, 53,509 people registered with Quitline. Using the number of people who self-identified as regular smokers in the 2006 national Census (597,792), it could be estimated that approximately 9% of smokers register with Quitline in a year. In 2008, this included 28,148 Quitline callers, 23,031 internet users, and 2330 txt2quit users.(56) Of these clients, 11,713 (22%) were Māori. In a separate external evaluation in 2007/08, a random sample of
nearly 4,000 Quitline clients were contacted at six months. Their six month continuous quit rate was reported to be 17% (assuming those lost to follow-up were not quit). If this rate can be applied to the entire Quitline clientele, that would be over 9,000 quitters each year – somewhat less than the Tobacco Use Survey estimate.

2.2.5 Summary

Tobacco smoking is an important cause of mortality and morbidity internationally and in New Zealand. It is also an important factor in health inequalities within New Zealand. Effective tobacco smoking cessation methods are available to New Zealanders at no, or low, cost. However cessation rates remain low and new ways to reduce these rates are needed.

2.3 Tobacco smoking and young adults

This section covers the prevalence of smoking in young adults, their interest in stopping smoking, effective methods for smoking cessation specific to young adults, and what young adults say they want in cessation support services. The term ‘young adult’ in research has been used to describe different age groups, often according to the background of the researchers. Young adults are also often included within studies of a wider age range targeting either ‘adolescents’ or ‘adults’. A commonly used age range, that is also used here, is 18 years to 25 years.

2.3.1 Tobacco smoking prevalence in young adults

Most people who smoke initiate tobacco smoking in adolescence despite the implementation of prevention interventions at a national level, such as smokefree environments legislation, age restrictions in cigarette purchasing, and mass media campaigns. In New Zealand, 33% of Quitline callers started smoking before 15 years of age and another 55% started between 15
and 24 years of age. During 2006 to 2008, there was little change in the proportion of 15-19 year-olds who were recorded as currently smoking (21%) in nation-wide surveys. This is of concern as smoking in adolescence predicts nicotine dependence in adulthood.

Smoking prevalence rates for New Zealand women are highest in young adults aged 20-24 years (33%). Although rates are more than twice as high for Māori women (61%) than non-Māori women (28%) in this age group. While the highest rates for New Zealand men are in those aged 25-29 years (41%), prevalence is still high (28.3%) in the 20-24 year age group and is again higher in Māori men than non-Māori men. This high prevalence amongst young adults has remained relatively stable since the 1990s, in contrast with the steady reductions in those aged 55 years and over.

In many other countries the highest prevalence of smoking occurs in young adults. For example, in Canada the highest proportion of people smoking occurs in those aged 18-29 years (28.3%) with the highest rate at 21 years of age (35.6%).

2.3.2 Tobacco smoking cessation in young adults

While most of the major health consequences of smoking occur in later life, a significant consequence of smoking as a young adult is addiction to nicotine. This means that although most young adults who smoke feel they will quit within the next few years, approximately half go on to smoke into their 60s. By this age, approximately half of those who smoke will die prematurely as a result of tobacco-induced diseases such as cardiovascular disease, COPD and cancer.

On an individual level, the more immediate benefits of quitting for a young adult are likely to include: resumption of taste and smell; increased spending money; increased respiratory fitness; fewer symptoms in those with asthma; and improvements in periodontal
Risk of stroke in young women, and cognitive impairments that are associated with regular smoking in young adults would also be reduced. Indeed some have shown that the risk of minor and major smoking-related diseases occurs in excess even in young adults with only a few years of smoking exposure.

2.3.2.1 Young adults intentions to quit smoking

Many large scale surveys have led researchers to conclude that the majority of young people who smoke do want to stop. Surveys in the US and United Kingdom (UK) found approximately two-thirds of young people who smoked wanted to quit. In New Zealand 65% of those aged 20-24 years said they would not smoke if they had their life over again. However, the desire to quit may not be as high in younger adolescents. The most recent New Zealand version of the Global Youth Tobacco Survey (the 2008 Year 10 In-depth Survey) found that under half (47%) of those who currently smoke aged 14-15 years wanted to ‘stop smoking now’.

Interestingly, although the proportion wanting to quit increased with age, the proportion who had attempted to quit in the past 12 months was higher in young adults (35% of 20-29 year olds) than in older age groups (18.2% of 60-64 year olds). US research also found young adults were more likely to report a serious quit attempt in the past year than older adults who smoked (48.6% versus 41.5%. Odds Ratio (OR) 1.33, 95% CI 1.09-1.64), although they did not differ significantly in motivation to quit (72% and 69%).

Although young adults have reported intentions to quit, qualitative research has found that there is often less sense of urgency to do so. In focus groups with US high school students, Balch found that they considered it important to quit eventually, but it was not a serious or urgent concern. Kishchuk et al found that Canadian university students were often coping with life changes and stresses, so quitting smoking took a lower priority.
than these other immediate concerns. Quitting smoking was seen as ‘another thing to do’ and smoking was also seen as ‘stress relief’ during these difficult times. In the UK, Fry et al found that continuing to smoke was influenced by powerful social factors such as peer groups, everyday routines, and a lack of anything more stimulating to do. Following a UK survey and interviews, Grimshaw et al concluded that cessation services needed to acknowledge that quitting is often not an imminent priority for this age group, despite the optimism of these young people that they would one day quit.

In line with this ambivalence or lack of urgency to quit, cessation services have reported difficulties with recruitment and retention of young adults. Gnich reported on a three-year pilot programme across Scotland with eight projects aiming to support young people who smoked (12-25 years of age) to quit. However, recruitment proved very difficult, with considerable time and effort resulting in insufficient participants to be able to draw conclusions about the projects’ effectiveness. Lipkus et al approached approximately 40,000 young people in US shopping malls and an amusement park. From this, only 402 people were eligible, consented and randomised to participate in a cessation study.

2.3.2.2 Effective tobacco smoking cessation support for young adults

Even if young adults do want to quit, there is little evidence of effective cessation interventions developed specifically for young adults. In one review of smoking cessation programmes across the US, only 5.6% were specifically targeting young adults.

Two recent reviews of smoking cessation intervention trials for those under 20 years of age found that many of the studies were underpowered statistically. They both concluded that interventions that tended to have more positive outcomes were complex and designed around issues for young people and their smoking. These interventions included some motivational enhancement (such as clarifying desire for change and reducing ambivalence
toward change, motivational interviewing, increasing willingness to change, response-contingent reinforcement, extrinsic rewards such as money or prizes, and stages-of-change techniques). Effects were also seen for programmes that used social influences (refusal assertion skill instruction, instruction in awareness of tobacco industry promotions, media and peer social influences, and correction of social informational inaccuracies) and cognitive-behavioural techniques (reasons for smoking and quitting, self-monitoring and how to cope effectively with stress, seeking out social support, relaxation, waiting out urges, self-management, and problem solving). (ibid)

Many of the individual studies on interventions designed specifically for young adults have produced negative results (76, 78-80) and/or had methodological issues. These include small sample size,(75, 78, 80-83) non-randomised studies,(35, 81) or using only self-report for cessation outcome without objective validation.(79, 84, 85) Furthermore, the majority of studies have been within the context of US colleges (universities), which may or may not be relevant in different circumstances such as in New Zealand.(35, 79, 82, 86) One large study was carried out in a population of military recruits, with an intervention specific to the Air Force, and therefore may not be generalisable to civilian populations.(84)

One of the high quality studies with a positive outcome used a theory-based internet programme for young adult students aged 18-24 years (n=257), based on social cognitive and problem behaviour theory.(86) This programme was delivered as part of a general interest college life online magazine, where the intervention group participants received $10 weekly incentives to visit. The control group received links to online health information and all students who smoked were also encouraged to enter a ‘Quit and Win’ competition. The trial demonstrated a significant increase in 30-day cessation at 30 weeks (40.5% versus 23.1%, OR 2.31 95%CI 1.58-3.40) but not in six month continuous abstinence rates. A point of difference in this study was that not all participants smoked daily or were highly addicted, and not all wanted to quit.
While several other internet-based programmes have been designed for young adults, most of them have struggled with recruitment and retention. (75, 81, 87) Escoffery et al described formative and process evaluations of a web-based intervention for university students that suffered from a high attrition rate. (81) Woodruff et al developed a virtual world real-time counselling intervention for a younger group (mean age 16 years) and experienced greater attrition in their intervention group than in the control group. (87) Patten et al, again targeting a younger age group (11-18 years), struggled to recruit, had a reduction in use over time, and did not find their internet intervention to be effective. (75) They suggested that the answer to the engagement challenge could be augmenting with more structured personal and proactive education components in person, by phone or by email.

Rabius also encountered retention as an issue with young adults in a large study that offered phone counselling on top of self-help materials to those randomised to the intervention group. (85) Only 52% of the young adults (n=420) were able to be followed for three months, compared with 66% of the older adults (n=3102; p=0.001). However, they did find a significantly higher self-reported cessation rate for the young adults in the phone counselling group at six months (8.8% versus 1.9%, p<0.05).

Another interesting theory-based intervention designed specifically for those aged 18-23 years used cognitive-behavioural techniques in a face-to-face interview, a self-help kit and a series of counselling emails. (82) Point prevalence abstinence difference at six months was not statistically significant between those receiving the intervention and a control group receiving a standard less-intensive adult programme (25% quit rate versus 14%, OR 2.0 95%CI 0.63-6.32; 59% verified quitting with a salivary cotinine test, giving 10.2% quit rate versus 5.7%, OR 1.92, 95%CI 0.35-10.32). However, this is more likely to have indicated an underpowered study (n= 83), than an ineffective intervention.
2.3.2.3 Young adults use of tobacco smoking cessation support

Where there is evidence for the effectiveness of smoking cessation support in adults, such as with counselling and nicotine replacement therapy, these tend to be under-used by young adults.(12) In comparisons with older adults, younger adults have been less likely to use pharmacotherapy or evidence-based behavioural support.(70, 88) For example, those aged 18-24 years were significantly less likely than older adults who smoked to use medications to quit (17.7% versus 32.5%, OR 0.45 95% CI 0.32-0.62) in the US 2005 National Health Interview Survey.(70)

In a New Zealand survey, the proportion of 20-24 year olds who were offered smoking cessation support, such as quitting advice, referral to a quitting programme or pharmacological support, in the past 12 months was significantly lower than for 25-64 year olds (16.8% versus 25-40%, respectively).(10) The majority (60.4%) of young men aged 15-19 years who smoked believed that people should be able to stop smoking without any support. This was significantly higher than in any other age groups. In this age group 15% reported that if they were thinking about quitting they would do it without any support. Indeed, the proportion of those who had recently attempted to quit with NRT was lowest in 15-19 year olds (8.8%) and 20-24 year olds (13.5%), compared with 50-59 year olds (27.4%).(10)

However in 2009, a respectable 11,552 young people (15-24 years) registered with Quitline.(89) Proportionally, 8.3% of people registering with Quitline services were aged 15-19 years and 14.5% were 20-24 years. Approximately three-quarters of these young clients used Quitline’s text messaging service (txt2quit) with smaller numbers using the telephone counselling or web services. Quitline has previously reported an increasing trend in young people accessing their services,(58) so perhaps more young adults will be accessing cessation support in the future.
2.3.2.4 Designing smoking cessation interventions for young adults

Many authors have recognised the paucity of research and effective services specifically designed for young adults who want to quit and have called for the need to redesign cessation services for young people.(16, 60, 90-94)

Young adults may have different smoking patterns than other adults, tending to smoke fewer cigarettes and less often.(60, 70, 73, 95) They are more likely to say they want to quit and more likely to report recent quit attempts,(10, 70, 95) but less likely to use effective cessation support,(10, 12, 70, 88, 95).

Young adults may have different beliefs about their smoking and about quitting than older adults and these may affect their requirements in cessation services.(16, 93) There are complex social aspects to their smoking and quitting,(14) and many believe there are positive consequences of smoking such as emotional benefits (helps to relax, parties are more fun, forget worries, or prevent boredom), self-confidence, and body image.(96) There may even be differences in their beliefs about illness that affect their opinions on healthcare in general.(97)

Stress in particular has been examined in university students where smoking appears to serve multiple functions such as: facilitating a social interaction when feeling isolated; acting as an idiom for distress, signalling non-verbally to others that they are stressed; modulating stress in relationships albeit briefly; providing a way to take a time-limited break and re-focus; and relieving boredom.(98)

As a result of their research, Kishchuk et al suggested cessation services for young adults should not be rigidly focused on quitting but grounded in opportunities for exploration of social and personal identities that exclude smoking.(16) They also suggested involving
naturally-occurring social groups rather than adult strangers and including ways of helping
students cope with significant stresses and demands they are facing.

Bader et al devised recommendations for young adult interventions based on a literature
review, young adult focus groups, and a review by experts. (15) The themes initiated by the
young adult focus groups were around the social connection of smoking and the fact that it is
easier to smoke than not smoke. With respect to cessation services the young adults felt that
providers should be ex-smokers, and services should be free, accessible and not require
appointments. Other suggestions included low-demand interventions, social support, settings
in naturally occurring social groups, and participating in activities incompatible with
smoking. The authors recommended that strategies for smoking cessation should be tailored
to fit young adults’ health beliefs, which tend to undervalue the health consequences of
smoking. One of the top priorities in their recommendations was ‘recruitment, engagement
and retention’. It was suggested that social marketing principles could be beneficial in
designing and promoting smoking cessation programmes for this purpose. They also
recommended that research differentiates this age group and gives young adults a voice in
research questions and in designing interventions.

“There was consensus on critical factors for smoking cessation methods, including
low or no cost, convenience and flexibility, interventions that place few demands on
participants, and innovative, non-traditional interventions specific to the unique needs of
young adults”.(15)

Many of these themes have been echoed by other researchers in their recommendations.
These have included making young adults aware of the social effects of smoking and quitting,
providing suggestions for alternative social tools and techniques, stress management and
enhancing self-confidence. (14, 72, 96, 99) However, Staten et al’s qualitative research with
18-24 year olds found that many were not interested in a smoking cessation programme at all
and thought they should ‘just quit’. (71) They stated that programmes for those struggling to
quit should consider cost and convenience as important. Programmes should include education on nicotine addiction and withdrawal, immediate and long-term benefits of quitting and feedback on physiology (e.g. heart rate, lung age), and supportive strategies such as distraction from cravings, managing emotions, relaxation, and positive self-talk/imaging as non-smoker self.

Gnich et al developed a list of principles and practices to guide engagement with young people from the suggestions of their stakeholders (Table 2.2). (74)

**Table 2-2: Suggested principles and practices to underpin youth smoking cessation services**

<table>
<thead>
<tr>
<th>Key principle or practice:</th>
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<tbody>
<tr>
<td>1. Proactively engaging with young people through multiple methods</td>
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<tr>
<td>2. Being client-centred and tailoring services to client needs</td>
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<td>3. Demonstrating trustworthiness and confidentiality</td>
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<td>4. Responding to need in a timely manner</td>
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<td>5. Focusing upon client empowerment</td>
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<td>6. Adopting a whole-person (holistic) approach</td>
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<td>7. Being non-judgemental</td>
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<td>8. Establishing rolling programmes which allow clients to 'dip in and out'</td>
</tr>
<tr>
<td>9. Making sessions fun</td>
</tr>
<tr>
<td>10. Facilitating access to NRT* as appropriate</td>
</tr>
<tr>
<td>11. Information giving and education given in response to clients' requests</td>
</tr>
<tr>
<td>12. Capitalizing on peer support</td>
</tr>
<tr>
<td>13. Working to develop a wider environment that does not support smoking</td>
</tr>
</tbody>
</table>

* Nicotine replacement therapy

[Source: Gnich 08 (74)]

### 2.3.3 Summary

Young adults have high rates of tobacco smoking internationally and in New Zealand. A high proportion of young adults who smoke say that they would rather not smoke. However there does appear to be some ambivalence and little urgency in their desires to quit. There is also
sparse evidence of effective tobacco smoking cessation strategies specifically for young adults. Where effective interventions exist, young adults tend to underutilise them. This may be partly because few interventions have been tailored for use in their age group. Suggestions for the design of tobacco smoking cessation services specifically for young adults include the consideration of social factors, health beliefs and fitting in with lifestyle factors.

2.4 The use of mobile phones in health

This section summarises the use of mobile phones in health services and in behaviour change support programmes. The potential benefits and limitations associated with the use of mobile phones in health and behaviour change programmes are then discussed.

2.4.1 The use of mobile phones

Since the introduction of mobile phone networks in the 1980s, the use of mobile phones has grown exponentially. By the end of 2008, there were an estimated 4.1 billion mobile cellular subscriptions in the world, approximately equivalent to ownership by 61% of the world's population. Some countries are reported to have more mobile phones than people. In the developing world, mobile phones reached 49.5% ownership by the end of 2008 from close to 0% ten years previously. This is faster than the growth of any other technology to date. For example, internet usage was estimated to have reached only 13% in the developing world and 23% globally, by the end of 2007. Mobile subscriptions overtook fixed telephone lines globally in 2002. Fixed telephone lines have remained under 20% for some years with decreases in developed countries and only small growth in developing countries. Therefore the mobile phone is the most widespread information and communications technology (ICT) in the world today.

The pattern of uptake of mobile phones has been described according to an ‘S’-shaped curve. That is, initially slow due to high cost and other barriers, then a rapid
increase as the general population takes it up, then flattening out again as the saturation phase is reached (see Figure 2-1). New Zealand appears to be in the saturation phase. The Commerce Commission reports more active mobile phone connections than people living in the country (4.9 million at December 2009 for 4.3 million people, or 114 per 100 population).(103) This reflects the use of two phones by many individuals (business and personal, or one on each major network).

**Figure 2-1: Example of an S-shaped curve for the uptake of a new product or technology**

![The Product Diffusion Curve](Source:www.mindtools.com)

There has also been rapid expansion in the use of text messaging (SMS) since the first commercial text message was sent in 1992. In the US alone, there were estimated to be 1.56 trillion SMS messages sent in 2009.(104) At the end of 2006, 72% of mobile phone users were reported to be using text messaging.

Newer mobile phone functions include cameras, sending/receiving pictures and videos, and accessing the internet via the mobile phone network or a mobile broadband connection. These rely on having a multimedia capable handset. In a 2005 survey of 4000 participants from 21 countries, 53% of mobile phone consumers said they were able to access multimedia services,
defined as data services like mobile email or browsing mobile websites.(105) Proportions varied by region and by age with those under 34 years being more likely to have a multimedia phone. Globally, mobile broadband connections reached 14% in developed countries by the end of 2008, but less than 1% in the developing world.(17)

The ‘digital divide’ describes the higher usage of technology by those in higher socio-economic positions than those in lower positions. The digital divide is reported to be much less of an issue with mobile phone usage than with other forms of technology such as internet usage.(106) This is reflected by the more rapid uptake of mobile phone usage globally, and can also be demonstrated within countries. In New Zealand in 2006, more households had access to mobile phones (86.2%) than computers (71.6%) or the internet (64.5%).(107)

A 2004 representative survey conducted in New Zealand found that there was no difference between the mobile phone use amongst Māori and the general population. Usage among Pacific people was almost as high.(108) Regular use of text messaging was higher among Māori and Pacific Island groups than NZ European in this survey. A survey in rural general practices found more Māori owned mobile phones with cameras (68%) than were owned by non-Māori (51%) (p=0.019).(109) There were also no significant differences by ethnicity in the acceptability of using their mobile phones for health care.

Similarly in the US, a 2009 survey found that the proportion with mobile phones was similar across different ethnic groups (e.g. ‘White’ 84%, ‘Black’ 83%, Hispanic 89%).(110) ‘Black’ and Hispanic people were more likely to use mobile functions than ‘Whites’, including sending text messages (47% and 59%, compared with 40%), accessing the internet (21% and 23%, compared with 12%), and sending/receiving instant messages (22% and 14%, compared with 8%). The margin of error for this survey was given as +/-2.4 percentage points.
There is also emerging evidence that those at highest need may actually be higher users of mobile phones. In the US, adults living in or near poverty were more likely to live in a household with mobile phones only (no fixed telephone line).(111) Adults living in mobile-only households were more likely to have experienced financial barriers to health care, not have a usual place to go for health care, not have health insurance, to have experienced serious psychological distress, to have been diagnosed with diabetes, and less likely to have received an influenza vaccination.

In Finland, a nationally representative survey of 7,292 adolescents found that mobile phones were used more in those with lower socioeconomic backgrounds and non-nuclear families, lower levels of achievement at school, poorer self-rated health and more self-reported depression than among other adolescents.(112) A previous Finnish survey found that the intensity of mobile phone use by adolescents was associated with tobacco smoking and alcohol use.(19) A 2000 representative survey of 17 year olds across France also found a link between heavy tobacco use and mobile phone ownership.(20) A US survey of 14-16 year olds suggested an association of text messaging, emailing and instant messaging with increased levels of alcohol use, tobacco use, and having an alcoholic parent.(113)

### 2.4.2 The use of mobile phones in health

M-health is a reasonably new term that has been defined as “the delivery of health-related services via mobile communications devices”.(114) Medical literature about the use of mobile phones in health has only started to increase since the early 2000s. Initially, mobile phones were mainly used as another form of communication with patients to improve the efficiency and effectiveness of existing health care services. They have also been used to collect data and monitor long-term conditions. Gradually, mobile phones are starting to be used to deliver interventions, either alone or in tandem with other modes of delivery. More recent exciting
advances have taken place in developing countries and with ‘smartphones’. These are all explained below.

Most of the early studies describe the sending of text messages from health service providers to their clients as reminders to either increase attendance rates at appointments,(21, 22, 115) or to improve adherence to treatment.(23, 24) Text messages have also been sent in this way to report test results to clients.(25, 26) Many of the interventions studied have been about using text messaging to improve communications with patients in the primary care setting.(22, 116) A more recent New Zealand survey found that young adults were happy to communicate with their primary care provider by text messaging.(117) This survey also found that young adults were already communicating about health issues by text message with their friends and families.

Another early study described the use of mobile phones for ‘ecological momentary assessment’ and data collection in the self-management of alcohol consumption. (118) This was carried out using an interactive voice response system (IVRS) and the stated advantages were instantaneous entry of data into the database and easy integration into daily life. This was a feasibility study and this method has since been used in at least one other small substance abuse study.(119) Other more recent examples of data collection by mobile phone include questionnaires downloaded onto mobile phones to collect physical activity data,(120) alcohol related behaviours in adolescents,(121) and mood in adolescents.(122)

There is a growing body of literature around mobile phone-based interventions for the management of long-term conditions between clinic visits. These include a variety of functions such as patients communicating results of home monitoring to healthcare providers, and providers responding with advice, updated care plans and medication instructions. Much of this research to date has been in people with diabetes mellitus – sending results of glucose monitoring and receiving advice on alterations to medications or diet.(27, 123, 124) There are
also broader interventions around cardiovascular disease ‘tele-monitoring’ that may or may not include mobile phones, but tend to use fixed telephone lines and internet connections as well. (125-127)

A 2008 review of the use of mobile phones to provide care and disease management support found 25 studies (20 randomised controlled trials and 5 controlled trials) covering 12 clinical areas. (128) The authors state that overall there were significant improvements in health outcomes and care processes. The specific areas improved included medication adherence, asthma symptoms, HbA1c in diabetes, stress levels, smoking cessation rates, appointment attendance, time to diagnosis and treatment, and training.

The potential for improving healthcare with mobile phones in developing countries is enormous and has been the subject of much recent discussion. (114, 129-131) Developing countries benefit where there is currently little infrastructure for standard telecommunications (fixed lines or internet) but mobile phone infrastructure is easier and cheaper to establish, and correspondingly the growth in coverage and uptake is currently exponential. One example from India describes the development of a specific mobile phone device with several other tools (such as automated decision support, plug in sensors, printer, user recognition) for use by local village health champions. (132) Mobile network connectivity allows the support of remote specialists, collection of data and ordering of supplies. Another example from Kenya uses a simpler automated text messaging (SMS) system for the community-based diagnosis and management of acute malnutrition in children. (133)

‘Smartphones’ are adding a new dimension to the use of mobile phones in health. Smartphones are mobile phones that run on an operating system (OS) that allows the downloading of applications onto the phone. (134) The benefits of this are almost full computer functions (including internet access) on the mobile phone. There were 5,805 health, medical and fitness applications available for one brand of smartphone (the Apple iphone) by
the beginning of 2010. Of the medical applications, 33% were for consumers, 32% for physicians, 17% for medical students, and 6% for other health professionals. The applications for use by consumers cover very similar areas to those already mentioned (e.g. medication reminders, remote monitoring, and self-management of long-term conditions).

2.4.3 The use of mobile phones for healthy behaviour change support

A further use of mobile phones in health is to deliver interventions designed to support individuals in making healthy behaviour change. Behaviour modification is an important part of many public health programmes that aim to prevent some of the major global disease burdens such as cardiovascular disease, diabetes and cancer. These programmes often attempt to motivate and support people to alter lifestyles that pose significant risks to individual and population health, such as smoking tobacco, alcohol and substance misuse, unhealthy diets and sedentary lifestyles.

There have been several recent general literature reviews in this area. Fjeldsoe reviewed published studies on the application of text messaging for delivering health behaviour change interventions up to March 2008. Of the 14 included studies, eight were randomised controlled trials (RCTs; although one was cluster randomised and one with a cross-over design), and the remaining six were before-after single group studies. They excluded studies that did not have pre-post design, where text messaging was not the main method of intervention delivery and that were not in English. The authors used Cohen’s formula and guideline to determine effect sizes of studies with a control group and sufficient data (six studies). The range of effect sizes was from 0.09 to 1.38, with the authors concluded that four studies had medium-large effects and two had small effect sizes.

Of the individual studies included, two of the interventions were designed to help people stop smoking, one to increase physical activity, and one was an ‘anti-obesity’ behaviour
modification. These ‘preventive health behaviour’ interventions tended to be initiated by the health providers/researchers. The remaining interventions were about self-management of asthma, hypertension, diabetes, and one for bulimia nervosa outpatient care. In these interventions, participants initiated the text message dialogue. All but two interventions used messages tailored to the participant, and five supplemented text messages with other strategies. Not all of the included studies were of high quality. Six studies were non-randomised and only five reported conducting sample size calculations. Accordingly, although eight reported significant positive findings, another five did not have statistical power to demonstrate the significance of their positive findings, and one reported no changes in behaviour.

A more recent review of the literature had similar inclusion criteria of text message-based studies for health behaviour change, but with more rigorous quality criteria of randomised or quasi-experimental controlled trials only.(30) This review also excluded studies on appointment reminders and adherence, and those where text messaging was an optional component of the intervention. Twelve studies were included. The authors reviewed the quality of included studies, finding several issues such as four studies that did not use validated measures. Three were not sufficiently powered to detect a difference in their primary outcome. Indeed, apart from one, the studies were small with between 16 and 126 participants. Of the nine that were sufficiently powered, eight were said to demonstrate the effectiveness of text messaging on behaviour change or health outcomes. Positive effects were seen in studies on weight loss, smoking cessation and diabetes management. New studies since the previous review included one intervention encouraging vitamin adherence, two programmes for weight loss, one to increase physical activity, and another about diabetes management. The frequency of text messaging in the interventions ranged from one message weekly to five each day. Most had an interactive component (only two were unidirectional) and all the disease prevention interventions used automated messaging.
A third review described ‘ecological momentary interventions’ as those that are delivered to people as they go about their daily lives.(135) These can be supplementary to other interventions or stand-alone. This was a wider review including all types of studies and palm-top computer-based interventions in addition to mobile phone interventions. They included studies that aimed to improve psychological or physical health or health behaviours using a mobile, electronic device to deliver a psychosocial intervention in everyday lives, and where the intervention was evaluated with respect to behaviour or symptom change. This review also covered other areas of brief intervention, such as reducing anxiety and eating disorder symptoms. The authors concluded that there is a promising evidence base for acceptability and efficacy for m-health interventions. However, several limitations are discussed. Studies do not address the issue of self-selection out of studies by those uncomfortable using mobile electronic devices. Most studies had relatively short follow-up periods. A variety of study designs have been used. The authors of this review make recommendations for future research. These include the need for more RCTs with longer term outcomes and patient perspectives, with comparisons against existing treatments. They also point to a need for research examining the association between adherence to the intervention (completing the desired duration or components of the programme) and its efficacy. Cost-effectiveness analyses are also recommended. (ibid)

More recently, mobile phones programmes solely for health promotion and the provision of information have been introduced. There do not appear to be any published trials as yet. One example of this is *SEXINFO*, which is a sexual health text messaging information service in the US.(136) Another US example is *txt4baby*, a text messaging health information service for mothers-to-be and new mothers.
2.4.4 The benefits of using mobile phones to deliver health interventions

Population health programmes can be costly and difficult to implement. Population change usually requires multifaceted efforts, ranging from individual level, such as face-to-face counselling, to population level delivery, such as mass media campaigns, taxation and regulation.(137) Individual programmes can be tailored to the participant, but often require significant health resources and may only reach a small proportion of the population. Population level efforts such as mass media campaigns may have a smaller effect but a far greater reach. Mobile phone programmes attempt to combine the benefits of both by providing an individual level programme (tailored in intensity and message), but that also can be delivered to very large and disparate populations. The ensuing benefits are reaching a large proportion of the target audience with far fewer health (particularly people) resources and therefore at lower cost and improved cost-effectiveness.

Delivering services and programmes by mobile phone means they are accessible for those who have difficulty attending a centre due to issues such as transport, cost, family care, time off work, and distance from available services. Programmes delivered by mobile phone do not require participants to attend a clinic or even to sit at their computer and open a specific webpage. This makes programmes far more proactive (initiated by the service) than many other services that may require action by the participant before they can start to impart information or provide support.(29, 30)

Mobile phones are well integrated into people’s daily lives, tending to be always on and always carried. Therefore, communication with participants in programmes can be regular and frequent, and messages can be delivered in a time-sensitive manner.(30-32, 34) Participants can view messages immediately if they have been sent at appropriate times (e.g. when they are due to take medication) or view them later at a time that suits them better.
Participants can also send a message or call to ask for support whenever they find they need it. (34)

Tailoring programmes to the participant so that the information provided is relevant to the individual, has been shown to improve their effectiveness. (49) Much of the research on tailoring technology-based programmes has been conducted with internet-based interventions. (138) While mobile phone-based interventions may collect and impart less detailed information, tailoring to the individual is still possible. (30, 31, 34) This can include personalising messages with the participant’s name and selecting relevant messages to be sent based on participant characteristics.

Once shown to be effective, mobile phone programmes could be easily scaled up for delivery to large multi-national populations. This has been demonstrated by the scaling up of a text messaging smoking cessation intervention (STOMP (34)) into a service across New Zealand (txt2quit) (139). This intervention is also the subject of a large trial (n=5800) in the UK (140). If ‘public health impact’ is indeed the sum of efficacy and reach, (141) then individualised mobile health programmes delivered to mass populations have the potential to significantly improve health.

2.4.4.1 The benefits of using mobile phones for health behaviour change interventions

Some aspects of mobile phones make them an ideal delivery method for interventions to support individual behavioural change for more healthy lifestyles. Behaviour change support is generally based on several theories including Social Cognitive Theory (SCT), (142) the Transtheoretical Model (TTM), (143) the Health Belief Model (HBM), (144) and the Theory of Planned Behaviour (TPB). (145) Similarities in concepts or important components across these theories are often noted. (146, 147) These include reviewing outcome expectations and
positive reinforcement to increase self-efficacy, encouraging social support, assistance with goal setting, as well as on-going support over a prolonged period of time. These components are discussed below with respect to how mobile phones can be useful.

Many theories involve an appraisal of positive and negative aspects of the behaviour and its expected outcomes. These positive and negative aspects may be called different things, such as benefits and barriers, pros and cons, behavioural beliefs, or outcome expectations.(146) Balancing the negative consequences of continued smoking (such as cost, smell, impaired taste, tobacco-related diseases) against the benefits of smoking, provides motivation to quit. However this motivation may be fleeting, particularly in the initial stages of quitting when withdrawal symptoms (the negative consequences of stopping smoking) are common.(147) Frequent and regular mobile phone messages during this time can provide reminders of that motivation. These messages can also reinforce expectations of the likelihood and value of future positive outcomes and health benefits, and of the short-lived nature of the current negative withdrawal symptoms.

Another major theory component is ‘self-efficacy’, which refers to the belief and confidence in a person’s ability to perform a certain behaviour (also called ‘perceived behavioural control’ by some theories).(146) Self-efficacy is said to be “a relatively consistent predictor of subsequent health behaviour change”.(148) Regular mobile phone messages can boost participants’ confidence in their ability to take some control, provide reminders of how long they have been quit, and reinforce how well they have done so far (e.g. “congrats you have reached 1 week smokefree!”). Prompting reflection on how stopping smoking has improved how they feel, what they can physically achieve, or relationships with others, should assist with this. This sense of satisfaction may maintain self-efficacy in continuing the behaviour. (147)
While the effectiveness of social support is not completely clear, positive reinforcement is an aspect of many behaviour change theories. Mobile phone interventions can encourage participants to ask for support from their ‘phone book’ in order to receive messages of support from their own network. This also makes a statement of intention and commitment to perform the behaviour that their social network may then hold them to. Behavioural intentions are an important factor in the Theory of Planned Behaviour.

Some theories describe identifying and planning for situations where the behaviour change may be difficult. For example, having a morning coffee or going out to a bar are common ‘cues’ to smoke for many people. Mobile phones can be used to ask for extra immediate help when confronted by these trigger situations. The participant can send a text message and receive an immediate automated response with advice on coping mechanisms. In the case of smoking cessation, this can also provide distraction for the few minutes necessary to help them to get through that nicotine craving or lapse.

One aspect where mobile phone programmes have an advantage over traditional services is being able to provide ongoing motivation and support over longer periods of time at a low cost. Relapse is a constant threat for many, long after they have successfully instigated the behaviour change. Providing ongoing support after the end of an intensive programme has been identified as important in smoking cessation. While there is currently little evidence of what works for relapse prevention, it seems sensible that ongoing messages of support and the availability of help on demand could be useful for some.

2.4.5 The limitations of using mobile phones to deliver health interventions

Several limitations of mobile phone health interventions are apparent from the literature described above. These include the limits on the amount of information that can be sent by mobile phone, the need to continue to engage participants and to measure that engagement,
understanding whether mobile phone intervention studies are generalisable, the need for more information to be published, and the possibility of mobile phone ‘addiction’. These are discussed in turn below.

The amount of information that can be provided by mobile phone interventions is limited. Text messages are limited in the number of characters that are allowed and video messages are limited in size (and therefore duration of the video clip). Some participants may want to access more information than this. Some interventions have used a website to provide further information as well as links to other relevant sites for those who want it.(150) Others provide access to a counsellor on the phone, or other tools and materials.(31)

Mobile phone-based interventions, as with other interventions, require participants to be engaged to open and view the messages and to take something from them. It can be difficult to know whether participants are engaged with mobile phone interventions, and to obtain some idea of the ‘adherence’ to the programme over time and the ‘dose’ of the programme received. Methods of detecting whether messages have been opened may be possible in certain circumstances, and may be useful in determining whether participants continued to view messages over time.

One common criticism of mobile phone interventions is whether they can be effective for all sub-groups of the population. While countries like New Zealand may report greater than 100% penetration of mobile phones and 90% coverage of the country, this does not actually mean that everyone uses a mobile phone. It also does not mean that everyone wants to use a mobile phone-based intervention. Research into the reasons why people choose not to participate in mobile phone health intervention studies might provide insights into generalisability that would guide future implementation into health services.
As yet there has been very little research reporting which components of mobile phone programmes are most effective. Generally programmes are developed as a whole package of complex components and are tested as such, often including other aspects beyond mobile phones. Qualitative research could be useful alongside trials of effectiveness. Qualitative methods have been recommended for complex interventions and for health technology assessment. These methods can be used to provide insights into the user experience of what was effective and which components may not be necessary. Other information that has generally not been included in published studies to date is the cost of development or of running the interventions.

There are also many more mobile phone-based health programmes than have been included in the reviews discussed above. Many by commercial organisations that may not evaluate with rigorous RCTs due to the time and cost involved, or who may not publish their own evaluations. Evaluations could usefully add to the body of knowledge about what works so that others can build on this to develop more effective programmes. In particular, smartphone health applications are easily developed and sold directly online. This can make it difficult for people to know if interventions are evidence-based or have been proven to be effective.

Some concerns have been raised over the possibility of addiction to mobile phones, particularly with text messaging in young people. A survey of 946 15-24 year-old Australians found ‘withdrawal’ or a feeling of loss without their mobile phone, excessive use of mobile phones, and a loss of control over their mobile phone use. The authors argue these could be seen as symptoms of behavioural addiction, which could cause problems for these young people and their educational achievement or future employment.

Finally, it is worth mentioning that there are mobile phone network industry guidelines protecting against unsolicited messages to mobile phones. Mobile phone health interventions will have to ensure that they meet the requirements of these guidelines, such as participants
consenting to receive messages and advising participants of easy methods to opt out of the programme.

2.5 Literature Review Summary

This literature review has outlined the importance of tobacco smoking for New Zealand as the single most important risk factor for disease and a significant cause of health inequalities. Evidence of effective methods to help people stop smoking is available, and many of these methods are available in New Zealand, such as a free-phone counselling service and subsidised nicotine replacement therapy. Young adults have the highest prevalence rates of tobacco smoking in the community and want to stop smoking as much as any other age group. However they do not tend to use available cessation services or pharmacological support. Many researchers have suggested that young adults have different smoking cessation support requirements from adults and services should be targeted accordingly. This includes dealing with social factors that promote smoking and work against quitting, and developing services that fit well within young adult lifestyles and priorities.

Mobile phones are ubiquitous, and can be considered the main means of communication for young adults. Mobile phones are increasingly being used to support traditional health services. This includes appointment reminders, notification of results, medication adherence reminders, and monitoring of long-term conditions between visits. A new area is the use of mobile phones to deliver interventions to change health-related behaviours, such as smoking cessation support, physical activity promotion and weight loss programmes. The benefits of such interventions include the wide reach, proactive nature, timeliness and tailoring of messages, and potential for scalability. The limitations include the limits on information that can be sent, little understanding of engagement and of effective components, and potential issues with generalisability and mobile phone addiction. A more specific and systematic
review of interventions using mobile phones for smoking cessation is presented in the following chapter.
3 Systematic Review and Meta-analysis of the use of Mobile Phones in Smoking Cessation

3.1 Introduction
A systematic review of mobile phone interventions for smoking cessation was conducted by the candidate and submitted to the Cochrane collaboration of systematic reviews. There had been several published Cochrane reviews of different methods of smoking cessation support previously but none examining mobile phone interventions specifically. One mobile phone trial had been included in the review of telephone counselling studies, however it was recognised that this intervention was significantly different from the others in the review. The need for a separate review of mobile phone-based interventions was identified in discussions between the Cochrane Tobacco Addiction Group and the candidate. A protocol was published in 2008 and the review was published in 2009 with the candidate as the lead author. This has been revised and updated by the candidate for this thesis.

3.2 Objectives
The aim of this review was to assess whether mobile phone based interventions are effective at helping people to stop smoking. The main objective was to determine the effectiveness of mobile phone-based interventions for tobacco smoking with respect to standard cessation outcomes in comparison with control groups in randomised trials.

3.3 Methods
This review was carried out according to the guidelines for systematic reviews outlined in the Cochrane Handbook and the policies of the Cochrane Tobacco Addiction Group.
3.3.1 Inclusion criteria

3.3.1.1 Types of studies

The studies to be included in this review were randomised or quasi-randomised trials. No language or publication date restrictions were applied.

3.3.1.2 Types of participants

Participants could be of any age and could include anyone who wanted to quit smoking. There are various ‘definitions’ of smokers such as those who smoke daily or those who have smoked at least 100 cigarettes in their lifetime. It was decided not to restrict to a particular definition but to report on the definitions used in the included studies.

3.3.1.3 Types of interventions

Studies were included that examined any type of mobile phone-based intervention. This included any intervention aimed at mobile phone users, based around delivery via mobile phone, and using any functions or applications that can be used or sent via a mobile phone. Trials were excluded where mobile phones were seen as an adjunct to face-to-face or internet programmes such as to remind participants of appointments or to contact participants between visits.

3.3.1.4 Types of outcome measures

The primary outcome of interest was smoking abstinence at six months after the start of the intervention, and longer wherever the data were available. Both sustained abstinence (no smoking since the target quit day or start of the programme) and point prevalence abstinence (no smoking in the past seven days) were considered. Both self-reported and biochemically verified smoking statuses were considered. Short-term cessation outcomes were also included where studies reported both long-term and short-term results.
3.3.2 Search strategy

Studies were identified using the following methods:

- The specialised register of the Tobacco Addiction Review group was searched using the terms 'mobile phone' 'cell phone' 'txt' 'pxt' 'sms' 'mms' in the title or abstract or as keywords.

- Other databases that were searched were Medline, Embase, Cinahl, PsycINFO and the Cochrane library using the following strategy with small modifications to suit the specific databases.

  (cellular phone/ or mobile phone* or "cell* adj phone*" or txt or pxt or sms or mms)

  AND

  (smoking/ or smoking cessation/ or tobacco use disorder/ or smok* or tobacco or cigar* or nicotine).

- The National Research Register Archive and the UK Clinical Research Network Portfolio for current projects in the UK and the ClinicalTrials register for ongoing or recently completed studies were also searched.

- Reference lists of identified studies were searched and attempts were made to contact the authors of ongoing studies.

3.3.3 Selection of studies

A comprehensive search was run by the candidate using the strategy outlined above. Citations were downloaded and duplicate citations deleted. From the abstracts and the titles of the downloaded citations, the candidate and one other reviewer (Hayden McRobbie, HM) identified potentially eligible studies and obtained full text copies of these studies. The candidate and the reviewer independently selected studies to be included against the criteria listed above and any disagreements were resolved by discussion. An arbiter was selected (Ron Borland, RB) but was not required. The Cochrane Tobacco Addiction Group also had
some input into the exclusion of some studies. Reasons for exclusion of studies were recorded.

3.3.4 Data collection

Methodological details were extracted from the included studies by the candidate using a standardised form. The articles were not blinded for authors, institution and journal, because the candidate and reviewer who performed the quality assessment were familiar with the literature. If an article did not contain enough information on methodological criteria, i.e. if one or more criteria were scored 'unclear', the candidate contacted the trial authors for additional information. A second reviewer (Ruey bin Lin, RL) independently extracted the data.

The data collected included the following.

Characteristics of the study participants:
- Definition of smoking status as used in the study
- Age and any other recorded characteristics of participants in the study
- Other inclusion criteria
- Exclusion criteria

Interventions used:
- Type and 'dose' of mobile phone intervention used
- Type of control/placebo intervention used
- Duration of intervention
- Duration of follow up

Assessment of risk of bias in included studies:
- Method of randomisation
- Presence or absence of blinding to treatment allocation (non-blinded/open label, single blind, double blind, triple blind)
• Quality of allocation concealment (adequate, unclear, inadequate, not used)
• Number of participants randomized, excluded and lost to follow up.
• Whether an intention to treat analysis was carried out
• Whether a power calculation was reported
• Duration, timing and location of the study

Measures of treatment effect:
• Smoking cessation at six months (self reported abstinence and/or biochemically verified abstinence)
• Smoking cessation at final follow up (if follow up greater than six months and where these data were available)
• Smoking cessation at four weeks (self reported abstinence and/or biochemically verified abstinence)
• Definition of smoking cessation as used in the study

3.3.5 Dealing with missing data

According to the policies of the Cochrane Tobacco Addiction Group, those trial participants who dropped out of the trials or were lost to follow up were regarded as continuing to smoke.

3.3.6 Data synthesis

A meta-analysis of the included studies was conducted, using the Mantel-Haenszel Risk Ratio, fixed-effect method, provided that there was no evidence of substantial statistical heterogeneity as assessed by the $I^2$ statistic.\(^{(156)}\) The $I^2$ statistic is a measure of the inconsistency in studies’ results, describing “the percentage of total variation across studies that is due to heterogeneity rather than chance”.\(^{(ibid)}\) Where meta-analysis was not possible summary and descriptive statistics were presented.
3.4 Results

3.4.1 Results of the search

One hundred and three studies were initially identified by the literature search strategy outlined above. The use of terms with multiple possible meanings in the search strategy (cell, txt, pxt, sms, mms) meant that many unrelated studies were identified and these were immediately excluded. Six letters about country-specific data on a potential link between the increase in mobile phone use and decline in adolescent smoking were excluded as they were not trials. This left nine remaining papers, four of which were excluded as they were small non-randomized feasibility studies.(35, 157-159) A further two studies were excluded because follow-up was for only eight weeks (160) or three months.(36) This programme was also considerably different in that the mobile phones were used to make proactive counselling phone calls for free to an HIV positive population.(Table 3-1)

Two articles described one trial - separately reporting main results(34) and an analysis of results for Māori compared with non-Māori.(161) There was some debate over whether to include the remaining article as the programme placed equal emphasis on internet/email and mobile phone components.(162) Against inclusion was the fact that the effect of these different components could not be separated. However it was decided to include it as the mobile phone components were seen as a very important focus of this 'digital multi-media smoking cessation intervention', and these components were similar to those in other included studies (daily information and motivational text messages and pre-recorded audio messages). Contact with this author revealed another soon-to-be-published study on the same intervention with a different sample which was included.(163)

One as yet unpublished pilot study was located and included after the author provided a report and data.(140) Therefore four trials, using two different programmes and reported in five papers, have been included in this review. At the time of revision for this thesis one further
paper was located by an already identified author. However this was again excluded due to only three month outcomes and no cessation outcomes. (164)

**Table 3-1: Characteristics of studies excluded from the systematic review**

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applegate 2007(160)</td>
<td>Abstract describing intervention to increase adherence to the use of nicotine replacement gum in people attempting to quit smoking. Duration 8 weeks.</td>
</tr>
<tr>
<td>Haug 2008(157)</td>
<td>Non randomized feasibility study. Duration 12 weeks</td>
</tr>
<tr>
<td>Haug 2009(164)</td>
<td>Randomised. Follow up only 3 months. No cessation outcomes.</td>
</tr>
<tr>
<td>Lazev 2004(158)</td>
<td>Not randomized. No control group. Feasibility study for the programme presented in Vidrine 06b.</td>
</tr>
<tr>
<td>Obermayer 2004(35)</td>
<td>Not randomized. No control group.</td>
</tr>
<tr>
<td>Riley 2008(159)</td>
<td>Small non randomized study with only 6 weeks follow up.</td>
</tr>
<tr>
<td>Vidrine 2006(36)</td>
<td>Randomized trial, follow up only 3 months.</td>
</tr>
</tbody>
</table>

**3.4.2 Description of included studies**

The first two trials (Rodgers 2005(34) and Free 2009(140)) were based on the same programme, initially developed by Rodgers et al in New Zealand and later adapted for use in the UK by Free et al. In both programmes people wanting to quit, who owned a mobile phone were recruited via advertising. The intervention involved participants setting a quit day within three weeks and then receiving an automated personalised programme of regular text messages. The messages were selected from a database depending on the participant characteristics and time from quit day - with daily messages leading up to quit day, an intensive month of 5-6 messages per day, followed by a maintenance phase of one message every two weeks. Messages included quitting advice and motivational messages based on brief intervention for smoking cessation, mixed in with some distraction/general interest messages. A database of Māori messages was included in the programme for Māori participants (in the New Zealand programme). Interaction with the programme consisted of polls and quizzes, and the ability to request further text messages on demand to help beat
cravings. Participants could also opt to be paired up with a Quit Buddy whom they could text message directly for extra social support. The control group in this trial received one text message every two weeks about the study.

The remaining two trials (Brendryen 2008a(162) and Brendryen 2008b(163)) involved a single fully automated programme delivered via both the internet and the mobile phone and the authors state that both modes of delivery were equally important. For the first six weeks, there was daily proactive contact by email (prompting daily visits to a unique webpage for that day) and by text message (1-3/day). Text messages were used to emphasise important educational points that also appeared on the website, act as a reminder about NRT (in one trial) and the craving helpline, provide motivation and raise awareness of participants own quit attempt. After six weeks the number and frequency of text messages gradually reduced to zero. The programme also involved user-initiated mobile phone calls to an interactive voice response service (IVRS) to log-on and proactive (programme-initiated) log-off calls asking whether they had been smoking (also automated via IVRS). The IVRS messages included feedback about the likely health effects of quitting, relapse prevention strategies and ensuring engagement with the programme. The control group in this study received a booklet about quitting, the national Quitline number and links to online resources. In one trial both groups received a sample packet of NRT and were able to order free NRT by email,(162) in the other trial there was no NRT included.(163)

The definition of smoking status was similar in all studies: daily smokers in Rodgers and Free; and those who smoke at least 5-10 cigarettes per day in both Brendryen studies. This no doubt led to similar nicotine dependence characteristics in participants: mean Fagerstrom Test of Nicotine Dependence (FTND) scores of 5 in Rodgers; 4.8 and 4.9 in Brendryen 2008a; 4.5 and 4.6 in Brendryen 2008b (not reported in this manner in Free). However participants did vary in some major characteristics. The Rodgers study had the youngest participants (mean age of 22 years) and more women than men (58% female). The other trials had similar mean
ages (36 years in Free and Brendreyn 2008a; 39 years in Brendreyn 2008b) and sex distribution (63% women in Free; 50% in the Brendreyn studies).

Control groups in all studies were based on ‘routine care’ which differs according to the setting of each study, from virtually nothing (one text message/fortnight in Rodgers and Free) to self-help booklets with (Brendreyn 2008a) or without (Brendreyn 2008b) access to free NRT.

Outcome measures were slightly different across studies. However all presented a form of short-term self-reported point prevalence abstinence defined as no smoking in the past seven days. This was variably taken at four weeks post-quit day, or six weeks post-randomisation where the quit date was set between one and three weeks from randomisation. Therefore these describe approximately the same time point. Two studies presented long-term outcomes at six months as point prevalence (no smoking in the past seven days) and continuous abstinence since quit day allowing up to three lapses (Rodgers) or up to five cigarettes (Free). The two Brendreyn studies used repeated point abstinence (abstinent on all previous measurement points) at six months and twelve months.

The Rodgers and Free studies attempted verification of self-reported quitting status. Both used salivary cotinine but with varying levels of compliance. Rodgers contacted 125 self-reported quitters at six weeks for salivary cotinine assessment although only 49 provided a sample. Free was more successful at six months with 30 of a possible 38 undertaking a salivary cotinine test. A summary of the included studies is shown in Table 3-2.
Table 3-2: Characteristics of studies included in the systematic review

<table>
<thead>
<tr>
<th>n</th>
<th>Country</th>
<th>Participants</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>400</td>
<td>Norway</td>
<td>Eligibility: 18 years+; smoking 10 or more cpd; want to quit on a set day; access to internet, email and mobile phone daily. Characteristics: 50.8%/ 49.8% female; mean age 35.9yrs/36.4yrs; average 18.3/18.1 cpd; FTND score = 4.8/4.9.</td>
<td>Fully automated programme delivered by email/internet &amp; mobile phone. Daily email and daily webpage. Daily text messages, daily user-initiated call to pre-recorded audio message &amp; proactive call from programme. Access to automated craving helpline. Plus sample pack NRT and access to free NRT via email ordering.</td>
<td>Control: booklet with quitting calendar/log, Quitline number, links to online resources, sample pack NRT and access to free NRT via email.</td>
<td>Point prevalence abstinence (no smoking in past 7 days) at 1, 3, 6 &amp; 12 months post-quit. Intention-to-treat analysis but 4 participants excluded post-randomisation.</td>
</tr>
<tr>
<td>296</td>
<td>Norway</td>
<td>Eligibility: 18 years+; smoking 15 or more cpd; want to quit on a set day; access to internet, email and mobile phone daily; willing to quit without NRT. Characteristics: 50.8%/ 49.8% female; mean age 35.9yrs/36.4yrs; average 18.3/18.1 cpd; FTND score = 4.8/4.9.</td>
<td>Fully automated programme delivered by email/internet &amp; mobile phone. Daily email and daily webpage. Daily text messages, daily user-initiated call to pre-recorded audio message &amp; proactive call from programme. Access to automated craving helpline.</td>
<td>Control: booklet.</td>
<td>Point prevalence abstinence (no smoking in past 7 days) at 1, 3, 6 &amp; 12 months post-quit. Intention-to-treat analysis but 6 participants excluded post-randomisation.</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Eligibility</td>
<td>Characteristics</td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Free 2009(140)</td>
<td>UK</td>
<td>16yrs and over; smoking daily and interested in quitting; current owner mobile phone</td>
<td>63% male; median age 36yrs; median 20 cigarettes/day; 7% FTND score &gt;5.</td>
<td>Participant nominates Quit Date (QD) and receives six month programme of regular personalised text messages with advice, support and distraction. Messages selected from database matched to participant characteristics. Free month of text messaging from QD. Optional Quit Buddy and Text Crave (messages on demand). Interactive polls/quizzes.</td>
<td>1 text message per fortnight.</td>
</tr>
<tr>
<td>Rodgers 2005(34)</td>
<td>New Zealand</td>
<td>16 years+; smoking daily; want to quit within next month; able to send &amp; receive text messages on own mobile phone</td>
<td>58% female; median age 22yrs; average 15 cpd; FTND score =5.</td>
<td>Participant nominates QD and receives six month programme of regular personalised text messages with advice, support and distraction. Messages selected from database matched to participant characteristics. Free month of text messaging from QD. Quit Buddy and Text Crave (messages on demand). Interactive polls/quizzes.</td>
<td>1 text message per fortnight.</td>
</tr>
</tbody>
</table>
3.4.3 Risk of bias in included studies

The factors considered important in smoking cessation studies by the Cochrane Tobacco Addiction Group are randomisation, allocation concealment, blinding and the treatment of missing outcome data (Table 3-3).

Randomisation sequence generation was considered adequate in all trials. Allocation concealment was considered adequate in all trials (although not reported in one study, the author provided this information on request). Blinding was an issue in two of the four trials (Rodgers and Free) where participants were aware whether they were receiving the intervention or not. In the two Brendryen trials participants were blind to allocation, in that they were not aware what others were receiving in comparison to what they were receiving. In all trials, researchers were either blind to allocation at follow-up (Rodgers and Free) or all follow-up data were collected by web-based questionnaire (Brendryen 2008a and 2008b). There were few other quality issues.

In the Rodgers study incentives for providing final follow-up data differed between groups. One month of free text messaging was received by the control group on completion of follow-up. However, the intervention group had already received their month of free text messaging from Quit Day and did not receive a further incentive at follow-up. This is likely to have caused the differential loss to follow-up at six months, as 69% in the active group provided data compared with 79% in the control group. This in turn may have affected the long-term results of this study. The authors also suggested that participants in the control group could have thought their month of free texting depended on reporting quitting. This may explain some of the unexpected increase in those reporting quitting in the control group from 109 at six weeks to 202 participants reporting no smoking in the past seven days at six months. The other two studies with long-term follow-up (Brendryen 2008a and 2008b) both demonstrated a decrease in the number reporting quitting from four weeks to six months,
although this was followed by an increase at twelve months in all groups. This demonstrates the importance of measuring continuous abstinence in long-term outcomes.

**Table 3-3: Assessment of bias in studies included in the systematic review**

<table>
<thead>
<tr>
<th>Study</th>
<th>Adequate sequence generation?</th>
<th>Allocation concealment?</th>
<th>Blinding?</th>
<th>Incomplete outcome data addressed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brendryen 2008a(162)</td>
<td>Yes. Central computerised randomisation</td>
<td>Yes.</td>
<td>Yes. Double blind</td>
<td>Yes. Loss to follow-up: 6 (control) &amp; 3 (intervention) at 4 weeks; Cumulative loss to follow-up 31 (control) and 24 (intervention) at 6 months.</td>
</tr>
<tr>
<td>Brendryen 2008b(163)</td>
<td>Yes. Central computerised randomisation; Stratified block randomisation was applied to ensure equal numbers of males and females in each group.</td>
<td>Yes. The names and identities of the subjects were concealed to the experimenter during randomisation</td>
<td>Yes. Double blind</td>
<td>Yes. Loss to follow-up: 19 (control) &amp; 5 (intervention) at 4 weeks; Cumulative loss to follow-up 38 (control) and 26 (intervention) at 6 months.</td>
</tr>
<tr>
<td>Free 2009(140)</td>
<td>Yes. Central computerised randomisation</td>
<td>Yes. Concealed until after assignment</td>
<td>Yes. Single blind</td>
<td>Yes. Loss to follow-up: 4 (control) &amp; 1 (intervention) at 4wks (98% follow-up); 8 (control) &amp; 8 (intervention) at 6 months (92% follow-up).</td>
</tr>
<tr>
<td>Rodgers 2008(34)</td>
<td>Yes. Central computerised randomisation</td>
<td>Yes. Concealed until after assignment</td>
<td>Yes. Single blind</td>
<td>Yes. Loss to follow-up: 35 control (95.9% follow-up) &amp; 46 intervention (94.6% follow-up) at 6wks; 179 control (79% follow-up) and 261 intervention (69.4% follow-up) at 6 months.</td>
</tr>
</tbody>
</table>
Intention-to-treat (ITT) analyses are presented in all trials. However two trials excluded those who had already quit or who were registered by family members without their consent after randomisation (Brendryen 2008a excluded 4 participants out of 400, Brendryen 2008b excluded 6 out of 296). Assuming those lost to follow-up to be still smoking is standard practice in cessation studies, however sensitivity analyses were used to present the effects of other possibilities on the results in Rodgers (such as last value carried forward).

3.4.4 Effects of interventions

It was decided to separate the analyses for those studies which were delivered solely by mobile phone (Rodgers and Free) and those delivered equally by mobile phone and Internet/email (Brendryen 2008a and 2008b). However, combining all studies for short term point prevalence where the outcome measured was the same in all four studies would produce very similar results to those presented here. Long-term outcome measures varied between the studies and so could not be combined in any case. Standard ITT analyses, where all missing data are considered as continuing to smoke, are presented. However complete case analyses of all permutations made minimal difference to the results. The largest study (Rodgers) with considerable numbers lost to follow-up published a sensitivity analysis around the consideration of missing data.

3.4.4.1 Mobile phone-only interventions

Six-month continuous abstinence (no smoking since quit day allowing up to three lapses or up to five cigarettes): As mentioned above, the Rodgers study suffered from differential loss to follow up at six months. The ITT analysis in this study showed 25.4% point prevalence abstinence rate in the intervention group (216/852) and 23.7% (202/853) in the control group (Relative risk (RR) 1.07 95% CI 0.91-1.26, p = 0.4), and a prolonged abstinence rate (allowing three or fewer lapses) of 7.5% (64/852) quit rate in the intervention group and 4.6% (39/853) quit rate in the control group (RR 1.64, 95%CI 1.12-2.42, p = 0.01).
The Free study was a pilot study, and therefore not powered to provide statistically significant results. Self-reported point prevalence and prolonged abstinence with fewer than five cigarettes at six months was 15/102 (14.7%) in the intervention group and 19/98 (19.4%) in the control group (RR 0.76, 95% CI 0.41-1.41).

There is substantial heterogeneity between these two studies with respect to long-term outcomes (as evidenced by $I^2 = 77\%$, where 0% indicates no heterogeneity(156)) and so these data have not been pooled.

Short-term self-reported point prevalence abstinence: Data for these outcomes have been pooled (Figure 3-1). At four weeks post-cessation (Free) or six weeks post-randomisation (Rodgers) (considered to approximate the same time period), mobile phone interventions appear to increase self-reported point prevalence abstinence (no smoking within past seven days) compared with control programmes (RR 2.18, 95%CI 1.80-2.65).

**Figure 3-1: Forrest plot of mobile phone-only intervention versus control, short-term self-reported point prevalence abstinence**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment Events</th>
<th>Control Events</th>
<th>M-H, Fixed, 95% CI</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free 2008a</td>
<td>26</td>
<td>102</td>
<td>10.1%</td>
<td>2.08 [1.11, 3.89]</td>
</tr>
<tr>
<td>Rodgers 2005</td>
<td>239</td>
<td>852</td>
<td>89.9%</td>
<td>2.20 [1.79, 2.70]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>954</td>
<td>951</td>
<td>100.0%</td>
<td>2.18 [1.80, 2.65]</td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2 = 0.03$, df = 1 ($P = 0.87$); $I^2 = 0\%$
Test for overall effect: $Z = 7.84$ ($P < 0.00001$)
3.4.4.2 Mobile phone and internet/email interventions

Twelve-month repeated point abstinence: These two studies (Brendryen 2008a and 2008b) using the same programme ("Happy Ending") presented twelve month repeated point prevalence (self-reported abstinence for the past seven days at one month, three months, six months AND twelve months) and demonstrated an increased quit rate in those receiving the programme compared to the control groups (RR 2.03, 95% CI 1.40, 2.94). (Figure 3-2)

Figure 3-2: Forrest plot of mobile phone and internet intervention versus control, 12-month self-reported repeated point prevalence abstinence

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Weight</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brendryen 2008a</td>
<td>44</td>
<td>200</td>
<td>26</td>
<td>200</td>
<td>72.2%</td>
</tr>
<tr>
<td>Brendryen 2008b</td>
<td>29</td>
<td>148</td>
<td>10</td>
<td>148</td>
<td>27.8%</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>348</td>
<td>348</td>
<td>100.0%</td>
<td>2.03 [1.40, 2.94]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 73 (26) vs 36 (26), Heterogeneity: Chi² = 1.70, df = 1 (P = 0.19); I² = 41%
Test for overall effect: Z = 3.75 (P = 0.0002)

Short-term self-reported point prevalence abstinence: Self-reported abstinence at four weeks post-cessation showed an RR of 1.83 (95%CI 1.48-2.27) in favour of the intervention.

3.4.4.3 Verified abstinence

There was insufficient data reported on verified smoking cessation to pool data across studies. Two studies used salivary cotinine testing as the biochemical measure but at different time points (Rodgers and Free), and two studies did not attempt verification (Brendryen 2008a and 2008b).

Rodgers attempted to verify smoking status in a random sample of 125 (35.9%) of self-reported quitters at six weeks. Overall 60.8% did not attend to complete the test: 62.7% (52/83) of those in the
intervention group who were invited to provide a cotinine sample did not attend, and 57.1% (24/42) of those invited in the control group did not attend. Of those who did provide a sample 54.8% (17/31) in the intervention group were verified as having quit, compared with 33.3% (6/18) in the control group.

Free attempted to verify all self-reported quitters at six months (38 participants). However, 16.7% (3/18) of self-reported quitters in the intervention group did not provide a sample and 25.0% (5/20) of self-reported quitters in the control group did not provide a cotinine sample. Of those providing samples, 53.3% (8/15) in the intervention group were verified as having quit by salivary cotinine level < 7ng/ml, and 40.0% (6/15) in the control group.

Therefore these two studies demonstrate a higher degree of over-reported quitting by those in the control groups than those in the intervention groups.

3.5 Discussion

3.5.1 Summary of main results

Few rigorous studies have been published on mobile phone-based smoking cessation interventions and as yet there is no evidence to support a long term effect of the programmes delivered solely by mobile phone. However, there is evidence of a short-term beneficial effect from the included studies. Two of which describe a very similar programme delivered solely by text messages (Rodgers(34) and Free(140)), and two involved the same automated programme with both internet/email and mobile phone components (Brendryen 2008a(162) and 2008b(163)). There is evidence that the mobile phone plus internet programme demonstrates long-term effectiveness to twelve months. However, the effects of the two delivery mechanisms used in this programme are not able to be separated. Even so,
the paradigm appears to be similar to the other two studies (i.e. automated messages, mostly proactive but with some reactive and interactive components).

There were some issues with the non-significant long-term results of the larger mobile phone Rodgers study. This study also had a much younger population than the other studies and many cessation programmes have struggled to show long-term effectiveness with young adults and adolescents. The authors of the smaller pilot study are currently undertaking a large randomised controlled trial of the same intervention and study design. The findings of this study will usefully contribute to a future review.

3.5.2 Overall completeness and applicability of the evidence

There were very few high quality studies available for this review. There were several studies that did not meet the Cochrane Tobacco Addiction Group criteria for inclusion, predominantly due to length of follow-up or lack of randomisation. At the time of publishing the original review the candidate was advised of several ongoing studies in this area. These are yet to be published. Gritz and Vidrine advised they were undertaking a large trial of an expanded version of the mobile phone proactive counselling intervention that was excluded from this review.(36) Ybarra et al have been working on a pilot text message intervention in Turkey. Borland et al in Australia advised they were comparing a text message intervention, an internet intervention and a combined intervention. Naughton et al in the UK was undertaking a feasibility trial of a computer-tailored intervention providing individualised written and text message support to pregnant women who wish to quit.

3.5.3 Quality of the evidence

With the publication of standards for measuring and reporting cessation outcomes in intervention studies it is hoped that six month outcomes will become the routine primary outcome.(165, 166) This
will ensure more transparent comparison of results between different interventions and allow for a more robust meta-analysis of findings. While continuous abstinence and intention-to-treat analysis are the recommended standards, it is desirable that researchers also present other data, such as complete cases, so that readers can determine the effects of any assumptions or imputations made. Repeated point prevalence is another useful outcome to report in that it can provide greater depth of information on motivation to re-try, and test for bringing forward quit attempts rather than increasing them in absolute terms.

In this review, only one study attempted verification at six months. However previous reviewers have stated that large community/population-based studies should not need to attempt verification due to the large cost and resources required to do so, the high refusal rates, and the fact that misrepresentation is generally small and rarely differential across intervention conditions. On the other hand, adolescents may be a special population where over-reporting of quitting is more likely and programmes based on new technology may be expected to have high proportions of young people (as seen in Rodgers(34)). Where verification is undertaken, full reporting on attendance and results should be presented.

In this review, over-reporting of quitting was demonstrated in two studies, although in small numbers. Over-reporting was seen in both control and intervention groups but more in the control groups, therefore reliance on self-report in these studies will potentially underestimate the effect of the intervention. Two studies did not attempt verification. Therefore the question arises: should the 'gold standard' outcome measures for cessation interventions be required, or is it acceptable to use self-reported quit status recognising that this is likely to be inflated but with minimal effect on the RR? Ultimately the feasibility of getting people to provide samples may be the arbiter. In programmes aimed at young people, where minimal direct contact, confidentiality, and
anonymity appear to be desired elements of a cessation intervention, even attempting verification may have adverse effects on the collection of follow-up data.

### 3.5.4 Agreements and disagreements with other studies or reviews

There have been no other similar reviews to date. However many experts have stated the need for innovative cessation support for young adults. (90-93) Mobile phone programmes provide an innovative option that may suit young adults as supporting their tendency to quit without assistance. There has been a Cochrane systematic review of self-help interventions for tobacco smoking cessation. (49) Self-help materials are those used by the participants to help them quit without the assistance of a health professional, counsellor or group. These are generally written, audio, video or computer-based materials. The review found a small significant effect of tailored materials compared with no intervention (n = 15,711; risk ratio 1.21; 95% confidence interval [CI] 1.05 to 1.39). The review also found that tailored materials (those that make use of participant characteristics to provide individualized programmes) were more effective than standard materials.

The findings here align with a recent review of mobile phones for behaviour change interventions. (29) This review concluded that text message-delivered interventions had positive short-term behavioural outcomes. There was great variability between the studies with only six of the included 14 studies randomised controlled trials, and only two were about smoking cessation support. (34, 35) The remainder were about physical activity, anti-obesity behaviour modification, bulimia nervosa, and diabetes/asthma/hypertension self-management.

### 3.5.5 Implications for practice

There is as yet no conclusive evidence of long-term benefit for programmes delivered solely by mobile phone. Mobile phone-based smoking cessation interventions have been shown to assist people
to stop smoking in the short-term. The interventions included in this review include: a purely text message-based programme with automated proactive text messages and some reactive (for help with cravings) and interactive (polls/quizzes) components; an automated email/daily internet page and mobile phone text/audio message programme with proactive and reactive components. The latter programme has also been shown to have benefit to twelve months. There is no reason to believe that mobile phone interventions would result in greater rates of relapse after the end of the programme than other interventions, so there is no reason to put off implementing such programmes particularly if they will be used by groups unlikely to access better evaluated and proven interventions.

Mobile phones have become a regular part of daily lives in many populations. Therefore it makes sense to use this common means of communication to provide access to smoking cessation support. Mobile phone programmes appear to be useful as an option to offer those who want to stop smoking. They have many advantages over most current treatment services: they can be delivered anywhere, at appropriate times, confidentially, and direct to the participant with minimal direct contact. These are characteristics which may be appreciated particularly by young people.

3.5.6 Implications for research

There are very few good quality studies of mobile phone-based cessation interventions. More rigorous studies of the long-term effects of mobile phone-based cessation interventions are needed to determine if the promising short-term effects can be maintained. To date, programmes have only used the text messaging or voice calling functions of mobile phones. Advances in mobile network technology may allow more in-depth and interactive content to be delivered by mobile phone, such as pictures, video and links to internet sites. These functions should be investigated to determine if they can be even more effective than the current simple content.

Researchers should ensure the use of standard outcomes measures of abstinence to allow comparison
and meta-analysis. One example is the standard proposed by UK researchers (the “Russell standard”) with criteria regarding duration of follow-up, continuous abstinence, verification, analysis approach and blinding.(165) Researchers should also present other data such as complete cases so that readers can determine the effects of any assumptions or imputations made. All studies attempting verification should fully report attendance and results in order that this information can be used to inform judgement on whether verification should or should not be required in the future.

3.6 Summary
A systematic review and meta-analysis of the use of mobile phones in tobacco smoking cessation found evidence of short-term increases in quit rates with mobile phone-based interventions. Longer term outcomes were mixed with benefit demonstrated for a mobile phone and internet-based intervention but not for a mobile phone-only intervention, possibly due to methodological issues. Therefore more research is required in order to support the long-term effectiveness of mobile phone interventions in smoking cessation, particularly among young adults.
4 Development of a Multimedia Mobile Phone Intervention for Smoking Cessation in Young Adults

4.1 Introduction

This chapter describes the process of developing a multimedia mobile phone smoking cessation intervention for young adults. The literature review in Chapter 2 established that there is a need for smoking cessation support for young adults. It described the need to develop such support programmes specifically for young adults, respecting their needs, their lifestyles and their views on smoking and cessation.

The systematic review of mobile phone interventions for smoking cessation established that these interventions can be effective. However, there was uncertainty around sustained effect and it is unclear whether such interventions are effective in young adults, specifically. Mobile phone interventions could be suitable for young adults as mobile phones tend to be well integrated into their daily lives. Interventions delivered in this way require little effort, provide support when it is required, and can be anonymous to some degree (they do not have to see anyone face-to-face) and confidential (no-one else needs to know they are participating). This approach respects young adults’ choice to participate or not, and reflects factors that may be important to them.

The programmes included in the systematic review all used text messages. New developments in mobile phone technology, such as video messaging, allow more advanced interventions that are better able to use behaviour change theory and may provide more engaging content. It was envisaged that this type of intervention may be more successful at supporting quit attempts. It was also hoped that a novel intervention using up-to-date technology may be more appealing to young adults and therefore encourage participation and successful quit attempts.
Therefore, the candidate proposed to develop a mobile phone-based smoking cessation intervention that built on this evidence, by tailoring the intervention for younger people and testing the effectiveness over a 6 month period. The rationale for the intervention and description of the methods and processes involved to develop and test the intervention are described below.

**Figure 4-1: Flow chart depicting the development process of the multimedia mobile phone cessation intervention**

This chapter describes the development of the intervention, which took place from July 2006 to August 2007 and involved several stages (Figure 4-1):
1. Exploring theories to guide intervention development (Section 4.2)
2. Gathering expert input and advice (Section 4.3)
3. Facilitating focus groups in a school for early input into design (Section 4.4)
4. Conducting an online survey for input into design from an older age group (Section 4.5)
5. Pre-testing several styles of content (Section 4.6)
6. Conducting a small pilot study of the intervention (Section 4.7)
7. Integrating findings from the above stages to inform final development of the intervention (Section 4.8)

4.2 Theoretical approach

The first stage involved exploring the theories that would guide the development of the intervention. The importance of a theoretical basis for developing behaviour change interventions has been demonstrated.(167) Theories and principles that have guided the intervention development are described below and include:

- Social Cognitive Theory, in particular the use of observational learning via role modelling to enhance self-efficacy
- Use of effective brief intervention techniques for smoking cessation
- Use of youth development principles

4.2.1 Social cognitive theory and observational learning

Social Cognitive Theory (SCT) is one of the most commonly used theories to explain health-related behaviour.(142) Self-efficacy (belief in your ability to undertake the behaviour) is a central concept in SCT. The theory states that in order to initiate a health behaviour change, it is important to enhance self-efficacy beliefs and positive expectations of the outcomes likely to arise from making the behaviour change. According to SCT, observational learning is one of the primary methods to achieve
this. That is, in addition to learning from their own experiences, people learn from the behaviour of others and the outcomes of their behaviour. By observing others’ behaviours and their favourable consequences, people are more likely to remember and replicate the behaviours – this is also known as ‘role modelling’. Role modelling is established as an effective tool for professional teaching and adult learning (168-170) and for children’s learning.(171) There is accumulating evidence from non-experimental clinical studies of its effectiveness for improving the acquisition of motor skills,(172) psychological responses,(173) and behavioural changes.(174-176) It has also been found to be effective in a variety of clinical contexts such as rehabilitation in sports medicine,(177) reduction of preoperative anxiety,(178) patient education,(179) and increasing screening-related behaviours.(180)

Role modelling has been conducted via video in many studies. In a descriptive review of published articles describing video behavioural modelling in clinical applications (1990-99), Krouse et al included 18 studies.(178) The majority of the applications were in populations of patients undergoing procedures of various sorts. The video modelling successfully improved knowledge about treatment options, reduced behaviours associated with anxiety in stressful situations, and in several of the nine studies teaching self-care practices, a significant change in behaviours was found in the short-term. Video role modelling has been used in sexual health behaviour change interventions predominantly to increase condom usage.(174, 175) It has also been used with children to increase fruit and vegetable intake.(176)

Bandura outlines four conditions necessary for successfully modelling behaviour for others to learn from. These include: Attention – the observer must first pay attention to the model; Retention – the observer must be able to remember the behaviour; Motor reproduction – the observer must be able to replicate the behaviour; and Motivation – the observer must want to demonstrate the behaviour.
4.2.1.1 Role modelling in smoking and smoking cessation

There is substantial evidence that role modelling by parents and peers is a key factor in the uptake of smoking by young people. Hill et al found that parental smoking was important even where parents held norms against teen smoking and did not involve their children in their smoking. (181) Unger et al demonstrated that peer influences on smoking appeared to be mediated via perceived positive social consequences (e.g. eliciting positive reactions from friends). (182) Two separate reviews attempting to integrate theory with adolescent substance use or smoking, have both concluded that there is evidence to support SCT and that experimental substance use “originates in the substance-specific attitudes and behaviours of people who serve as an adolescent’s role models”. (183, 184) They both concluded that parents, friends and admired peers contribute strongly to adolescents smoking. Their suggestions for the future included the need to make substance-using role models less salient and substance-abstaining models more salient, teaching refusal skills and enhancing refusal self-efficacy.

However, there has been little research into using role modelling for smoking cessation. Lichtenstein trialled a video referral to a cessation programme that showed role models testifying to the acceptability and usefulness of the programme. (185) Participants were more likely to attend the cessation service than those just given advice to quit (although there were other differences between the groups). Secker-Walker included a video of four young women going through the quitting process as part of a wider community-based intervention. (186) Unfortunately the effectiveness of the video intervention was not separately evaluated. Video smoking cessation ‘education’ (rather than modelling) interventions have been trialled in primary care, (187) and targeted towards African Americans, (188, 189) with some modest increases in quit rates. One study reported that the features of the video most highly endorsed by the participants were: seeing others quit smoking; dealing with stress and bad feelings; talking about what to do with urges to smoke; and observing ways to obtain peer support. (190)
Lipkus used a video to motivate teens to use self-help cessation materials, including a group of teens discussing elements of the materials such as the cost of smoking and negative effects on skin.(76) However this was not the question being studied and was provided to both arms in the study so little could be learned about its effectiveness.

Videos of role models were included in an internet cessation intervention, and were automatically matched with respect to sex and ethnicity of the participant.(191) Again, this was only one part of an extensive internet programme and so the relative importance of these videos in the overall success of the programme is not clear.

Video role modelling for cessation has been used outside the research arena in several ways. Glaxo pharmaceutical company used it in advertising for their nicotine replacement therapy lozenges.(192) They gave ‘ordinary’ people video cameras to tape themselves narrating their efforts to quit over 13 weeks. These were then edited by professionals and turned into advertisements for television (TV) and the internet. The advertising agency involved was quoted as saying: “smokers really relate to each other. A smoker to smoker dialogue is really important”. In New Zealand, The Quit Group’s video diaries documentary-style TV campaign involved a camera crew following ‘ordinary’ New Zealanders through their quit attempts. Again these were turned into a series of TV clips following one person’s story at a time. These clips were used in advertisements for the Quitline service. This campaign was launched in July 2006 and carried on for several years (following new quitters all the time) due to its popularity [personal communication, The Quit Group]. However, the programme was not formally evaluated.

4.2.1.2 Types of role models

Role models could be famous people (recognisable to participants and thereby providing some extra motivation to undertake the same behaviours) or ‘masters’ of the behaviours in question
(demonstrating flawless conduct or ‘how it should be done’). However it was the intention in this intervention to use ‘coping models’, where the observer watches a person who presents various coping strategies for dealing with the difficulties in changing behaviour.(172) Schunk demonstrated this well with video role modelling for children learning maths.(171) The coping models initially demonstrated the typical fears and deficiencies of children struggling with maths. In the video, the children gradually improved their performance and gained self-confidence, illustrating how determination and positive thoughts could overcome difficulties. This was more successful than the ‘mastery models’ (teachers) who demonstrated faultless execution of the maths problems for the children to follow.

Model similarity, in which the observer identifies with the model with respect to age, gender, and culture, is likely to be important in coping models.(193) This was also shown in cessation in one of the video-based studies, where African-American women who smoked reported higher identification with a female African-American model compared with other non-African-American models.(194)

### 4.2.1.3 Summary

Following Social Cognitive Theory as a basis for developing the intervention, the intention was to use video messages following the personal stories of young quitters (‘role models’) as they go through a quit attempt. These role models would talk about common difficulties and issues that arise during quitting, and the strategies and techniques they used to cope with these issues. The role models would ideally be similar to the target audience. The aim being that participants would pick up relevant cues and information specific to their context, resulting in increased confidence (self-efficacy) to stop smoking, and problem-solving skills to increase the likelihood of their quit attempt being successful.
4.2.2 Effective brief interventions for smoking cessation

It was also important that the intervention recommend behaviour change techniques that are known to be effective and commonly used in brief counselling or self-help interventions for smoking cessation. In a systematic review of internet-based interventions for behaviour change, Webb found that the more behaviour change techniques used, the larger the effects on behaviour. (167) This review included randomised controlled studies where the primary components of the intervention were delivered via the internet and a measure of behaviour related to health was included. Their meta-analysis on 85 studies (n=43,236) found a small effect on health behaviour overall. The commonly used techniques with positive effects on behaviour change in this review were: modelling, relapse prevention/coping planning, facilitating social comparison, goal setting, action planning, and provision of feedback on performance.

With respect to effective and commonly used techniques for smoking cessation, one of the most commonly cited sources is the updated 2008 US Guidelines on Treating Tobacco Use and Dependence. (54) This document recommends the use of ‘practical counselling’ and ‘social support’. These are covered in Table 4-1 and Table 4-2 below, along with some description of the main elements included.

4.2.2.1 Recognise danger situations and develop coping skills

One of the commonly used techniques in counselling for smoking cessation is to help the participant identify their trigger situations and cues that tend to make them want to smoke. The next step is to plan and practice coping strategies for these situations. (143) This has often involved advice to avoid the situations where possible, such as not drinking alcohol or having coffee with friends that smoke. It may involve planning other activities as a distraction during usual smoking times such as breaks at
work or first thing in the morning. For example, there is some evidence to suggest that exercise can be effective at replacing smoking and reducing cravings.(195)

Table 4-1: Common elements of ‘practical counselling’ in smoking cessation as recommended in the US ‘Treating Tobacco Use & Dependence’ 2008

<table>
<thead>
<tr>
<th>Practical counselling (problem solving/ skills training) treatment component</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recognize danger situations:</strong></td>
<td>• Negative affect and stress</td>
</tr>
<tr>
<td>– Identify events, internal states, or activities that increase the risk of</td>
<td>• Being around other tobacco users</td>
</tr>
<tr>
<td>smoking or relapse.</td>
<td>• Drinking alcohol</td>
</tr>
<tr>
<td></td>
<td>• Experiencing urges</td>
</tr>
<tr>
<td></td>
<td>• Smoking cues and availability of cigarettes</td>
</tr>
<tr>
<td><strong>Develop coping skills:</strong></td>
<td>• Learning to anticipate and avoid temptation and trigger situations</td>
</tr>
<tr>
<td>– Identify and practice coping or problem solving skills. Typically, these</td>
<td>• Learning cognitive strategies that will reduce negative moods</td>
</tr>
<tr>
<td>skills are intended to cope with danger situations.</td>
<td>• Accomplishing lifestyle changes that reduce stress, improve quality of</td>
</tr>
<tr>
<td></td>
<td>life, and reduce exposure to smoking cues</td>
</tr>
<tr>
<td></td>
<td>• Learning cognitive and behavioral activities to cope with smoking</td>
</tr>
<tr>
<td></td>
<td>urges (e.g., distracting attention; changing routines)</td>
</tr>
<tr>
<td><strong>Provide basic information</strong></td>
<td>• The fact that any smoking (even a single puff) increases the likelihood</td>
</tr>
<tr>
<td>– Provide basic information about smoking and successful quitting.</td>
<td>of a full relapse</td>
</tr>
<tr>
<td></td>
<td>• Withdrawal symptoms typically peak within 1–2 weeks after quitting but</td>
</tr>
<tr>
<td></td>
<td>may persist for months. These symptoms include negative mood, urges to</td>
</tr>
<tr>
<td></td>
<td>smoke, and difficulty concentrating.</td>
</tr>
<tr>
<td></td>
<td>• The addictive nature of smoking</td>
</tr>
</tbody>
</table>

(Source: Fiore 08(54))
4.2.2.2 Provide basic information

Providing basic information on nicotine addiction and withdrawal symptoms can be used to assist smokers to weigh up the current and likely future negative consequences against the benefits of continued smoking. (147) This is often included in the motivational interviewing approach to cessation counselling, which is defined as ‘a directive client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence’. (196) There is a need to reinforce expectations of the likelihood and value of future positive outcomes and health benefits, and of the short-lived nature of the current negative withdrawal symptoms.

4.2.2.3 Providing relapse prevention training

Another related element is providing training and skills to try to prevent relapse. The Cochrane Systematic Review of interventions designed to prevent relapse to smoking was unable to identify any particularly effective methods. (149) However, many cessation services still include some form of relapse prevention training. Prevention training may include ways to manage negative affect, which can be described as feeling ‘angry’, ‘stressed out’, ‘wanting to relax’, and ‘feeling sad’. There is some evidence that feelings of self-efficacy to resist smoking in the presence of negative affect can predict success. (197-199) Social cues to smoke such as hanging out with friends, feeling bored, at a party, someone offering a cigarette, or seeing someone else smoking, are common triggers for a ‘relapse’ to smoking after successfully quitting. Developing ways of dealing with these cues may be important. (198, 199)
Table 4-2: Common elements of treatment ‘social support’ for smoking cessation as recommended in the US ‘Treating Tobacco Use & Dependence’ 2008

<table>
<thead>
<tr>
<th>Supportive treatment component</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Encourage the patient in the quit attempt. | • Note that effective tobacco dependence treatments are now available.  
• Note that one-half of all people who have ever smoked have now quit.  
• Communicate belief in patient’s ability to quit. |
| Communicate caring and concern | • Ask how patient feels about quitting.  
• Directly express concern and willingness to help as often as needed.  
• Ask about the patient’s fears and ambivalence regarding quitting. |
| Encourage the patient to talk about the quitting process. | Ask about:  
• Reasons the patient wants to quit.  
• Concerns or worries about quitting.  
• Success the patient has achieved.  
• Difficulties encountered while quitting. |

(Source: Fiore 08(54))

4.2.2.4 Encourage and communicate caring and concern

Positive reinforcement has been commonly used in behaviour change approaches to boost participants’ confidence in their ability to take some control and provide reminders of how well they have done so far.(146) Prompting reflection on how stopping smoking has improved how they feel can provide some satisfaction thereby maintaining self-efficacy in continuing the behaviour.(147) Encouraging the potential quitter to set short-term achievable goals can be a part of this process as achieving these goals will increase self-efficacy to attempt a longer period.(144)

Although the US guidelines include setting a quit date and telling friends and family, they no longer include encouraging support from their social network.(54) However, encouraging social support is commonly used in cessation counselling, as there is evidence that those without good support from
their social network (particularly partners and household members) are less likely to successfully quit. The involvement of friends and emotional support from family are also commonly emphasised by young people as an important component of a cessation service. Even so, the evidence is mixed and a Cochrane Systematic Review of interventions that explicitly aimed to increase partner support did not find them to be effective.

4.2.2.5 Summary

The development of the intervention for this trial aimed to use behaviour change techniques for smoking cessation that were based on current evidence. These behaviour change techniques include: identifying triggers and cues; planning coping strategies to counteract triggers and cues such as exercise; information on withdrawal symptoms and positive outcome expectations; provision of support and positive reinforcement; setting a quit date and letting others know; encouraging social support from their networks; and providing relapse prevention training.

4.2.3 Youth development principles

The third theoretical underpinning to the development of the intervention was the use of youth development principles. These principles came from the Ministry of Youth Affairs’ 2002 Youth Development Strategy Aotearoa, which was the current strategy at the time of designing the intervention. Some of the specific objectives for health in the strategy were:

- Promoting the use of a positive youth development approach in providing youth services and addressing the barriers to accessing services
- Encouraging young people’s involvement at all levels in services that have contact with young people
- Encouraging regular consultation with young people in service planning and delivery
- Encouraging the use of peer educators as part of service delivery
The strategy also stated that a ‘large net of social support’ acts as a protective factor for young people, as do thinking skills, problem solving, seeing things from others’ perspectives, and positive social interactions.

These principles were incorporated into the development of the intervention in two main ways. Firstly, young people were highly involved in the design of the intervention through the formative research phase. Secondly, youth development principles were reflected in the content of the intervention. The strategy encouraged the use of peer role models in connecting young people with peers with similar experiences. The principle of engagement encouraged consideration of methods to engage participants with the wider ‘community’ of participants going through the study, such as via a participants-only website and submitting their own video messages to be viewed by other participants. The principles also acted as a reminder that the messages needed to address both risk and protective factors and promote a range of skills that young people would need to quit. The intervention could be seen as a way to increase their sense of control over what happens to them. For example, taking control of their habit, as well as being able to choose the extent of their participation and elements of their programme.

A further aspect of this was whether educating young people about the ‘manipulation’ of smokers by large multinational billion-dollar tobacco companies could help to engage them and lead to a desire for control and independence from tobacco. This was demonstrated in the successful youth-specific anti-tobacco industry mass media campaign in the US (the “Truth” campaign).(203, 204) This involved mass media advertisements showing young people confronting the tobacco industry. This campaign has been shown to lead to negative beliefs about the tobacco industry that are associated with a lower likelihood of progression along a continuum of smoking intentions and behaviour.(203) It also reduced receptivity to pro-tobacco marketing influences and was associated with greater
assertion of independence from tobacco industry manipulation.(203) Therefore it was decided to add this anti-tobacco industry aspect into the intervention also.

4.2.4 Other considerations in intervention development

As well as the theoretical underpinnings outlined above, the intervention needed to ‘appeal’ to young adults to encourage participation and retention in the programme. Techniques from social marketing were considered. Social marketing involves using proven marketing techniques to promote healthy behaviours.(205, 206) It has been stated that “choosing the right context, channels and message that will motivate people to pay attention and use the health information, are among the greatest health communication and social marketing challenges”.(205) Reviews have shown that social marketing interventions can be effective in tackling tobacco use and other public health issues.(207)

The social marketing techniques that informed the development include ‘market segmentation’ with tailoring and use of appropriate language. ‘Tailoring’ in marketing tends to divide the population into ‘segments’ according to personal and demographic variables and then aligns messages with the target segment’s needs and interests.(206) This was considered in the development of the role models and the language they would use. ‘Branding’ involves the use of imagery to encourage emulation of healthy behaviours as ‘cool’ or socially accepted. For example the US ‘Truth’ campaign explicitly branded anti-tobacco health messages as ‘resisting manipulation by big business’.(203, 204)

‘Personalising the risk’ of the negative health effects of smoking can be seen in Quitline’s TV advertising campaign. ‘Ordinary’ New Zealanders talked about suffering the health effects of smoking to make them more ‘real’ to others (for example, the ‘Adrian campaign’).(208)

A further social marketing technique is countering current pro-tobacco imagery. For example, despite New Zealand’s tobacco advertising bans, images of smokers are included in movies that are popular
with young people. Here, smoking is portrayed as realistic, socially acceptable,(209, 210) and associated with positive outcomes such as power, sex, romance, and social status.(211) Social marketing smoking cessation interventions aim to counteract these messages by portraying ‘normal’ or ‘role model’ young people wanting to quit because smoking makes their breath smell bad, causes premature skin ageing and costs money.

A final technique that was used was extensive pre-testing with the target audience. The National Cancer Institute’s social marketing wheel describes a process of developing health messages that involves: (206)

- Planning and strategy development using behavioural theory and formative research;
- Developing and pretesting concepts, messages and materials;
- Implementing the programme;
- Assessing effectiveness and making refinements.

### 4.2.5 Summary

In summary, the main theoretical underpinnings and principles used to guide the development of the intervention were: Social Cognitive Theory and the use of role modelling to enhance self-efficacy; the use of effective behaviour change techniques for smoking cessation; and the principles of youth development particularly around engagement. Consideration was also given to social marketing techniques to ensure the intervention would be appealing to young adults.
4.3 Expert input and advice

A group was established by the candidate in order to provide expert input and advice on the content from the perspectives of smoking cessation, youth health, Māori health, public health, psychology, social marketing, and media production. Membership was invited from the co-investigators, partner organisations (Mai Media Ltd), and content production staff, who all agreed to a Terms of Reference. This group met monthly during the twelve-month intervention development period.

The group began by agreeing to the theoretical approaches for the development of the intervention as outlined above. The group then agreed on the development process including focus groups, an online survey, submission of content from young people, pre-testing early content, and a pilot study (see Figure 4-1). Each of these development stages are described below. The group received reports from the candidate on the findings from each of the intervention development stages and provided feedback on content as it was developed.

4.4 Focus Groups

The first stage involved focus groups undertaken in a high school. Planning for this stage took place prior to funding for the larger project with a small grant from the Oakley Mental Health Foundation in order to inform the candidate’s wider area of mobile phone research.

4.4.1 Aims

The purpose of the focus groups was to obtain a breadth of information on current and potential uses of mobile phones amongst young people, and their opinions on the usefulness of specific planned mobile phone programmes targeting young people.
4.4.2 Methods

4.4.2.1 Study population

The candidate approached a low decile (in an area with a high deprivation index) multicultural high school in Auckland and obtained consent from the principal to undertake focus groups for this purpose in the school. Key staff members (Deputy Principal and School Guidance Counsellor) were consulted about the conduct of the focus groups. Eligibility criteria required that students were from 16 to 18 years of age and were able to provide informed consent. A range of ethnicities were included and groups were stratified by ethnicity and sex. The key staff members decided a purposeful sampling method would be the most efficient and useful method of recruiting students. They approached students in the appropriate age group and invited them to participate in the focus groups. They were given the participant information sheets and ‘panui’ (letter of invitation) to take home to their caregivers. The panui outlined the approach to students and the purpose of the research, and offered parents and caregivers the opportunity to contact researchers directly to discuss further. Four focus groups were planned with between six and ten participants in each.

4.4.2.2 Focus group conduct

Students who volunteered to participate were released from class time to attend the focus groups. A trained focus group facilitator from the ‘Centre for Child and Family Policy Research’ (CCFPR), University of Auckland, facilitated the focus groups. A Māori researcher (Puti Wilson) was involved in the study design and attended the focus groups with the Māori and Pacific students to ensure tikanga (Māori culture) was respected. The facilitator discussed the participant information sheets (Appendix 1), gave verbal information on the study and gave students the opportunity to ask questions. Students had previously been advised that the focus groups would be separated by sex and ethnicity, as this was thought to be important to them. They were also advised that the discussions would be audio-taped but their contribution would be completely anonymous. Those who were keen
to continue provided written informed consent. The discussion then began based on the focus group discussion guidelines (Appendix 2) and also included the facilitator showing various media styles to the students. The groups concluded with the students being offered refreshments.

Table 4-3: Examples of questions from the focus group discussion guidelines

<table>
<thead>
<tr>
<th>1. What do you use your mobile phone/s for? What sorts of things do you like to do with your mobile phone? Prompts: Listen to music, play games, surf the net, download ringtones, video calling, watch videos/TV, look at cartoons, text, call</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. What sorts of things do you like to do to relax? What would you most like to receive over your mobile phone to help you relax?</td>
</tr>
<tr>
<td>3. Who would you most like to watch working through similar problems to see how they cope? Prompts: People like you (same age/circumstances)? Famous people? Someone you know? Someone older than you who has been there?</td>
</tr>
<tr>
<td>4. What do you do when you feel you need/want support? Prompt: Who do you go to? (who is most likely to provide support?) How do they support you? What do they do to support you?</td>
</tr>
<tr>
<td>5. Could mobile phones be useful in getting social support? How?</td>
</tr>
</tbody>
</table>

4.4.2.3 Data collection measures

Focus group discussion guidelines with questions and prompts were developed by the candidate in consultation with the Māori researcher (Table 4-3 and Appendix 2). The same format was used for all groups. The discussions were audio-taped and later transcribed, along with notes taken during the groups by the facilitator and the Māori researcher.

4.4.2.4 Analysis

Staff at the Centre for Child and Family Policy Research transcribed discussions and provided a summary of the responses of each group to the questions, and a general thematic analysis of the
findings. The initial thematic analysis was interpreted by the candidate to inform development of the smoking cessation intervention content.

4.4.2.5 Ethics Approval

Ethics approval was provided by the University of Auckland Human Participants Ethics Committee [reference no: 2006/306].

4.4.3 Results

In total, 27 students, 12 male and 15 female, participated in the focus group discussions. Four focus groups (n = 4-10) were conducted by gender and were also based on the predominant ethnic groups at the school: one group with Pacific and Māori male students; one with Pacific female students; one with Indian male students; and one with Indian female students.

The themes that were identified were around the costs of mobile phone use, relaxation and distraction, social support and problem solving, understanding their issues and confidentiality. These are described below.

*Mobile phone use:* Only two students did not have a mobile phone but they both had access to one at home. Students reported that they were not allowed to use mobile phones at school. However, most left their phones on all the time, even at school (in vibrate mode), with a few (Māori, Pacific and Indian) saying they switched them off in religious functions. Most students only used text messaging on their phones due to cost considerations. Although, some did specify that they listened to music or played games on their phones (males more than females). Some had used other functions, such as browsing the internet, but most said anything other than texting was too expensive. Students were not interested in using their phones to contact people outside their established social networks.
Relaxation and distraction: The students did have a variety of activities that they used to help them relax (sleeping, eating, exercising, taking a bath, listening to music). They were asked to suggest things they could do with their mobile phones for relaxation or distraction, and most said that music and music videos could be used to support relaxation. Some mentioned jokes, funny pictures, games, movies, or soap operas.

Social support and problem-solving: There were differences between the groups in who they go to for social support. For Indian boys it was cousins, Indian girls talked about adult family members, while the Māori and Pacific students said they go to friends or ‘sort it out themselves’. Some Pacific students mentioned their church pastor. It was seen as important that the person would understand how they felt. Most saw the mobile phone only as a means of communicating with those important people either by calling or texting. Pacific and Māori students expressed a preference for discussing issues and problems face-to-face.

People who could understand their issues: All groups thought that videos to illustrate strategies for dealing with problems could be useful. They commented that it would be important that the characters shared similar ethnic characteristics in order to be able to relate to them. One Indian student said, “better to see an Indian person as other ethnic groups do things differently”. They also thought they should be of the same age group. A few students (Indian males) said that famous people in the videos could be acceptable, and one Pacific student said it would be good to have people who had been through the same problem. It was important that the person would understand their issues.

Confidentiality: Confidentiality came up as an important theme for the students. Video calling was not popular, with some students disliking the idea of being identified.
The students were also asked specifically about their opinions on possible mobile phone health programmes. Some aspects were particularly appealing such as positive reinforcement messages and text messaging to provide them with information on topics of their choosing, for example information on drugs and alcohol. Some liked the idea of video clips and some liked the idea of music for relaxation. Overall, they were positive about a mobile phone programme that would support them to deal with issues they might face. They would want to be able to select which aspects of the programme they wanted to use. One of the students who was not in favour of such a programme said:

“I actually think to use mobile phones is a bad idea because [you] lose interaction. [For] a lot of people who go through stress and pressure, taking socialising between people away [means you] won’t have the same interaction. Can’t talk to [a] stranger, don’t know they care”.

4.4.4 Discussion

The initial focus groups provided valuable feedback on how adolescents used their mobile phones and how they perceived a programme delivered over the mobile phone could work. Overall, they were supportive, particularly of text messages for information and positive reinforcement. For video messages, the person in the video was considered to be very important, and they suggested people similar to them would be appreciated. Confidentiality was also an important factor for the participants.

These findings are consistent with previous studies with adolescents about desired components of smoking cessation studies. These have included confidentiality, the importance of the ‘staff’, the involvement of peers who understand their issues, and respecting their choice to participate or not.(72, 212) The findings also align with the idea of ‘coping role models’ who are similar to participants with respect to age and ethnicity [from Section 4.2.1.2 (171)].
A strength of this process was having separate focus groups for the different ethnic groups and genders. This allowed the young people to feel comfortable raising issues they thought students from other cultures might not understand. The limitation was that this was a very small study with a purposefully selected group of participants in a narrow age range. Therefore input from a wider group was also considered necessary.

4.4.4.1 Implications for the intervention development

While confidentiality is assured in a mobile phone intervention, these findings did raise the need to continue to include text messages as well as video messages. This confirmed that the selection of the role models in the video messages was very important, and emphasised the need to carefully consider the content of messages around problem solving and social support.
4.5 Online Survey

The next stage in the development process was to obtain input into intervention design from a larger sample and from a wider range of ages and ethnicities than had been included in the focus groups. Mai Media Ltd, a Māori-owned and led media organisation, had approached the candidate and offered their support for this research. Therefore, it was decided to use their young adult-oriented Auckland radio station, ‘Mai FM’, to promote an online survey. This radio station particularly targeted young Māori and Pacific people but was widely popular with youth and young adults across Auckland.

4.5.1 Aims

The purpose of the online survey was to obtain information from young adults about current and potential uses of mobile phones and their opinions on the usefulness of a health-related mobile phone programme.

4.5.2 Methods

4.5.2.1 Study Population

Participants were recruited via an advertisement posted on Mai FM’s website. This advertised a University of Auckland online survey about mobile phones and remained on the Mai FM website for one week. The advertisement contained a link direct to the survey. The eligibility criteria for the survey were: resident in New Zealand; 16 years of age or over; and own a mobile phone.

4.5.2.2 Survey Conduct

Once the participant clicked on the link from Mai FM’s website, they were taken to the participant information sheet (PIS) (Appendix 3). The PIS was based on a template developed by the University
of Auckland Human Participants Ethics Committee specifically for online surveys. At the bottom of the page there was a button for consenting that had to be checked before the participant could continue to the survey pages. On completion of the survey all participants were entered into a prize draw for a portable digital audio player.

4.5.2.3 Data collection measures

The questionnaire was designed by the candidate and reviewed by co-investigators. This was then transferred into a web-surveyor tool. (Appendix 3) The questionnaire was tested in this online format by staff at Clinical Trials Research Unit (CTRU) at the University of Auckland, prior to commencement.

4.5.2.4 Analysis

The candidate conducted descriptive quantitative analyses of the data in Excel, calculating proportions, means and standard deviations. Qualitative comments were also analysed using simple thematic analysis.

4.5.2.5 Ethics Approval

The design for the survey, recruitment and consent processes, participant information sheet, advertisement and the questions to be included were reviewed and given approval by the University of Auckland Human Participants Ethics Committee [reference no: 2006/360].

4.5.3 Results

A total of 172 participants participated in the survey. Four were excluded due to incomplete survey forms. A further 13 were under 16 years of age and so were excluded from this analysis. There were
also two repeat entries (where the same person completed the survey twice). These duplicates were removed. This left 153 responses to be analysed.

The mean age of participants was 24 years (standard deviation (SD)=8). The majority of participants were under 25 years of age (58%, n=96) although the oldest participant was 52 years of age. Nearly half the participants were New Zealand (NZ) European (n=74), one quarter were Māori (n=38), 15% were Pacific (n=23), with smaller numbers of Asian (n=7), Indian (n=5) and ‘Others’ (Figure 4-2).

**Figure 4-2: Online survey participants by self-selected ethnicity**

Sixty-four participants (42%) said they turn their mobile phones off at some time. The most commonly specified times were overnight, or in certain situations such as in meetings, at movies or concerts, and at school or in lectures.
When asked about video messaging, 35% (n=53) stated that they were able to view video messages on their phone while another 10% (n=15) did not know. Of those who knew they could view video messages, over half (55%) were receiving at least one video message each week (Table 4-4). Similar proportions reported sending video messages on a weekly basis. Twenty-one participants (14%) were able to make video calls on their phones, but only eight participants (5%) were actually making video calls regularly.

Table 4-4: Online survey participants receiving video messages weekly

<table>
<thead>
<tr>
<th>Number of video messages usually received per week by those who can view video messages (N=53)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No video messages</td>
<td>24</td>
<td>45%</td>
</tr>
<tr>
<td>One video message/week</td>
<td>19</td>
<td>36%</td>
</tr>
<tr>
<td>2-5 video messages/week</td>
<td>8</td>
<td>15%</td>
</tr>
<tr>
<td>More than 5 video messages/week</td>
<td>2</td>
<td>4%</td>
</tr>
</tbody>
</table>

Participants were asked what sort of things they liked to do on their mobile phones and they were able to select as many of the given options as appropriate. As would be expected, almost all said they used text messaging (99%, n=151) and calling (90%, n=137). More than half played games on their phones (59%, n=91). Substantial numbers also entered competitions (41%, n=62), completed downloads onto their phones (40%, n=61), and listened to music (38%, n=58). Only a quarter of participants said they browsed the internet on their phones (27%, n=41) or watched videos (25%, n=38). A small number said they watched cartoons on their phones (3%, n=5).

They were also asked what new or free applications they would most like on their mobile phone. Pre-specified options were given and participants were able to select more than one if appropriate or to specify other things they would want (Table 4-5). Music, ring-tones and music videos were the most popular options.
### Table 4-5: Online survey responses to what they would most like on their mobile phones

<table>
<thead>
<tr>
<th>What they would like to get on their mobile phones:</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Music</td>
<td>103</td>
<td>67%</td>
</tr>
<tr>
<td>Music videos</td>
<td>77</td>
<td>50%</td>
</tr>
<tr>
<td>Other videos</td>
<td>29</td>
<td>19%</td>
</tr>
<tr>
<td>Games</td>
<td>53</td>
<td>35%</td>
</tr>
<tr>
<td>Ring-tones</td>
<td>84</td>
<td>55%</td>
</tr>
<tr>
<td>Jokes</td>
<td>35</td>
<td>23%</td>
</tr>
<tr>
<td>Access to downloads</td>
<td>36</td>
<td>24%</td>
</tr>
<tr>
<td>TV</td>
<td>66</td>
<td>43%</td>
</tr>
<tr>
<td>None of these</td>
<td>15</td>
<td>10%</td>
</tr>
<tr>
<td>Other (specified as: Pacific Islands music/news, pictures, video recording time, GPS for locational functions, video calling, picture calling, headline news)</td>
<td>6</td>
<td>4%</td>
</tr>
</tbody>
</table>

Participants were specifically asked what they would like to receive over their mobile phones to help them relax, and the majority of participants selected music (75%, n=114). The other categories were fairly evenly selected: videos (35%, n=53), TV (26%, n=40), games (30%, n=46), cartoons (16%, n=24), jokes (26%, n=40), and competitions (30%, n=46). Twelve per cent (n=19) selected nothing. One person suggested the sound of water.

Participants were asked if they would be likely to pass on something good (like a good joke) they received over the phone on to their friends. Seventy-eight percent (n=120) said they would be likely to pass it on. Of those that said they would not, the most common reason was that it would be a waste of money (42%, n=14). However, some also felt that it was too much like ‘spamming’ or sending unwanted material (21%, n=7).

Participants were asked to imagine receiving video messages over the phone to help them to be healthier, for example to stop smoking or to exercise more. In this scenario they were asked to specify how many such messages they would want to receive each day. The responses were quite varied.
However, the largest proportion (42%, n=64) specified one message per day would be appropriate. The second most popular option was less than one message per day (28%, n=43), closely followed by two to five messages per day (20%, n=31). Nine per cent (n=14) opted for more than five messages per day.

As part of such a programme they were asked to specify if they would be interested in interacting with other participants who were also receiving the programme. In response, 18% (n=27) said they would prefer not to have any contact with other participants in such a programme. However, the remainder opted for the specified options as shown in Table 4-6, with a message board appearing to be the most popular option for this group.

**Table 4-6: Online Survey participants’ preferred methods for interactivity**

<table>
<thead>
<tr>
<th>Preferred method for interacting with other participants</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Writing a blog</td>
<td>41</td>
<td>27%</td>
</tr>
<tr>
<td>Reading someone else’s blog</td>
<td>55</td>
<td>36%</td>
</tr>
<tr>
<td>Writing messages on a message board</td>
<td>61</td>
<td>40%</td>
</tr>
<tr>
<td>Reading messages on a message board</td>
<td>53</td>
<td>35%</td>
</tr>
<tr>
<td>Being paired with a ‘buddy’</td>
<td>45</td>
<td>29%</td>
</tr>
<tr>
<td>Prefer no contact with other participants</td>
<td>27</td>
<td>18%</td>
</tr>
</tbody>
</table>

**4.5.4 Discussion**

In summary, the participants in the online survey reported greater use of mobile phone functions other than text messaging, than that found in the focus groups. This may reflect the older age group where cost may not be quite the same barrier as for school students. Approximately one-third of participants knew that they could use video messaging and over half of these were using it regularly. In general, the participants could imagine a mobile phone programme that aimed to help them be healthier, with 71% saying they would like to get at least one message per day from such a programme. An
interesting finding was that 82% would like to interact with others going through the same programme.

The strength of this survey was that it successfully recruited a large number of participants with reasonable numbers from the target groups (young adults, Māori and Pacific). The limitations included that the survey did not use a representative or random sampling frame. Recruitment was advertised via the internet and anyone was able to complete a survey. As it was promoted on a website and was about mobile phones, it is possible that those who volunteered to participate were more likely to be quite technologically literate. This may have affected the generalisability of responses to questions about what they currently do on mobile phones and what they could imagine doing as part of a health programme via mobile phones. Also participation was not restricted to people who smoke or people who would like to stop smoking. Therefore, the responses may not be representative of the target group.

4.5.4.1 Implications for the intervention development

It was of concern that only 35% of participants knew that they could view video messages on their phones. It was considered at the time that the use of other mobile phone functions (beyond text messaging and calling) were in the early phases of adoption. According to the ‘S’ curve of diffusion of technology (Figure 2-1), it was envisaged that New Zealand might be at the start of the exponential increase in adoption by the general population. This would mean that the use of video would increase dramatically in the short to medium term. Therefore it was decided to continue with plans for a video message-based intervention.

These findings confirmed that one or two messages per day would be sufficient for most participants, and prompted the investigation of methods to support interactivity between participants in the intervention.
4.6 Pre-testing Project

The next stage in development involved obtaining some youth-developed video content of various different styles and testing these with other young people to inform content and style of videos for the intervention. During this stage a summer student (Ms Amy Zhuang) joined the team and facilitated the online survey component of the pre-testing project.

4.6.1 Aims

To obtain feedback from young people on the most appealing style of videos in order to guide further content development for the programme.

4.6.2 Methods

4.6.2.1 Content for pre-testing

Several methods were used to pre-test a range of youth-developed video material. Initially two tertiary media training institutions, the Film Television Media Studies production group from the University of Auckland and a media studies group from Unitec University in Auckland, were approached about participation. Interested students from these groups attended a short presentation. A one-page brief described the intent of the proposed smoking cessation programme but left the style of video or animation open to their interpretation.

Secondly, an advertisement was placed online with Student Job Search, a popular service among University students seeking part time employment. This asked for 30-second video clips that would help young people who want to quit smoking. Those submitting up to five clips were given a small amount of money for each clip. Finally, an advertisement was placed with Student Job Search for young people who had stopped smoking to be filmed telling their quitting story. Four young people
were interviewed by the candidate while being filmed professionally by the University of Auckland Centre for Academic Development (CAD) TV producer.

All of the video content was reviewed by the candidate. The content was easily categorised into distinct styles: ‘animation’; ‘interviews with young people’; ‘multimedia productions’; and ‘professionally filmed videos’. Five pieces of content were selected to best represent the different styles of video that had been submitted. These included one animation, one multimedia mix of images, interview and music, two casual interviews with a young person talking about smoking and quitting, and one professionally filmed video of a young person talking about why they had quit. These videos were also reviewed by the expert advisory group.

4.6.2.2 Study population

Due to the previous successful recruitment to the online survey, an advertisement was once again posted on the website of Mai FM (the popular Auckland young adult oriented radio station). This advertised a University of Auckland online study and remained on the Mai FM website for two weeks. The advertisement contained a link direct to the study. The eligibility criteria for the survey were: resident in New Zealand; and 16 years of age or over.

4.6.2.3 Conduct of the pre-testing study

The link took participants directly to the participant information sheet (PIS), which was developed in accordance with the University of Auckland Human Participants Ethics Committee template for online surveys. Participants confirmed their consent by clicking on a button at the bottom of the PIS that took them directly to the study questionnaire. They could abandon the study at any time or be returned to the Mai FM website by clicking ‘No’. A prize draw for a portable digital media player was offered to the participants as an incentive for completing and submitting the survey.
The candidate was responsible for designing the study, obtaining ethics approval, designing the questionnaire, undertaking a final analysis and interpretation of findings. A summer student (Ms Amy Zhuang) facilitated the conduct of the pre-testing study, entered the questionnaire into the online survey tool, extracted the data and performed an initial analysis of the results.

4.6.2.4 Data collection measures

A questionnaire was developed, reviewed and refined by the candidate, and then tested by CTRU staff. (Appendix 4) It was developed as an online questionnaire using the ‘web-surveyor’ tool that allowed an html (webpage language) link to open and play the video content. In this way, the pre-testing participants could view each clip and answer a series of questions specific to that video. Towards the end of the questionnaire were more general questions and links to be able to watch the video clips again if they needed to do so to answer the questions. Participants rated each video out of ten according to how much they liked it, as well as answering more specific questions about each video and placing them in order of preference.

4.6.2.5 Analysis

Basic descriptive quantitative analyses were performed in Excel. All free text responses were examined by the candidate in order to gain a more in-depth understanding of participants’ perspectives on the video styles. These are summarised below with some representative direct quotes included.

4.6.2.6 Ethics approval

The design for the survey, recruitment and consent processes, PIS, advertisement and the questions to be included were reviewed and given approval by the University of Auckland Human Participants Ethics Committee [reference no: 2006/360].
4.6.3 Results

A total of 44 participants responded, although three abandoned the survey and did not submit any feedback, leaving 41 responses to be analysed.

The mean age of participants was 24 years (SD=8) with a range of 16 years to 45 years. Three-quarters were female (n=31). Twelve participants (29%) described themselves as daily smokers. The mix of self-reported ethnicities was very similar to that seen in the previous online survey using the same recruitment method (Table 4-7).

Table 4-7: Pre-testing project participants’ self-selected ethnic group

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ European/Pakeha</td>
<td>18</td>
<td>44%</td>
</tr>
<tr>
<td>Māori</td>
<td>9</td>
<td>22%</td>
</tr>
<tr>
<td>Pacific</td>
<td>7</td>
<td>17%</td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>Indian</td>
<td>3</td>
<td>7%</td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>5%</td>
</tr>
</tbody>
</table>

The five video clips embedded in the questionnaire are described in Table 4-8 in the order they were seen in the questionnaire. After watching each clip, participants were asked to give the clip a rating out of 10 - 10 meaning they really liked it and 1 meaning they really disliked the clip. The first Casual Interview had the highest average score (Table 4-8). This pattern was repeated regardless of subgroup. For example, Māori participants and participants who smoked gave the highest average scores to the first casual interview. However, participants were later asked to position the five clips from their most preferred to least preferred, and the highest proportion (39% of participants) placed the animation clip first.
Table 4-8: Pre-testing project description of pre-tested video clips

<table>
<thead>
<tr>
<th>Description</th>
<th>Average score (out of 10)</th>
<th>% ranking clip as their first preference (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-made animated clip of smoking Ninja</td>
<td>5.33</td>
<td>39% (16)</td>
</tr>
<tr>
<td>Mix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-made clip with mix of music, graphics, &amp; interview with a young male doctor</td>
<td>5.17</td>
<td>17% (7)</td>
</tr>
<tr>
<td>Casual interview</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-made video of young female smoker answering questions about smoking</td>
<td>6.76</td>
<td>22% (9)</td>
</tr>
<tr>
<td>Studio interview</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professionally made video of young female ex-smoker talking about quitting</td>
<td>5.23</td>
<td>7% (3)</td>
</tr>
<tr>
<td>Casual interview 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-made video of young female answering questions about smoking</td>
<td>5.31</td>
<td>7% (3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 missing</td>
</tr>
</tbody>
</table>

In further comments about why they scored the animation clip the way they did, those who scored it five or less (out of ten) often commented that it was not funny, whereas those who scored it greater than five often commented that it was funny. Three participants (all female) said they could not understand the clip. Two participants said they were offended by this clip. Their reasons were:

‘...video clip the ninja looked really evil and it looked like it was an animated version of a virus on a computer, it was kind of scary.’ Female 16 years

‘I myself is a smoker and watching the clip made me feel shamed and very offended as it sets a bad name for people like me. Especially the quote at the end of the clip, "A smoking ninja is a sad ninja"...That saying is telling the viewers that smokers are’ Female 18 years

The reasons given for scoring the ‘Mix’ clip low were that it was boring (six participants) or hard to understand due to the quality of the clip (ten participants). Seventeen participants (41%) responded
that they could not relate to the person in the video. Six of these participants commented that they were non-smokers and this was the reason they did not relate to the person. Two participants said it was because they didn’t like what he said.

“I understand what he was trying to say but I dont wana hear from a theorist I wana hear from a real person who knows what its like to smoke and be addicted. It’s like having someone tell you how to have a baby, when they've never had any themselves!!!!!!” Female 27 years

“not why I smoke” Female 32 years

The first Casual Interview video was popular. Most who gave it a low score commented that it was boring. Positive comments were predominantly about it being ‘real’ and ‘honest’ and liking what the person said about quitting with, or for, your partner.

“I liked this clip because she, like me is a smoker and so i have better understanding and feel like i'm not in this alone.” Female 18 years

“relevant to me. identifiable situation of a partner and one of the factors of smoking or not. atmosphere casual and not set up. her tone and language also not scripted or pre-thought out answer.” Female 27 years

“It was pretty good, because she expressed the problem that all of us have with regards to quitting. Also it was nice to know that we all shared the same problem.” Male 31 years

Seven participants (17%) said they could not relate to the person in the clip – four because they were non-smokers and three because they considered that they ‘think differently’ than them (only one of these three participants smoked).

The Studio Interview appeared to be less popular predominantly due to participants not relating to the person in the video (n=17, 41%), or what she said.

“she didnt really talk properly, kinda fast, and what she said was pretty stupid” Female 17 years

“didnt understand the message she was trying to get out how are we suppose to know what she is talking about if she is just talking about people not being hot if they smoke” Female 16 years
The second Casual Interview was less popular than the first, with the majority of people who gave it a low score either complaining about the quality of the video (n=8, 21%), or not relating to the person in the video (n=10, 21%).

“Good example to use but she doesn’t sound like a smoker. Don’t want non-smokers point of view! what would they know about the addiction!” Female 27 years

“i didn’t really enjoy it because of course we smokers would stop in a minute if we could for just about anything e.g sports, family, hobbies etc: but it’s harder than you think and she wasn’t giving a good enough answer to help others do so” Female 18 years

“Umm she just didint sound convincing, she was ‘like i dont no’ type of person.” Female 33 years

After rating and ranking all the videos, participants were asked “In general, what style of video clip do you prefer watching?” The most popularly selected category was animations (37%, n=15) with reasons including that they could be more entertaining and involve humour. The second most commonly selected category was casual interviews (27%, n=11) with comments about it being more real.

“Because I feel like I can relate to it more as it is honest and another ordinary person like me not someone reguarded a celebrity.” Female 16 years

“It has a more human touch, can relate to the people, motivates (if they can why can't we) and drives home the message.” Male 31 years

Some suggestions for improving the videos included: pictures and facts on the health effects of smoking; improving the quality of the videos; and having a wider variety of interesting people. Participants were asked who they would like to see in the videos (Table 4-9).
Table 4-9: Pretesting participants’ responses to who should be in the videos

<table>
<thead>
<tr>
<th></th>
<th>n (N=30)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>The people we had in our clips were good</td>
<td>5</td>
<td>17%</td>
</tr>
<tr>
<td>Someone famous</td>
<td>7</td>
<td>23%</td>
</tr>
<tr>
<td>A variety of people of different ages and sexes.</td>
<td>5</td>
<td>17%</td>
</tr>
<tr>
<td>Younger people</td>
<td>2</td>
<td>7%</td>
</tr>
<tr>
<td>Someone like me (Female 25 years)</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Other suggestions included people who already quit, had a tobacco related disease or had nearly died</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When asked if they would join a similar health programme (on a different subject) twenty-five participants (61%) selected maybe; nine participants (22%) selected yes; and seven participants (17%) selected no.

4.6.4 Discussion

Overall, the feedback from the participants in the pre-testing survey showed animations and the casual interview style to be the most popular video styles. The appeal of animations is their ability to contain humour. However, it may be difficult to create something that appeals to everyone. Casual interviews were seen as being real and credible. Some of the themes that came through were about the importance of the quality of the video and of the individual in the video. Participants did not appreciate any video clips that did not have high sound and picture quality. Being able to relate to the person in the video clips was very important to participants. They rated clips low if they did not consider the person to be ‘real’ and believable as someone who smokes. The ‘story’ in the video clips also needed to be realistic, honest and believable.

There do not appear to be any similar studies comparing different styles of videos for use in a health intervention in the literature. The findings on the importance of relating to the role model and their
(213, 214) From this research, including the priority group’s experiences, values, beliefs and social factors into materials and messages may increase their relevance and use. Many studies using role models have attempted to tailor the models and their stories to their target audience, particularly with respect to age, sex and ethnicity. (174, 180, 191) However, these studies have not separately examined the importance of this on their participants’ perspectives of the role models or on their outcomes.

A strength of this project was the ease with which the videos could be set up online to be viewed as part of an online survey. This was easier than setting up mobile phone delivery for this small study. Participants included a reasonable mix of ethnicities and ages, although only one quarter of participants were male.

There were several potential limitations of this pre-testing project. The videos were viewed via an online survey rather than directly on participants’ mobile phones. Yet the intervention was being developed for mobile phone delivery. This method was chosen for practical reasons, and as this was about video ‘styles’ rather than the feasibility of sending them over the phone this was considered appropriate. Smoking was not an eligibility criterion for this study and more non-smokers than smokers participated. Again this project was to determine video ‘styles’ that young adults appreciated and so it was not considered necessary to restrict it to smokers or people wanting to quit. However, this may have limited the generalisability of the findings to the target group.

4.6.4.1 Implications for the intervention development

Professionally filmed ‘casual’ style videos with ex-smokers talking confidently about their quitting experiences were supported. This study reinforced the need for the role models to be ex-smokers who could describe their own real stories about smoking and quitting. It also confirmed the need to involve young adults in the selection of the role models for the intervention. The use of animations could also
be further investigated. Some initial content was produced using this feedback and then further tested in a pilot study.
4.7 Pilot Study

The following stage involved developing some initial intervention content and then testing it fully in a pilot study that would replicate the processes to be followed in the full trial. All of the above input from experts and young adults was used to inform the development of the content. This involved auditioning role models, selecting one, writing an outline for her video clips based on her own story and effective smoking cessation techniques, filming and editing the video clips, and compiling the clips into a chronological programme. Some anti-tobacco industry content was also developed with school drama students and included in the programme. Full study processes and questionnaires for the main trial were established for the pilot study, with the exception of randomisation. The pilot study was conducted from June 2007 to August 2007.

4.7.1 Aims

The pilot study was conducted to test the video message intervention and the mobile phone delivery system, and to obtain feedback from participants regarding their satisfaction with the programme. In particular the aims of the pilot study were to:

- Determine the feasibility of delivering the intervention
- Test baseline data collection forms and processes
- Obtain feedback from young people on the appropriateness, applicability and enjoyment of the programme

4.7.2 Methods

4.7.2.1 Content Development for Piloting

An advertisement was placed with Student Job Search and a popular website for young actors looking for work. The advertisement specified the role was for smokers or ex-smokers only, who were prepared to be filmed for a smoking cessation research programme where short video clips would be
sent out to participants’ mobile phones. Twenty-seven young adults attended the film studios to film audition videos with the University of Auckland CAD TV producer (Richard Smith). For the audition video they were asked to first talk freely about their own smoking or quitting, and then to follow a script.

All of the short audition video clips were set up to be shown to young people on a laptop computer. Young adults who had previously expressed an interest in consultation on the programme were invited to attend group sessions or individual sessions. Young adult workers at Mai FM radio station also participated in a group session. The participants in these sessions were asked to rate all the role models (from 1-27) according to how much they would want to continue watching them. They also recorded their initial impressions of each role model on paper forms. Nineteen people, aged between 18 years and 36 years, completed the ratings. Eight were Māori, three Pacific and eight NZ European. One was an ex-smoker and the remainder were smokers.

The top-rating female actor (Reana) was universally popular and so she was selected to be filmed first for the pilot study. The following process for filming the role models was established with Reana and was later repeated for all the role models. Reana was interviewed about her smoking history and quitting experiences. The interview questions and an example of one of the role model’s responses are shown in Appendix 5. Her story was converted into a chronological series of messages from a lead up to four weeks after quitting. Each message was based around a particular issue associated with quitting and how the model coped with that issue, or around how to keep motivated and stay quit. These were provided to the role model in bullet point form to ensure that they would put it into their own words (example in Appendix 6).

The role model was coached by the candidate and directed by Richard Smith (Centre for Academic Development TV producer). She was advised that the aim was to appear as if she was filming her
own video diary (like ‘myspace’) in her own house, talking about her quitting attempt as if it was happening at the time. Each video clip would need to appear casual and ‘real’, and would need to have a beginning, middle and definite end. These were recorded as 30 second vignettes in a ‘video diary’ style using the model’s own words. The clips were edited by Richard Smith, and ‘wrapped’ with the study’s logo shown at the start and finish of each clip.

4.7.2.1.1 Anti-tobacco industry video content development
The candidate and a co-investigator (Dr Simon Denny) approached two high school drama classes about participating in the project. Facts about the tobacco industry were discussed, such as their methods for promoting their products, additives to cigarettes, how much profit they make, and the effects of some of the components in cigarette smoke. The students were then assisted to produce short video clips, predominantly of students talking about proven ill-effects of smoking and behaviours of the tobacco industry in a manner consistent with the ‘Truth’ anti-tobacco industry media campaign, as discussed in section 4.2.3. These were filmed on location at the schools by Richard Smith.

4.7.2.1.2 Pilot study programme regimen
A programme was developed with two video messages per day based around the chronological video diary clips from the role model, interspersed with some of the student anti-tobacco industry videos and a small number of text messages. The video clips were arranged into a pre-set schedule to deliver two messages per day in a chronological sequence starting with a lead-up to Quit Day, messages for Quit Day, then post-Quit Day.

4.7.2.2 Technical Development for Piloting
The candidate developed a ‘systems requirements’ document which outlined the requirements for the system functions that would be necessary to deliver the messages and run the study (shown in
Appendix 7). The system was developed by the IT Senior Developer in the CTRU. These functions started with the management of online registration of interest and an eligibility questionnaire (Form A, Appendix 8). All registrations were recorded with the mobile phone number as the unique identifier for each potential participant from that point on. Each mobile phone number could only be registered once. However, if a participant changed mobile phone numbers, this could be manually changed in the system to ensure the programme continued.

The submission of Form A information indicating eligibility for the study would trigger an automated text (SMS) message to that mobile number directing the participant to read the participant information sheet (PIS, Appendix 9) and reply if they wished to consent to participate in the study. An appropriate reply (“I consent”) to this message would trigger a further text message directing the participant to complete an online baseline data collection form (Forms B and C, Appendix 10 and 11). Form C included the self-selection of a Quit Day and two appropriate time bands (per 24-hour clock) to receive messages from the programme. The system would then use the Quit Date, the selected time periods, and the pre-determined programme of messages to automatically schedule message delivery to each participant.

The video clips were hosted on a ‘Wireless Application Protocol’ (WAP) site. A text message with the URL address for the appropriate video message would be sent to each participant at each appropriate time-point:

“Hi from the team at STUB IT. Please view your latest STUB IT video clip with this link

http://digitest/quitmedia/?ppid=1234”.

By highlighting (scrolling over or selecting) the URL - http://digitest/quitmedia/?ppid=1234 - within the text message, the video message would automatically download and play on the phone. Download times would vary depending on geographical location – within central locations it would only take a few seconds. However, if outside the quickest mobile network it could be considerably slower. Video
messages could be viewed immediately on receipt or at a later time as appropriate. The text message could be kept and the URL used multiple times to view the clip. The video clip itself could also be saved onto the phone but this was not promoted to participants as continuing to do so would soon overload the capacity of some phones.

The system was also set up to allow participants to request extra text messages for support on demand. Participants were advised they could text message a keyword to the programme’s ‘shortcode’ (a 4-digit number) and they would immediately receive a text message in response. For the pilot study, these messages contained general tips on managing cravings. As required by the mobile communications network, the system was also set up to recognise participants sending a text message with the word ‘Stop’ and would automatically stop sending messages to that mobile phone number (although these participants were still followed up for data collection).

For study management purposes the system would allocate the participant a ‘status’ that would be updated according to whether they were ‘registered’, ‘eligible’, ‘consented’, completed baseline data collection and ‘randomised’, ‘withdrawn’ or had ‘completed’ the study. The system provided online real-time reports on the numbers of participants in each of these statuses, along with other reports requested by the candidate (such as registered participants by where they heard about the study) and those necessary for study management (such as participants who had not completed forms when due, and participants requiring verification of quitting status).

4.7.2.2.1 Partnership for technical development
Vodafone New Zealand Ltd agreed to support the trial of a multimedia mobile phone cessation intervention. Vodafone is a mobile telecommunications company providing services to 2.5 million New Zealanders. At the time of this pilot study there were only two providers of mobile telecommunications and Vodafone claimed to have more than half of the market share [personal communication, Vodafone NZ Ltd]. Vodafone provided a free shortcode (4-digit number) and free access to their mobile phone network for the duration of the research. The connection to the network
was established and tested in this pilot study. This meant that all participants needed to be on the Vodafone mobile phone network.

### 4.7.2.3 Study population

Participants were recruited via advertising on *Mai FM* radio station and a direct link from the *Mai FM* website. Advertising commenced two weeks prior to the pilot going live in order to create some interest and give potential participants a chance to consider quitting. Potential participants who registered their interest received an email response about the study saying they would be advised when the study was ready to start. Once the pilot went live, they were directed to the STUB IT website where they self-completed the eligibility questionnaire (Form A, Appendix 8). Eligibility criteria were the same as those planned for the full trial:

- 16yrs or over
- Vodafone customers, able to receive video messages on their phone
- Daily smoker
- Wanting to quit within the next 3 weeks
- Able to provide informed consent

Those not meeting the eligibility criteria were advised to call *Quitline* for help with stopping smoking.

### 4.7.2.4 Registration process

Eligible participants were advised to read the participant information sheet (PIS) available on the website (Appendix 9). Registered participants who did not complete the eligibility checklist were phoned by study staff and the checklist completed over the phone. Eligible participants were then sent a text message and advised that they must reply with the words “I consent” after reading the PIS in order to proceed. Participants received daily automated reminders for up to three days or until the
response was received. Unrecognised responses (those that did not say “I consent”) were manually checked by study staff and could be manually included by verbal consent or asked to re-text. On receipt of the appropriate response, participants were directed by text message to return to the website and complete baseline data collection. Those not completing the online questionnaire were sent daily text message reminders and were then phoned after three days by study staff and the questionnaire completed over the phone.

4.7.2.5 Intervention/study conduct

After baseline data collection, the system assigned the programme to each individual according to their quit date and preferred timings for messages. The programme consisted of two messages per day for four weeks - daily video messages from the role model, anti-tobacco industry video messages and text messages (see programme schedule in Appendix 12). All participants received the same programme. Participants were able to request messages at any time to help deal with cravings for cigarettes as they occurred. There were no costs to participants to take part in the study.

4.7.2.6 Data collection measures

At the end of the four-week programme, participants were called by study staff to complete a follow-up questionnaire over the phone (Appendix 13). These interviews were carried out by the candidate and one other staff member. Several attempts were made to follow-up non-responders using a variety of contact details collected at baseline. This included questions about their satisfaction with the programme, their opinion on the different aspects of the programme, any issues with receiving the programme, and whether the programme assisted them to stop smoking.
4.7.2.7 Analysis

This was a pilot study and therefore not designed to provide sufficient data to demonstrate effectiveness or detect improvements in health outcomes for participants. A basic descriptive analysis examined participants’ opinions on the programme, and any particular issues by age, gender, ethnic group, or other baseline characteristics.

4.7.2.8 Ethics approval

All study procedures and documents were approved by the Ministry of Health’s Northern Region X Ethics Committee (Ref: NTX/06/10/130).

4.7.3 Results

Seventeen participants registered with the pilot study (Table 4-10).

Table 4-10: Pilot study baseline participant characteristics

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Māori</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>NZ European</td>
<td>3</td>
<td>18%</td>
</tr>
<tr>
<td>Pacific</td>
<td>4</td>
<td>24%</td>
</tr>
<tr>
<td>Indian</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>12%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Personal income*</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 15,000</td>
<td>5</td>
<td>29%</td>
</tr>
<tr>
<td>Between 15,000 and 30,000</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Between 30,001 and 45,000</td>
<td>7</td>
<td>41%</td>
</tr>
<tr>
<td>Between 45,001 and 60,000</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Over 60,000</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Don’t wish to answer</td>
<td>2</td>
<td>12%</td>
</tr>
</tbody>
</table>

*recorded in NZ dollars per annum
4.7.3.1 Baseline participant characteristics

Participants’ ages ranged from 18 years to 51 years with a mean age of 25 years (SD=8). Six participants self-identified as Māori (35%) and four as Pacific (24%). Approximately two-thirds were female, with most participants being on low to medium incomes (Table 4-10).

Table 4-11: Pilot study participants’ baseline nicotine dependence and concerns about quitting

<table>
<thead>
<tr>
<th>Smoke first cigarette of the day within 30 minutes of waking</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>29%</td>
</tr>
</tbody>
</table>

Hooked on Nicotine Checklist (HONC)

<table>
<thead>
<tr>
<th>Have you ever tried to stop smoking before but couldn’t?</th>
<th>14</th>
<th>82%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you smoke now because it is really hard to quit?</td>
<td>11</td>
<td>65%</td>
</tr>
<tr>
<td>Have you ever felt like you were addicted to tobacco?</td>
<td>13</td>
<td>76%</td>
</tr>
<tr>
<td>Do you ever have strong cravings to smoke?</td>
<td>14</td>
<td>82%</td>
</tr>
<tr>
<td>Have you ever felt like you really needed a cigarette?</td>
<td>17</td>
<td>100%</td>
</tr>
<tr>
<td>Do you find it hard to keep from smoking in places where you are not supposed to?</td>
<td>8</td>
<td>47%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>When you have tried to stop smoking (or if you haven’t used tobacco for a while), did you feel...</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>It was hard to concentrate?</td>
<td>8</td>
<td>47%</td>
</tr>
<tr>
<td>More irritable?</td>
<td>12</td>
<td>71%</td>
</tr>
<tr>
<td>A strong need or urge to smoke?</td>
<td>15</td>
<td>88%</td>
</tr>
<tr>
<td>Nervous, restless or anxious?</td>
<td>7</td>
<td>41%</td>
</tr>
</tbody>
</table>

During your quit attempt are you concerned about...

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Putting on weight</td>
<td>9</td>
<td>53%</td>
</tr>
<tr>
<td>Peer pressure to smoke</td>
<td>7</td>
<td>41%</td>
</tr>
<tr>
<td>Feeling isolated</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Stress</td>
<td>13</td>
<td>76%</td>
</tr>
<tr>
<td>Family pressure</td>
<td>3</td>
<td>18%</td>
</tr>
<tr>
<td>Failing at quit attempt</td>
<td>13</td>
<td>76%</td>
</tr>
</tbody>
</table>

All participants smoked manufactured cigarettes and one-third also smoked roll-your-own cigarettes (loose tobacco). The average number of cigarettes smoked per day was ten and the average weekly
cost of cigarettes was $65.60. Fourteen participants (82%) had tried to quit before. Some of the measures of nicotine dependence are shown in Table 4-11. The majority of participants did feel addicted (n=13, 76%), and most participants were concerned about stress and failing in their quit attempt (n=13, 76%). On average participants scored ‘yes’ to seven out of a possible ten markers of nicotine dependence on the Hooked On Nicotine Checklist (HONC). Participants were asked how confident they were to quit this time on a scale of 0% (not confident) to 100% (fully confident). Their mean score was 66% (SD=24).

Nine participants (53%) were familiar with video messaging on their phones already. Half of the participants (n=9, 53%) spent under $31 per month on their mobile phone, five (30%) spent between $31 and $100 per month, and three participants (18%) spent over $100 per month on their mobile phone.

Two participants withdrew immediately after registration (prior to receiving the programme). This was most likely to be due to a Vodafone issue that occurred in the first few days where participants were erroneously being charged to view the video clips. This meant that any participants who did not have credit on pre-paid phones (as opposed to those on post-pay plans) were unable to open and view the video clips. Vodafone fixed this error and reimbursed participants who had been charged.

**4.7.3.2 General feedback about the intervention**

Two participants were unable to be contacted at the end of the programme after four weeks. Therefore, thirteen participants (77%) provided follow up data. Nine of those thirteen participants (69%) stated that they liked the intervention, three (23%) said they liked it most of the time, and only one participant did not like the intervention. Participants were asked to specify in free text what they liked most and least about the programme and these comments are shown in Table 4-12.
Table 4-12: What pilot study participants liked about the intervention

<table>
<thead>
<tr>
<th>What did you like the most?</th>
<th>What did you like the least?</th>
</tr>
</thead>
<tbody>
<tr>
<td>the support was there</td>
<td>too often, got annoying</td>
</tr>
<tr>
<td>texting was constant, good backup to remind you what you were doing</td>
<td>the credit issue</td>
</tr>
<tr>
<td>reminders &amp; info, video &amp; txt combo (variety)</td>
<td>credit issue, couldn’t open clips</td>
</tr>
<tr>
<td>encouraging ones were good</td>
<td>got bored, someone else moaning about quitting, being reminded about how hard it is</td>
</tr>
<tr>
<td>look forward to clips coming in, knew they were coming</td>
<td>beginning, not knowing how to download</td>
</tr>
<tr>
<td>advice, crave, good tips</td>
<td>didn’t work, trouble opening the files, didn’t see lots of them</td>
</tr>
<tr>
<td>good reminder to keep going</td>
<td>boring video clips that were not professional</td>
</tr>
<tr>
<td>supportive, liked it all</td>
<td>nothing, it was really helpful</td>
</tr>
<tr>
<td>limited to technical people, know it is good but need info on how to do it</td>
<td></td>
</tr>
<tr>
<td>interesting &amp; relevant, clips not too long, not too intrusive, reminder</td>
<td>not always able to see them at the time if at work</td>
</tr>
<tr>
<td>fav clip was deaths greater than mva/suicide</td>
<td></td>
</tr>
<tr>
<td>it was different, continuous updates by text &amp; video, quitting suggestions like using gum</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Nine participants (69%) thought the quantity of messages was about right: “*roughly related to cig breaks, were good distraction at this time*”. Only one (8%) said there were too many messages, and three (23%) said there were not enough messages:

- “*could have three to break up day, morning/lunch/dinner, need to fill your time*”
- “*four a day would be good*”
- “*three - morning, lunch, before dinner*”

One participant (8%) said the programme needed more ‘professional’ messages, suggesting animations or graphics. However, another two (15%) thought it was good that they were not too professional, commenting that it looked like “*she was at home and was naturally coming out with it rather than scripted*” and that it was “*not fake*”. 

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All except one participant (an international student with English language difficulties) said the language used was appropriate and there was nothing offensive. The quality of the videos was considered to be good by all participants except three (23%) who said not all clips were good quality but commented that it might be their handsets.

Nine participants (69%) said they saved and watched video clips later if they really liked them; three participants (23%) deleted the clips after viewing. Five participants (39%) liked being able to pick the appropriate time periods and two others were happy with the default periods (early morning and evening). Some participants commented on particular times that suited them, which included first thing in the morning, afternoon, evening, or work break times. Participants reported a mixture of watching the clips as soon as they arrive, a few minutes later, or a few hours later, depending on what they were doing at the time. Two commented that it was inappropriate to view them at work so would have to wait until after work to watch them. Participants appeared to be happy that if a message arrived at an inappropriate time they could just view it later.

| Table 4-13: Pilot study participants’ responses to the role model video messages |
|---------------------------------|----------|-----|
|                                 | n | %    |
| **Was the role model was believable?** |         |      |
| Yes                             | 7 | 54%  |
| Most of the time                | 4 | 31%  |
| No                              | 1 | 8%   |
| Did not answer                  | 1 | 8%   |
| **Could you relate to what the role model was saying?** |         |      |
| Yes                             | 8 | 62%  |
| Most of the time                | 4 | 31%  |
| No                              | 1 | 8%   |
4.7.3.3 **Feedback about the role model videos**

Participants were specifically asked about the role model video clips and whether they found the role model believable and could relate to what she said (Table 4-13).

Comments about the role model videos brought up several themes. Three pointed out that everyone goes through withdrawal differently so they could not always relate to the role model’s experiences. One participant felt she was very similar to the role model and this was helpful. Another participant commented that what the role model said was relevant (like talking about drinking, gym, and boyfriend). One participant commented: “felt like I wasn’t just on my own because she was going through it too”. Four stated that they liked these clips to start with but later started to get bored with them as they were too similar or there was too much ‘moaning’. One commented that the role model did not say anything new for people who had tried to quit lots of times before.

Nine participants (69%) said they would like to have more role models to choose from. However, three said they would not like more choice because it would be confusing (n=2, 15%) or because it was good to get used to the one person and have a connection with them (n=1, 8%). When commenting on this question, one participant said they would like to see a professional, one said younger people, one said someone of similar ethnicity to them, and one said they would like to see someone who had tried lots of times to quit.

4.7.3.4 **Feedback on other video and text messages**

Seven participants (54%) responded that they liked the other video clips, one (8%) said they liked them most of the time, three (23%) did not like them, and two (15%) said they did not see any of these clips. Two specifically commented that they did not like the anti-tobacco industry focus. Eight participants (62%) said they would have liked more text messages (the remaining five said the
amount of text messages was about right) and eleven (85%) said they would specifically like more facts and quitting tips. Four (31%) commented that they particularly liked the ‘crave’ function (texting in to receive instant messages to help beat cravings) and seven participants (54%) said they would like more ‘crave’ messages. The remainder had forgotten about the crave function and had not used it at all.

4.7.3.5  Feedback on technical aspects of the intervention

Participants were asked if they had experienced any technical issues during the pilot study. Seven participants (54%) said they had had some difficulty opening video clips:

- Four did not know how to open them initially
  - two had contacted study staff for advice
  - one said it took them a while to work it out
  - one had given up until she was phoned by the research assistant and then she tried again and watched the remainder of the programme
- Two participants complained about the Vodafone credit issue (that is, not being able to open clips initially if they had no credit on a prepaid phone, which was later remedied)
- Three said they had problems with the Vodafone network being down at times or poor network overage in some places

4.7.3.6  Smoking outcomes

Nine participants (69%) reported that they had stopped smoking during the pilot study. Four participants did not stop smoking. However, two of them had cut down on the number of cigarettes smoked. All of the participants who quit and the two participants who had cut down reported that the intervention had helped them to stop or cut down. The anti-tobacco industry clips were least often
selected as being helpful in stopping smoking (Table 4-14). The text messages and quit tips and facts were most often selected as being helpful in stopping smoking.

Table 4-14: Pilot study participants’ responses to which aspects helped them quit

<table>
<thead>
<tr>
<th>Which aspects helped you to stop smoking?</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Text messages</td>
<td>11</td>
<td>85%</td>
</tr>
<tr>
<td>Role model video messages</td>
<td>9</td>
<td>69%</td>
</tr>
<tr>
<td>Other video messages</td>
<td>7</td>
<td>54%</td>
</tr>
<tr>
<td>Crave messages</td>
<td>8</td>
<td>62%</td>
</tr>
<tr>
<td>Facts and quitting tips</td>
<td>10</td>
<td>77%</td>
</tr>
</tbody>
</table>

Comments about what was useful covered several areas. Four participants mentioned setting a quit date and providing motivation to initiate a quit attempt. Three participants talked about the intervention acting as a good reminder of what they were doing. Three mentioned support or knowing that others were trying to quit was helpful. Two said the quitting tips were helpful. One said the facts particularly helped her and that it differed from seeing similar facts on TV because they had been personally sent to her. Two participants said it was good at first but they got bored with it or sick of it after a while. Two specifically said that if they had not participated they would not have quit smoking.

4.7.4 Discussion

The pilot study involved developing some early video message content for the intervention based on the feedback from experts and young people, and testing this content using the mobile phone delivery system being developed for the main trial. In general, the pilot study found that it was possible to send out an automated programme of video messages at pre-scheduled times to multiple participants across Auckland.
There were very few issues uncovered. Firstly, Vodafone NZ Ltd was supporting the study by providing free access to their network. However, this ‘zero-rating’ process (of making it free to participants) was initially unsuccessful and participants were charged for viewing the video clips. Once this was ascertained, Vodafone remedied the error and reimbursed participants. Those participants with no credit available on pre-paid phones were unable to view any clips until this situation was remedied. This could have affected their full participation and appreciation of the intervention. There were some other technical issues, such as participants initially not knowing how to open the video clips and difficulties downloading clips in some areas of Auckland. It was clear that these issues would need to be more fully explained to participants at the start of the full trial.

The pilot study also aimed to test registration and consent processes and baseline online data collection forms for the full trial. These processes all went smoothly in the pilot study with no issues identified. All participants were able to fully complete the process of baseline data collection without any issues and there was no negative feedback from participants. Two participants did withdraw from the study immediately after baseline. However it was felt this was likely to have resulted from being unable to view the video clips due to the credit issue as described above.

The third aim of the pilot study was to obtain feedback from young people on the appropriateness, applicability and enjoyment of the programme. In general the feedback was positive with all participants except one saying they liked it or liked it most of the time, and all participants except two saying it helped them to quit or cut down their smoking. The majority thought the number of messages was about right and most liked being able to select time periods. Participants confirmed the need to offer a choice of role models and to consider offering the ability to change the frequency and timing of messages and to change the role model during the intervention. They provided a caution against the role model video clips being too negative (too much ‘moaning’ or stress). Their feedback
also affirmed the need to include plenty of text messages and the crave function, but identified the need to re-consider the other anti-tobacco industry video messages.

A strength of this pilot study was the ability to have it fully set up with all study processes as for the full trial and with the intervention as it was intended to be delivered. This enabled all processes to be fully tested and initial difficulties, such as the mistaken charging of participants, to be sorted prior to commencing the full trial. It also facilitated valuable feedback on the intended intervention and its delivery to participants. The pilot study was not powered to examine smoking cessation outcomes. However, it was encouraging that nine participants reported having quit smoking at four weeks. The limitations included the mistaken charging of participants, as mentioned above, which may have affected the full participation and feedback from participants. Two participants were unable to be contacted for follow-up data collection and it is possible that they may have experienced other issues which were not identified in this analysis. This was a small study but it was only ever intended to be a small pilot to test processes and delivery mechanisms, and a target sample size had not been set.

### 4.7.4.1 Implications for intervention development

The pilot study affirmed that a multimedia mobile phone cessation intervention was feasible and was acceptable to participants. The lessons learned for the final intervention development were: to include instructions about viewing clips; to provide more choice of role model and the ability to change role models; to ensure the video clips were not too negative; and to reconsider the anti-tobacco industry videos that were in the pilot study.
4.8 Final Intervention Programme Development

All of the above described stages (theoretical basis, expert advice, focus groups, online survey, pre-testing and pilot study) were used to inform the final development of the intervention content.

4.8.1 Role model stories

The role model video clips used in the pilot study were included in the final intervention. Feedback around the role model clips confirmed the need to include a choice of role models, and ability to change role models during the programme. Five further role models were selected using the ratings provided by the target audience as described in Section 4.7.2.1. Equal numbers of male and female role models were used. Initially two Māori role models, one Asian role model, and three NZ European role models were selected. The selected role models were all interviewed over the phone to elicit their own smoking and quitting histories for use in preparing the scripts (Appendix 5). At this stage, it was decided not to film the Asian role model as he had made up his previous story and had never been a smoker. In considering the ‘type’ of role model that might be missing from our selection, our Māori co-investigator (Dr Dale Bramley) felt that there was no ‘traditional’ Māori story of someone who might use the support of whanau (extended family) and their Māori community in their quitting attempt. Therefore, contacts in a Māori smoking cessation service were asked if they could recommend such a young person who might be interested in becoming a role model for the intervention. The sixth role model was recruited in this manner.

The quitting stories of each of the role models were used to develop ‘bullet point’ scripts for a number (30-40) of short video diary messages by the candidate and study manager with some assistance from the Māori scriptwriters at Mai Media Ltd (see example in Appendix 6). The role models were given direction to record videos in a casual ‘video diary’ style in their own words. The role models were also directed to ensure the video messages were positively framed, encouraging or ended on a positive note. The videos were filmed in the University’s studio by the CAD TV producer.
(Richard Smith), although attempts were made to ensure the videos looked like they were filmed in the role models’ homes. The candidate attended almost all filming sessions (otherwise attended by the study manager) and reviewed all of the edited video clips to ensure those that were used were appropriate and only provided proven effective quitting tips and advice.

Each of the role model’s stories were arranged in a chronological order of clips from pre-quit preparation, countdown to quit day, quit day, then day-by-day to four weeks post-quit day. Supporting text messages were added where appropriate. For example, where the role model talked about using nicotine replacement therapy (NRT), a text message would follow to describe how to obtain subsidised NRT from Quitline. At the end of the four weeks the role model ‘signed off’ from their video diary, although a few infrequent text messages from the role models were written to be sent after this time.

4.8.2 Other content

The anti-tobacco industry videos in the pilot study were not overly popular or considered useful and so these were not used in the final programme. One of the investigators (Dr Simon Denny) was able to obtain permission from the US Centers for Disease Control (CDC) to use some of their original mass media campaign advertisements. These were sent to the candidate and the most appropriate were selected, converted to the correct format and included in the programme.

Animations had been identified as a popular format by young people, particularly in the pretesting project. The Freelance Animation School in Auckland was approached by the candidate and they agreed to design a student project around developing animated clips for the intervention. A brief for the animations was presented to the tutors with an emphasis on the use of humour and appeal to young adults. Students’ initial designs and drawings were presented and reviewed by the candidate
and the expert advisory group. The best designs were selected and were then further worked up by the
entire class at the school into a number of completed clips that were included in the final programme.

Instruction messages were also developed. Scripts were written for instructions on opening clips,
opting out of the programme, getting extra support and changing role model selection. These were
filmed as video messages by one of the Mai FM radio presenters, with the same information also
included in text messages. The same actor also recorded video messages for the control programme
which included simple healthy eating messages.

4.8.3 Intervention schedule

All of these elements plus supporting text messages were then arranged into a multifaceted
programme schedule of messages. An example of the full schedule is shown in the Appendix 14. This
schedule was divided into several phases as shown in Table 4-15.

Table 4-15: Final intervention development programme schedule

<table>
<thead>
<tr>
<th>Phase</th>
<th>Number of messages</th>
<th>Timing and duration of phase</th>
<th>Format of messages in each phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countdown to Quit Day</td>
<td>1/day</td>
<td>For 1 week prior to QD</td>
<td>Role model videos and text messages</td>
</tr>
<tr>
<td>Quit day (QD)</td>
<td>3/day</td>
<td>1 day (QD)</td>
<td>Role model videos and text messages</td>
</tr>
<tr>
<td>Intensive phase</td>
<td>3/day</td>
<td>For 4 weeks post-QD</td>
<td>Role model videos and text messages</td>
</tr>
<tr>
<td>Maintenance phase</td>
<td>1 every 2 days</td>
<td>For 2 weeks post-Intensive phase</td>
<td>Text messages, other mixed videos</td>
</tr>
<tr>
<td>Maintenance continued</td>
<td>1 every 4 days</td>
<td>For approx. 20 weeks until 6 months post-randomisation</td>
<td>Text messages, other mixed videos</td>
</tr>
</tbody>
</table>
Firstly, the countdown phase included the compulsory instructional video and text messages at the start of the programme (e.g. opening clips, opting out of the programme) plus preparing for quit day stories from the role models. The role model video diary formed the core framework of the schedule for the countdown through the intensive phase. These were interspersed with text messages supporting the role model story or providing other quitting tips and facts. The maintenance phase included the other video content (animations and the US mass media advertisements) and text messages.

4.8.4 Help on demand

The ‘Crave’ function was appreciated by those pilot study participants who used it. It was decided to expand the available messages on demand to include different contexts and lapses. Four categories of ‘Crave’ were developed to reflect three of the contexts that commonly trigger cues or cravings to smoke: boredom, stress, and drinking with friends. There was a ‘general’ crave category for any other context. Participants would be able to text in the keyword appropriate to their current situation (e.g. “crave bored”) and the system would recognise this and automatically select a message from the appropriate database. In this way the participant would receive an immediate message that was relevant to their current situation with contextual advice.

Video and text messages were developed for each of these categories with suggestions for distraction or techniques to get through the cravings in those situations. These were predominantly based on known effective techniques from behaviour change for smoking cessation. Video messages were filmed by the role models. Scriptwriters from Mai FM also wrote some relevant humorous scripts that were acted by two young actors.

A ‘Relapse’ function was also developed for participants who had a lapse (a few puffs or a few cigarettes) in order to try to prevent a full relapse to regular smoking. Several series of three messages
were written to be sent to participants texting in ‘relapse’ that would provide immediate advice and distraction, motivation to keep going with the quit attempt, and finally would prompt the participant to get extra support - by going to the website and increasing their messages, or from others.

4.8.5 Website development

A participants’ only website was included in line with the principles of youth development on engagement, feedback from online survey participants about engagement with others going through the programme, and feedback from pilot study participants about being able to change role models. This was not compulsory, but was considered to be a complementary aspect, particularly to enhance participants’ feelings of control and their engagement with the programme in general.

The website was given an overall design and content by the candidate and then developed by CTRU’s senior developer with assistance from CTRU’s web designer. The appearance of the website was intended to be like common social networking sites at the time, with the ability to change certain features such as the colour profile and layout. Participants would ‘log on’ using their mobile phone number from the main public page (www.stubit.co.nz, see screenshot Appendix 15). From there they could access a personal webpage and a shared participants’ webpage.

The main features were on the personal webpage and included the ability to review video messages that had been sent out already as part of their programme, to change their selected time periods for receiving messages, and to change their role model (swap one for another) or add in another role model story. The effect of adding another role model differed depending on the phase the participant was currently in. During the intensive phase (see Table 4-15) a second role model story would start at the appropriate day (from quit day) so the participant would receive daily messages from two role models each day. During the maintenance phase a new role model story would start from quit day particularly to assist those who had relapsed and wanted to try to quit again or who needed new
motivation to quit. Both would have the effect of increasing the number of messages the participant received. On the shared webpage for all participants they could view ‘Frequently asked questions’ about the study or about quitting, links to *Quitline*, and video content that was submitted by other participants in the study.
4.9 Discussion

This chapter has described the process of developing the intervention programme, including identifying appropriate theoretical perspectives and principles to guide development, obtaining expert input and advice, facilitating focus groups and completing an online survey for early input into design, a pre-testing project to trial several styles of content, and a small pilot study of the intervention.(215)

4.9.1 Summary of findings

The themes to be used were observational learning from Social Cognitive Theory, effective behavioural change techniques for smoking cessation and youth development principles. The focus groups and the online survey provided input around the importance of confidentiality, the use of peers who understand the issues and who are similar to them, and respecting young people’s choices. Other interesting findings were that not many were currently using video on their phones and that cost was a major consideration in what young people do on their phones. The pre-testing project provided support for animations and casual interview styles, and reinforced the importance of good quality video and audio. The most important feedback was the need for people in the videos to be seen as real and credible as smokers, and for their messages to be believable. The pilot study confirmed that the intervention was feasible and the small number of technical issues could be remedied. Feedback from participants was that most aspects of the messages were appreciated; however there was a need to ensure they were not overly negative and to provide more choice of role models. All of the input was considered in the final development of the intervention content.

4.9.2 Strengths and limitations of the development process

The strengths of this intervention development process include the decision made prior to commencement that the intervention should be theoretically-based. It was useful to have this framework to ensure the intervention was consistent in referring to constructs such as observational
learning, self-efficacy, normalising the behaviour change and positive outcome expectations for quitting smoking. It was also useful to have effective behaviour change techniques for smoking cessation as a framework for ensuring all tips and advice given were evidence-based. The principles of youth development and processes from social marketing were important in designing aspects of the intervention with engagement of the target audience in mind. The use of these frameworks should ensure the intervention is meaningful and replicable by other researchers and practitioners.

A second strength of the process was the large number of young adults who were involved in providing input into the development of the intervention. Again, this was supported by adolescent development principles and aligned with social marketing techniques to ensure that the developed programme would appeal to young people. Valuable input was provided that improved the intervention and made the programme more useful for young people in their quit attempts. This process also stimulated engagement between researchers and young people, and may have helped to stimulate interest in research and in smoking cessation outside of the trial itself.

A further important strength was that Māori were involved at all levels and throughout the development process. In the very early stages of planning, CTRU’s Māori Research Advisory Committee provided advice and guidance on the proposal. A Māori co-investigator (Dr Dale Bramley) was involved at the steering and expert advisory levels. He also reviewed developed content and provided advice on how to improve its appropriateness for Māori. Māori smoking cessation advisors were given presentations on the development process at several stages and their input was considered during intervention development. A Māori media company was involved in the early stages of development, including assisting with recruiting participants for the development phase, selecting role models and assisting with scripts. Many young Māori were involved in all stages providing their input into the development of the intervention. Young Māori helped to select the role models, three of whom were Māori. One of the role models had a particularly whanau-based story in
order to provide appropriate advice for young Māori wanting to stop smoking in that context. The Māori co-investigator assisted in the interpretation of findings from the input from young Māori during the development phase.

Possible limitations of the process include the generalisability of the findings to the wider target population of young adults wanting to stop smoking. The majority of participants in the development process were recruited through *Mai FM* and tertiary institutions. This group may not have been representative of the wider population, particularly with respect to their technological proficiency. Also, participation at this stage did not require them to want to stop smoking (with the exception of the pilot study). Again the findings of this process may not be representative of the population who want to quit – the target audience of the intervention. This also meant that while there was no difficulty obtaining participation from young people during the development process, this could not indicate whether there would be difficulties recruiting people who want to quit to the main trial.

### 4.9.3 How the developed intervention differed from other cessation programmes

The literature review outlined the need to develop novel smoking cessation support specifically for young adults that would fit in with their lifestyles and their thoughts on quitting, that would respect their choices, and that used other young people who had been in a similar position. A cessation support programme was subsequently developed that tried to address these issues via mobile phone video diary messages from young quitters. The developed intervention differed from other programmes in that it:

- Was based on behaviour change theory (social cognitive theory) and observational learning via young role models
- Was based on evidence of effective behaviour change techniques for smoking cessation
- Involved a large number of young people in its development
- Involved young Māori in its development
- Was extensively pre-tested with young people in a variety of ways
- Provided a choice of six young role models and allowed participants to change or add role models during the intervention
- Was personal, proactive and direct, delivered via mobile phone video and text messages
- Provided help on demand with immediate text and video message responses that were context-appropriate for both cravings and lapses
- Provided a six-month smoking cessation intervention with countdown, intensive and maintenance phases

The developed programme was a unique, and reasonably complex, smoking cessation intervention delivered in a novel manner via mobile phones. To assess whether the developed intervention was effective in improving smoking cessation rates in young adults, a randomised controlled trial was conducted. The randomised controlled trial is presented in the following chapter.
5 Randomised Controlled Trial of a Multimedia Mobile Phone Intervention for Smoking Cessation

5.1 Introduction
The literature review in Chapter 2 found that there was a need for novel smoking cessation interventions designed for young adults that incorporated their lifestyles and beliefs about smoking. Mobile phones are integrated into the daily lives of most young adults. Mobile phone-based interventions have shown some evidence of effectiveness in supporting healthy behaviour change including smoking cessation. Advances in mobile phone technology allowed the development of a multimedia theoretically-based smoking cessation intervention to be delivered by mobile phone. A small pilot study confirmed the feasibility and acceptability of this intervention. The next step was to test the intervention’s effectiveness in a randomised controlled trial (RCT). This chapter describes the aims, methods and results of the RCT.

5.2 Aims
The primary aim of the trial was to assess whether a video-based smoking cessation intervention delivered via mobile phone could be effective at increasing smoking cessation rates compared with a control group with minimal mobile phone-based general health support.

5.3 Methods
The RCT was conducted between October 2007 and August 2009.

5.3.1 Study Population
Participants for the study were daily smokers who wanted to quit. The study catchment area was initially the greater Auckland region. However, this was later broadened to include the Northern
Region (as defined by the Ministry of Health Ethics Committee regions), and even later to include participants from anywhere in New Zealand. There was no upper age limit to the inclusion criteria although the majority of recruitment (as described below) was targeted at young adults.

5.3.1.1 Inclusion and exclusion criteria

Participants were considered eligible for the study if they were:

- 16 years of age or older
- Current daily smokers
- Interested in quitting
- Able to provide informed consent to participate in the study
- Current users of, or planned upgrade to, a Vodafone multimedia mobile phone (explained further in Section 5.3.1.2 below)
- Currently resident in Auckland (later changed to the northern region and then the country)

Participants were excluded if they were:

- Found to be a non-smoker on verification testing
- Enrolled in an internet or other mobile phone-based smoking cessation programme

5.3.1.2 Mobile phone criteria

Vodafone New Zealand Ltd (mobile telecommunications company) supported the RCT by providing a free shortcode (4-digit number, 5552) and free access to their mobile phone network. At the time there was only one other mobile telecommunications network in New Zealand. The intervention was not able to be delivered on this network at that time. This meant that all participants needed to be on the Vodafone mobile phone network.
It was important that potential participants were not excluded due to being unable to afford the mobile phone technology required to view the programme. Vodafone NZ Ltd assured the investigators that most “relatively new” phones would be able to access the programme. The capability to open and view video messages was not related to video calling or the third generation (‘3G’) network. It did require the phones to have a screen capable of viewing pictures.

In order to ensure potential participants were not excluded on this basis, a process was put in place for those who did not have a video message-capable phone to be referred into the study and provided with a loan phone for the study period. These referrals were only available through established networks, where the referring ‘official’ would ‘vouch’ for the potential participant as a known smoker who wished to quit. This process was an attempt to prevent people pretending to smoke in order to receive a loan phone. Referral networks were set up through smoking cessation services and student health services who signed up to be ‘official referrers’.

5.3.2 Recruitment processes

Recruitment was initially targeted to youth and young adults, particularly young Māori, with the aim of 30% of participants being Māori. For this purpose Mai Media Ltd was contracted to design and run radio and print advertising. Mai Media Ltd was at that time a Māori-led media company with radio stations (Mai FM network) and links with mainstream and Māori media, particularly radio, TV and print, advertising and music. Their target audience is young Māori, but also young adults in general.

The candidate also established multiple other recruitment sources that were managed from the study centre. These included:

- Advertising in online magazines such as Rip it up, Vice, NZ Girl, and Student Job Search
• Online advertising with Trade Me, Smokingnotourfuture (HSC), Te Reo Marama, Facebook, ASH, and Youtube
• Mobile phone advertising with Hooha (where participants have registered to receive advertisements via their mobile phones)
• Magazine advertising with Tu Mai, Vice, and Craccum student magazine
• Media releases resulting in a national newspaper article (Sunday Star Times), local newspaper articles, three appearances on national TV (6pm news and Breakfast), three radio station interviews, and multiple online news articles
• Tertiary institutions in the Auckland region (online advertising, newsletter advertisements, billboards on campus, personal approaches on campus, campus magazines, leaflets in campus orientation packs, and radio advertisements with the BNet student radio stations)
• Phantom postering (posters on billboards) in Auckland central city cafes and venues
• Student Health Services nationally (cards in waiting rooms and advice from staff)
• Primary Healthcare practices in the Auckland region (cards/posters in waiting rooms and advice from staff)
• Smoking cessation services nationally (promoted via email networks, email newsletters, personal contacts, presentations at multiple hui (meetings), conferences, workshops, and posters at hospitals)
• School nurses (promoted via presentations and personal contacts)
• Public Health smokefree services nationally (promoted via personal visits)
• Adolescent health services (promoted via presentations to centres and workshops)
• Sexual Health Services and Family Planning Clinics in Auckland (posters and cards in waiting rooms)
• Foodstuffs Staff Health Programme
• Handing out cards at Auckland Netball events
5.3.3  Registration and informed consent process

All advertisements advised interested people to register via text message, free phone call (0800 number) or online (www.stubit.co.nz). On receipt of a text message the system sent an automated response advising that potential participants should check eligibility to enter the study online or by ringing the 0800 number. The research assistant (RA) worked through this list calling potential participants who had not proceeded with the eligibility check.

The public website prompted completion of a short eligibility questionnaire (see eligibility criteria above; Form A, Appendix 8). The free call 0800 number consisted of an automated interactive voice recognition software (IVRS) system asking the same eligibility questions and recording answers. Those who were ineligible on any criteria were advised immediately (‘Sorry you are not eligible to participate in this study’) and advised of other cessation assistance available (e.g. Quitline).

Those who were eligible were advised to read the participant information sheet (PIS) available on the public website or they could ask for it to be emailed or mailed if preferred (Appendix 16). They were also advised that they would receive a text message to confirm their consent to participate and that they must reply to this message in order to proceed with the study. This trial followed the same text message-based consent process that was used successfully in a previous mobile phone trial (34) and in the pilot study. All eligible participants were sent a text message asking them to confirm they had read the PIS and wished to participate in the study. They were asked to reply with the words “I consent” by text.

Those who did not reply to the consent text message received automated reminders daily for up to three days. On receipt of the appropriate response to the text consent message, participants were sent a text with a link to the web-based data collection form to directly enter their baseline data. If the
information had not been entered after one day, they were again sent text reminders daily for up to four days. After this the RA phoned the participant and collected the baseline data by phone.

Official recruitment networks to refer confirmed smokers who wished to quit and who required a loan phone were also established. Referrers were required to sign a declaration that they would only refer those they knew to be smokers. They could then provide names and mobile phone numbers via fax, text message, email or phone call to the RA. The RA would then call these potential participants to check eligibility criteria and to advise that the participant must attend a study centre to receive the loan phone. At that visit the participant was asked to undertake a salivary cotinine test (see Section 5.3.8.2) and the RA would confirm their smoking status. These participants were then given written information on the terms and conditions of the phone loan and signed a loan agreement outlining their responsibilities and details for returning the phone. This process is outlined in Figure 5-1.
Figure 5-1: RCT flowchart of registration processes

**Standard process**

1. Advertising for recruitment
2. Eligibility criteria met via IVRS phone or online check
3. View PIS online or emailed/posted out
   Consent text message sent
4. Participant sends “I consent” text message
5. Random selection for eligibility verification cotinine testing
6. Sent link to web-based forms for baseline data collection
7. Daily reminders to complete forms

**Phone upgrade group**

1. Approved referral sources sign declaration that they will refer only known smokers who want to quit
2. Official referrer refers potential participant
3. RA phones registrants for eligibility assessment
4. Attends study centre – Tested & confirmed as smoker
   Reads PIS and consents
   Completes baseline data collection
   Signs loan arrangement & provided with phone

Randomised
5.3.4 Randomisation

On receipt of baseline data, participants were immediately allocated to control or intervention groups by computerised randomisation. The randomisation process included stratified minimisation by age (25 years and under, over 25 years), ethnicity (Māori, non- Māori), video message-capable phone ownership (yes/loan provided) and smoking/dependence level (time to first cigarette (ttfc) 30 minutes or less/ttfc more than 30 minutes) to ensure a balance on the key factors which may influence success of the intervention.

5.3.5 Bias and blinding

Due to the nature of the study intervention this trial could only be single-blind as study participants were aware of treatment allocation. Allocation was concealed to all research assistants collecting follow-up data.

A sub-sample of eligible participants was randomly selected by computer to undertake a baseline verification of smoking status test. These people were mailed a salivary cotinine test pack and instructions, and were asked to complete the test and mail back to the study centre. The purpose of this test was to confirm that participants were indeed smokers at the start of the study.

All participants were advised at the start of the study that all reports of quitting would be verified by testing in order to reinforce the importance of reporting outcomes truthfully. All those who did report quitting were mailed a salivary cotinine test pack and instructions, and were asked to complete the test and mail back to the study centre. Those who did not return the test were phoned by the RA and if necessary a further test pack was sent. All staff involved in reading the completed test results were blind to treatment allocation.
5.3.6  **Intervention and control groups**

Both groups were asked to nominate a target Quit Date (QD) to stop smoking, between one and three weeks from the date they completed the baseline questionnaire. This date was used to anchor the intervention and control programmes. They were also asked to select two appropriate time periods (in a 24-hour day) during which it would be appropriate to receive messages from the programme. In other words they were able to ensure they would not receive any messages at inappropriate times.

Participants in both groups were advised of other available assistance for quitting including the benefits of using Nicotine Replacement Therapy (NRT). Both groups were advised that they could request that the programme cease, that is, that they would no longer be sent any messages to their mobile phones. Participants were able to phone, text or email this request.

5.3.6.1  **Intervention group**

Participants allocated to the intervention group were shown (online) photographs and a brief biography of the possible role models (Appendix 17) and were asked to select which role model they would like to receive messages from. They were advised that they could return to the website to change this selection later.

These participants then began to receive a programme of regular short video messages sent to their mobile phone. The programme of messages was automatically set for each participant by the software programme according to their self-selected QD, role model, and appropriate time periods. All of the messages were pre-set into a chronological order according to four phases (Figure 5-2). An example of a full programme is shown in Appendix 14.
The core of the programme was the role model video messages. These were filmed as a video diary of their experience of a quitting attempt. The programme was set so the role model appeared to be a few days in advance of the participant’s quit attempt (according to their QD). The participant would receive daily video messages from the role model during the count-down, quit day, and intensive phases of the programme. These messages were approximately 30 seconds long and were structured around an issue or difficulty the role model was currently experiencing and how they overcame that issue. Other messages were interspersed so that the participant would not know exactly what type of message they were receiving each time. This included text messages following up on the key theme of the role model’s message (e.g. where to obtain NRT when this had been discussed by the role model). During the maintenance phase the participant received a small number of text messages from the role model, plus the animated video messages (from the Freelance Animation School students).
and the CDC-supplied advertisements on the harms of smoking and the tobacco industry. A fuller description of the content of the programme and how it was developed is included in Chapter 4.

Other features of the programme included ‘pulling’ or requesting messages on demand. Two such features were developed:

1. Text CRAVE: participants could text the word ‘crave’ to the shortcode (5552) and would receive an immediate message back from a database of messages with various tips and techniques to beat cravings. These could be context specific so that ‘crave bored’, ‘crave stress’, ‘crave drinking’ (three important triggers for young adult smokers (98, 198, 199)) would automatically select messages that were appropriate to these situations.

2. Text RELAPSE: participants could text the word ‘relapse’ to the shortcode to receive some immediate support for a lapse in their quitting attempt. This included an immediate message, another ten minutes later and another one hour later. These included a video and two text messages designed to provide motivation to keep the quit attempt going and advice on getting further support from the programme (by increasing the number of messages or adding role models via the website) and elsewhere.

A participants-only website was developed, accessible from the public website by password (mobile phone number) for those in the intervention group. Here participants could view (and rate if they wished) the video messages they had already been sent. They were directed here to change their selected appropriate time periods or to change their selected role model. They could also add in another role model to start following if they wished. This would increase the number of messages that they were receiving and could be done at any time during the intensive and maintenance phases. Participants were encouraged to submit their own short video messages of their own best quitting tips for possible display on the participants’ website if considered appropriate by the study team.
5.3.6.2 Control group

Participants received fortnightly video messages with general health messages and reminders about trial follow-up. The schedule of the control intervention is shown in Appendix 18.

5.3.7 Outcomes

5.3.7.1 Primary Outcome

The primary outcome for this study was continuous abstinence at six months after the target quit date. This was defined according to the ‘Russell Standard’, which proposes six criteria for cessation trials where there is a target QD(165):

1. Follow-up for six or twelve months from target QD

2. Self-report of abstinence over the whole follow-up period allowing up to five cigarettes in total

3. Biochemical verification of abstinence at the six or twelve month follow-up point (although where there is no face-to-face contact, biochemical verification may be impracticable)

4. Intention to treat approach where data from all randomised smokers are included in the analysis unless they have died or moved to an untraceable address, and all are counted as smokers if their status at final follow-up cannot be determined

5. Protocol violators are followed-up and their true smoking status used in the analysis

6. Collection of follow-up data is blind to smokers’ allocation to trial group.
### 5.3.7.2 Secondary Outcomes

Secondary outcomes included:

- Point prevalence abstinence (no smoking at all in the past seven days) at four weeks, twelve weeks and six months after QD
- Change in confidence in ability to quit, and then remain quit, from baseline to quit day, at four weeks and six months
- Number of relapses and quit attempts during intervention period at six months
- Cravings/urges to smoke at four weeks
- Use of any nicotine replacement therapy (NRT) during quit attempt at four weeks
- Participant satisfaction with the intervention, aspects of the intervention and overall helpfulness of the programme to participants
- Adverse events: motor vehicle accidents that occurred during the study period that were related temporally to using the mobile phone while driving (216)

### 5.3.8 Data collection measures and verification

Baseline data and outcomes data at four weeks and six months post-QD were all collected via online questionnaires (Form D and E, Appendix 19 and 20). Participants were prompted by text message to go to the website to complete the questionnaires. Participants would receive daily reminder text messages for five days or until the questionnaire had been submitted. Once logged on with their mobile phone number, the appropriate form would be available for completion. Forms had multiple pages with multiple submission points, meaning that data would be collected at various points through-out the completion of the form. With the most important questions on the first page (e.g. primary outcome data), this ensured capture of vital data even if the participant did not complete the questionnaire.
At two other time points – QD and twelve weeks post-QD – data collection took place with stand-alone text message questions (see Table 5-1).

Table 5-1: RCT summary schedule of treatment and follow-up

<table>
<thead>
<tr>
<th>Method of data collection at each point</th>
<th>Baseline</th>
<th>QD</th>
<th>4 weeks post QD</th>
<th>12 weeks post QD</th>
<th>6 months post QD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics, smoking history etc</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Salivary cotinine verification</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Confidence in ability to quit/remain quit</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Use of NRT</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Withdrawal symptoms</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction questions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cigarettes per day, relapses, attempts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.3.8.1 Measures used

Demographic questions included self-identification of ethnicity using standard Statistics New Zealand categories. (217) The Statistics New Zealand prioritisation system was used where more than one ethnicity was selected. This ensures that where Māori has been selected, this ethnicity was prioritised over other selected ethnic groups. Secondly, Pacific ethnic groups were prioritised over others except Māori. Income level and occupation were used as indicators of socio-economic status. As participants were expected to be a mixture of students, young adults and parents, many of the other socioeconomic measures, such as level of education and household income, would not have been appropriate for all. Frequency of mobile phone use and usual monthly spend on mobile phone, were used to gauge the level of familiarity and integration into daily life at the start of the study.
Standard measures for the ‘dose’ or amount of smoking, such as the number of cigarettes smoked per day and the age the participant started smoking (as an indicator of years of smoking) were used. It is common practice in New Zealand for many young people to smoke ‘roll-your-owns’ or loose tobacco as it can be cheaper (due to lower taxation) and can be made to stretch to more cigarettes.(5) Therefore, it was also important to ask the type of cigarettes smoked (roll-your-own v. manufactured cigarettes) and the grams of tobacco smoked per week, where appropriate. Quitting history included the number of previous quit attempts, the services or products used, and the length of the longest quit attempt.

The level of nicotine dependence was determined by questions from the Fagerstrom Test of Nicotine Dependence (FTND). The FTND is the most commonly used measure of the level of dependence on nicotine in smoking cessation studies, and the baseline level of dependence has been correlated with the likelihood of success at quitting.(218) Recently, New Zealand researchers have questioned the validity of some of the FTND questions that were developed prior to the introduction of significant tobacco control efforts, such as smokefree environments legislation. Therefore, only two of the FTND questions were included – the number of cigarettes smoked per day and the time to the first cigarette of the day. These two questions have been compared to the FTND with high concordance (Cohen’s kappa=0.74) and have been shown to have good sensitivity (79.5%) and specificity (96.5%).(219)

The Hooked on Nicotine Checklist (HONC) was also used as an alternative measure of nicotine dependence developed specifically for young people. This measure worked well in the pilot. The HONC consists of 10 questions with yes/no answers (Appendix 21). It has been shown to have high test-retest reliability (intraclass correlation 0.88, p<0.001) and internal consistency and validity.(220-222) More recently, each additional positive HONC symptom more than doubled the likelihood of a failed quit attempt in college students (OR 2.30, 95% CI 1.9-2.8).(223)
The severity of nicotine withdrawal symptoms was assessed using the Mood and Physical Symptoms Scale (MPSS).\(^\text{(224)}\) The scale has been shown to be sensitive to abstinence and to predict relapse. We used two of the MPSS questions that ask for ratings of urges to smoke on a 0-5 point scale: “Over the past week how much of the time have you felt the urge to smoke?” and “How strong have those urges been?” These ratings have been shown to correlate highly with changes in mood and other symptoms of withdrawal.

Confidence in ability to quit at this attempt (self-efficacy) was also assessed, in line with social cognitive theory. Confidence in ability to quit has been shown to predict actual quitting \(^\text{(225, 226)}\) and relapse to be less frequent if self-efficacy remains high.\(^\text{(227)}\) This was asked by web-based questionnaire and by text message with the same response scale of 0% (not confident at all), 50% moderately confident, to 100% (extremely confident). A single measure has been shown to be as good as multiple measures of self-efficacy.\(^\text{(228)}\)

### 5.3.8.2 Verification of smoking status

A random sub-sample (10%) of eligible participants at baseline and all participants reporting quitting were asked to undertake confirmation of smoking/quit status with salivary cotinine testing. Cotinine has a half-life of between 15 and 40 hours providing an indication of tobacco use in the previous 2-3 days.\(^\text{(229)}\) Salivary cotinine levels are able to distinguish smokers from non-smokers with a usual cut-off of 10 ng/ml.\(^\text{(165)}\) *NicAlert*™ cotinine salivary test strips provide a semi-quantitative measure with colour zones (from 0 to 6) indicating the amount of cotinine equivalents (i.e. both cotinine and hydroxycotinine) in the sample. In our comparison with the gold standard gas chromatography, we demonstrated a sensitivity of 93%, specificity 95%, and positive predictive value 95%.\(^\text{(230)}\) In the 86 samples, there were no differences in classification (smoker/non-smoker) between two independent readers. Such test strips offer a cheap and easy method of verifying self-reported quitting in large-scale community-based smoking cessation studies where the use of self-completion tests is desirable.
Participants were posted *NicAlert™* test strips and asked to test their saliva using the strips, then send the test strips back to researchers at the CTRU in stamped addressed envelopes. Previous studies have demonstrated the stability of saliva samples sent through the mail. (231, 232) Those who did not return the strips after a reminder were contacted by study staff and if necessary further test packs were sent out. All test strips were double-read independently by CTRU staff, and in the case of discrepancy, arbitrated by a third staff member.

### 5.3.9 Sample size calculations

A target sample size of 1,300 participants was set in order to detect a relative risk of 1.75 for a control group 6-month quit rate of 8.5% (intervention group quit rate of 15%), with 90% power at p=0.05. This was based on data from CTRU’s previous smoking cessation study (STOMP (34)) with a relative risk of 2.2, 95% confidence interval 1.79-2.70. However, with respect to absolute quit rates, the STOMP outcome was point prevalence of quitting (within past 7 days) and was measured at 6 weeks. Therefore, continuous abstinence measured at six months, as proposed here, was thought likely to be much lower than the 13% and 28% quit rates seen in control and active groups in that study. The economic evaluation of the Quitline service used a range of 9%-11.6% continuous abstinence rate for 6-12 months, based on a cohort survey of participants with a 9% rate including all survey non-responders as non-quitters, and a quit rate amongst respondents of 20%. (233)

A loss to follow-up of 20% was used in calculating the sample size for this trial. In the STOMP trial, follow-up at 6 months was 79% in the group receiving an incentive for follow-up and 69% in the group with no incentive. A reimbursement for participants’ time was planned for the final follow-up, so this level was used to guide the predicted level of loss.
5.3.10 Statistical Analyses

Main analyses were based on the intention-to-treat principle as recommended for cessation studies. Simple chi-squared analyses were used to compare the proportion quit at different stages of follow-up, with estimation of relative risks, 95% confidence intervals and two-sided p-values. The role of possible effect modifiers and confounders (such as age, ethnicity, gender, level of nicotine dependence and video phone ownership/free upgrade) were planned with standard logistic regression analyses. Analyses were also planned for Māori participants as compared with non-Māori participants (with the assistance of Dr Dale Bramley, Māori co-investigator). Early changes in confidence scores (on a visual analogue scale) for those who had quit at four weeks were analysed to determine if this could predict the final outcome.

5.3.11 Study Organisation

The candidate was the principal investigator and the study centre was the Clinical Trials Research Unit, University of Auckland. A Trial Steering Committee was convened to provide strategic oversight and governance of the trial and consisted of the candidate and the co-investigators (as listed in the Acknowledgements). The candidate acted as the study manager for much of the study duration and at other times was assisted by a part-time study manager. A part-time research assistant assisted with data collection. The CTRU web publisher developed the logo and the ‘look and feel’ for the print promotions and the study website.

The data management team at the CTRU provided input into case record forms and data management, and developed Oracle databases for the study information. A CTRU software developer built the web-based forms for the questionnaires. Participants entered their own data directly into the web-based forms using their mobile phone number as their password and unique identifier. The research assistant could also enter data directly into web-based forms when conducting questionnaires over the phone.
(for those who had not completed the forms themselves). Validation rules and logic checks were built directly into the forms with notes to participants if they entered obviously erroneous information.

Access to study data was strictly limited by password protection. Reports on study progress were available in real time from the study website. The software developer monitored the IT programme during the course of the study.

5.3.12 Consultation with Māori

Dr Dale Bramley, Māori co-investigator, was involved in the design of the study and in particular advised on recruiting Māori participants, the identification of ethnicity by participants, and the interpretation of findings regarding Māori participants’ data. The CTRU Māori Research Advisory Committee reviewed the original funding application for the study and provided advice on ensuring the programme’s appropriateness for Māori, recruitment of Māori participants and the naming of the programme. At various stages throughout the development of the intervention and the design of the trial, the candidate presented to national and regional hui (meetings) with those working in the smoking cessation or tobacco control context. Feedback and input was provided at these occasions that was used to further refine processes, particularly around recruiting Māori participants. Mai Media Ltd, a Māori owned and led (at the time) marketing and media organisation, approached the candidate to offer their support for mobile phone smoking cessation for Māori. This organisation was consulted and ultimately given the task of recruiting young Māori and Pacific participants. They provided advice on how to promote the study to rangatahi (young Māori) and also developed the radio advertisements and the name for the programme.
5.3.13 Ethics Approval and Trial Registration

Ethics approval for the RCT was obtained from the Northern Region X Ethics Committee (NTX/06/10/130). Ethics Committee oversight was transferred to the MultiRegion Ethics Committee in August 2008 as described below (Section 1.2.14.1). The trial was registered prior to commencement with the Australian New Zealand Clinical Trials Registry (ACTRN12606000476538).

5.3.14 Amendments to Study Protocol

Amendments to the study protocol were made during the study period and are outlined below.

5.3.14.1 Study catchment area

Recruitment was much lower than anticipated. One of the methods used to increase recruitment was to expand the study catchment area. As the study had initially been approved by the Northern Region X Ethics Committee, they approved extending to the full Northern Region of New Zealand (from Auckland) under their jurisdiction in April of 2008. Later the Multi-region Ethics Committee was approached and approved extending the study to the whole of New Zealand in June 2008.

5.3.14.2 Reimbursements for participants

The original plan for reimbursing participants for their time and participation in research was that Vodafone NZ Ltd would provide free top-ups or credit data charges directly onto participants’ phone accounts. However, by the time the study period started, Vodafone announced that they would be unable to provide this. Instead they provided 50 new Vodafone mobile phones that were to be given away as a result of monthly prize draws for newly randomised participants and for those completing the study.
The Multi-region Ethics Committee approved the addition of vouchers for all randomised participants as reimbursements for their involvement in August 2008. This consisted of $30 vouchers at randomisation and a further $20 at completion of final data collection. Participants were given the choice of petrol, Vodafone or supermarket vouchers. Participants already in the study at this time were also advised (by email and text message) that vouchers were available to them and if they responded with their choice they were sent vouchers to the same amount.

5.4 Results

5.4.1 Recruitment

As indicated above recruitment started very slowly. The recruitment rate aimed for was approximately 100 participants per month. However, at the end of the first two months fewer than 70 participants had been randomised. A variety of extra methods were introduced sequentially in order to be able to determine which were the most effective. The sequential focus was (with more details shown above in section 5.3.1):

- Mai Media: radio and print advertising, and a press release
- Internet advertising, mobile phone campaign
- Phantom postering, distribution of cards/flyers around Auckland
- Tertiary institutions in Auckland
- Second media release and approaches to local media in the northern region and Māori media
- Primary care, sexual health services, smoking cessation services, public health services, adolescent services Auckland and northern region
- Employers, sports networks, school nurses
- Third media release to local media outside the northern region
- Smoking cessation services outside the northern region and national websites
Most new recruitment methods actually had little effect on the overall recruitment rate (Figure 5-3). The largest upswing in recruitment occurred after the move to an expanded national catchment area and the introduction of reimbursements (in August 2008) with accompanying media and promotions work.

**Figure 5-3: RCT cumulative recruitment rate – number of randomisations by month**

Those participants who were recruited during August 2008 (n=16) were asked to volunteer to complete three emailed questions in order to guide further promotions and recruitment decisions (Table 5-2). The majority were from outside Auckland and had heard about the study from the radio, internet or friends and family. Eleven of these participants said they would refer their friends and family to STUB IT (four would not predominantly because they felt they had not received much from the programme and one was unsure). This prompted a campaign to encourage those registered with STUB IT to refer their friends and family to the study.
Table 5-2: RCT August 2008 participants’ reasons for entering the study

<table>
<thead>
<tr>
<th>What attracted you to our programme over other stop smoking programmes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Because its a study’</td>
</tr>
<tr>
<td>‘It uses mobile phones to communicate’</td>
</tr>
<tr>
<td>‘Sounded like it would be helpful’</td>
</tr>
<tr>
<td>‘Its easy to use and in modern times. I always have my phone with me so its easy to send a message if I relapse or crave for sme suport and when i get a video msg i can watch it straight away. If I was on ums or patches and i ran out and had no $$ wel tough luck really’</td>
</tr>
<tr>
<td>‘The fact it was free, and I had nothing to lose other than a bad habit’</td>
</tr>
<tr>
<td>‘Multimedia campaign – technically advanced conceptually’</td>
</tr>
<tr>
<td>‘It uses video messages on mobile phones to encourage me’</td>
</tr>
<tr>
<td>‘Branding, draw to win a phone. also a more modern and customised approach (via mobile)’</td>
</tr>
<tr>
<td>‘I wanted to try something new that didn’t use patches or gum’</td>
</tr>
<tr>
<td>‘I thought it was a good way of getting support.’</td>
</tr>
<tr>
<td>‘It uses mobile phones to communicate and the on going’</td>
</tr>
<tr>
<td>‘Setting a quit date because I had not thought about that and getting messages on my phone’</td>
</tr>
<tr>
<td>‘I used alan carr’s book and your program’</td>
</tr>
<tr>
<td>‘How you communicate over text’.</td>
</tr>
<tr>
<td>‘The promotion and video msgs’</td>
</tr>
<tr>
<td>‘It was a mobile strategy’</td>
</tr>
</tbody>
</table>

Unfortunately, the upswing in recruitment was temporary. When the recruitment rate flattened out again the Trial Steering Committee, upon review of the budget, decided to close recruitment in February 2009 with 226 randomised participants.

5.4.2 Registrations and randomisations

A total of 868 people registered their interest in the study via the online eligibility questionnaire (74%, n=640) or via the IVRS free phone line (22%, n=195). The remainder (4%, n=33) completed the eligibility check on the phone with the research assistant. Forty-three per cent (n=377) of these people were considered ineligible for the study. The reasons for ineligibility are shown in Table 5-3.
Table 5-3: RCT registrants’ reasons for ineligibility (N=377)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not a Vodafone NZ customer</td>
<td>42</td>
</tr>
<tr>
<td>Stated they could not play video messages on phone</td>
<td>103</td>
</tr>
<tr>
<td>Not a resident (when the catchment area was restricted)</td>
<td>32</td>
</tr>
<tr>
<td>Age &lt; 16 years</td>
<td>28</td>
</tr>
<tr>
<td>Stated did not smoke cigarettes every day</td>
<td>54</td>
</tr>
<tr>
<td>Was not ready to quit</td>
<td>100</td>
</tr>
<tr>
<td>Enrolled in other internet/mobile stop smoking programme</td>
<td>21</td>
</tr>
<tr>
<td>Total number of reasons(^1)</td>
<td>380</td>
</tr>
</tbody>
</table>

\(^1\) There could be more than one reason per participant

Of those eligible (n=491), 49 actively withdrew prior to baseline data collection, and 216 did not complete the baseline data collection form - 34 of these started completing the baseline form but did not finish it. This was despite text message reminders and attempts by the research assistant to contact these people and encourage them to enter the study.

A total of 226 participants were randomised, giving a registration to randomisation rate of 26%. Due to the self-completion nature of the follow-up questionnaires online, it was possible for participants to provide only some (not all) follow-up data. Therefore, the ‘lost to follow-up’ numbers presented in the CONSORT diagram (Figure 5-4) are those with no primary outcome data at six months, and no point prevalence smoking data at four and twelve weeks.
Registered
N=868

Randomised
N=226

Allocated to intervention
n=110
4 weeks n=81
Lost to follow-up =29
12 weeks n=79
Lost to follow-up =31
6 months n=75
Lost to follow-up =35

Allocated to control
n=116
4 weeks n=93
Lost to follow-up =23
12 weeks n=87
Lost to follow-up =29
6 months n=92
Lost to follow-up =24

Ineligible n=377
Withdrawn prior to baseline n=49
Eligible but did not complete baseline data collection n=216
5.4.2.1 Data collection response rates

On their target QD, randomised participants were sent a text message question about their level of confidence to quit on this occasion. Almost all (96%, n=217) participants responded by text message. Of these, 63% (n=137) responded the same day and another 17% (n=37) responded within the next two days. Participants who did not respond were sent daily text message reminders for up to five days or until they responded.

At four weeks post-QD participants were sent a text message with a link to their online form for data collection, and daily reminders by text message for up to five days or until the form was completed. Only 47% (n=106) completed the online form. The remainder were rung by the RA after failing to complete the online form in five days. Another 24% (n=54) completed the form on the phone with the RA, and 29% (n=66) refused or were not contactable.

At twelve weeks post-QD, participants were again sent a text message question asking about their smoking status at that time. Seventy-six per cent (n=172) responded with a text message response. Of these, 51% (n=88) responded the same day and another 17% (n=38) responded within the next two days after daily text message reminders.

At 24 weeks post-QD, the system set up to send the text messages to participants and alerts to the RA for uncompleted forms (as per the four week process) initially failed. Therefore the RA was required to ring all of the participants until the system was repaired. The overall response rate at 24 weeks data collection was 62% (n=165).

5.4.3 Baseline participant characteristics

Baseline characteristics of all randomised participants are shown in Table 5-4. Due to the targeted (towards young adults) recruitment strategies, the mean age of participants overall was 27 years
(SD=8). However, there was no upper age limit and the oldest person in the study was 63 years old.

The majority of participants were of New Zealand European ethnicity. Approximately 24% of participants self-identified as Māori, slightly less than the target of 30%.

Table 5-4: RCT participants’ baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention (N=110)</th>
<th>Control (N=116)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>27.5 years</td>
<td>(9.5)</td>
<td>26.6 years</td>
</tr>
<tr>
<td>Female</td>
<td>58</td>
<td>52.7</td>
<td>49</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>55</td>
<td>50.0</td>
<td>63</td>
</tr>
<tr>
<td>Māori</td>
<td>24</td>
<td>21.8</td>
<td>30</td>
</tr>
<tr>
<td>Pacific</td>
<td>12</td>
<td>10.9</td>
<td>5</td>
</tr>
<tr>
<td>Asian</td>
<td>10</td>
<td>9.1</td>
<td>13</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>5.5</td>
<td>5</td>
</tr>
<tr>
<td>Missing</td>
<td>3</td>
<td>2.7</td>
<td>0</td>
</tr>
<tr>
<td>Current employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fulltime employment</td>
<td>58</td>
<td>52.7</td>
<td>63</td>
</tr>
<tr>
<td>Part-time employment</td>
<td>13</td>
<td>11.8</td>
<td>13</td>
</tr>
<tr>
<td>Student</td>
<td>19</td>
<td>17.3</td>
<td>27</td>
</tr>
<tr>
<td>Home-maker</td>
<td>4</td>
<td>3.6</td>
<td>8</td>
</tr>
<tr>
<td>Retired</td>
<td>1</td>
<td>0.9</td>
<td>0</td>
</tr>
<tr>
<td>Social security</td>
<td>1</td>
<td>0.9</td>
<td>0</td>
</tr>
<tr>
<td>Unemployed</td>
<td>6</td>
<td>5.5</td>
<td>3</td>
</tr>
<tr>
<td>Don’t wish to answer</td>
<td>4</td>
<td>3.6</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>3.6</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total income in previous 12 months</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $15,000</td>
<td>24</td>
<td>21.8</td>
<td>33</td>
</tr>
<tr>
<td>Between 15,000 and 30,000</td>
<td>29</td>
<td>26.4</td>
<td>18</td>
</tr>
<tr>
<td>Between 30,001 and 45,000</td>
<td>23</td>
<td>20.9</td>
<td>23</td>
</tr>
<tr>
<td>Between 45,001 and 60,000</td>
<td>12</td>
<td>10.9</td>
<td>17</td>
</tr>
<tr>
<td>Over 60,000</td>
<td>7</td>
<td>6.4</td>
<td>12</td>
</tr>
<tr>
<td>Don’t wish to answer</td>
<td>15</td>
<td>13.6</td>
<td>13</td>
</tr>
</tbody>
</table>

*per annum, in NZ dollars
Interestingly, the proportions of Māori (23.9%), Pacific (7.5%) and Asian (10.2%) participants were all higher than those reported by Quitline in 2009 (21.2%, 5.6%, and 3.4%, respectively).(89) The equal proportions of male and female participants was consistent with Quitline callers (52% female clients in 2009 (89), and with the proportions of reported smokers in New Zealand (49% female, 2006 Census (41)).

Nearly two-thirds of participants were employed and 20% were students. Twenty-five per cent of participants earned less than NZ$15,000 in the past twelve months. Lower income groups were well represented, 46% earning less than $30,001 and another 20% earning between $30,001 and $45,000 in the past twelve months.

Baseline smoking characteristics were very similar in the two groups (Table 5-5). The Hooked on Nicotine Checklist (HONC) score represents the number of questions responded to positively out of ten addiction-related questions (Appendix 21). At baseline, participants had an overall mean score of 8 (SD=2) indicating a highly addicted cohort in comparison with other studies (Wellman 2008, median HONC score 4.3 (223); Wellman 2005, median 7.1(234)).
Table 5-5: RCT participants’ baseline smoking characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention (N=110)</th>
<th></th>
<th>Control (N=116)</th>
<th></th>
<th>Overall N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age started smoking, mean (SD)</td>
<td>14.9 yrs (3.5)</td>
<td>15 yrs (3.2)</td>
<td>range 3-36 yrs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoke manufactured cigs</td>
<td>103 93.6</td>
<td>105 90.5</td>
<td>208 92.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoke roll-your-own tobacco</td>
<td>71 64.5</td>
<td>64 55.2</td>
<td>135 59.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How soon after waking do you smoke?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 5 minutes</td>
<td>26 23.6</td>
<td>27 23.3</td>
<td>53 23.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 - 30 minutes</td>
<td>45 40.9</td>
<td>52 44.8</td>
<td>97 42.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 - 60 minutes</td>
<td>21 19.1</td>
<td>24 20.7</td>
<td>45 19.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After 60 minutes</td>
<td>18 16.4</td>
<td>13 11.2</td>
<td>31 13.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever tried to quit smoking but couldn’t?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8 7.3</td>
<td>12 10.3</td>
<td>20 8.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>102 92.7</td>
<td>104 89.7</td>
<td>206 91.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you smoke now because it is really hard to quit?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
<td>22 20</td>
<td>16 13.8</td>
<td>38 16.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>13 11.8</td>
<td>18 15.5</td>
<td>31 13.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>75 68.2</td>
<td>82 70.7</td>
<td>157 69.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever felt addicted to tobacco?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>12 10.9</td>
<td>9 7.8</td>
<td>21 9.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>98 89.1</td>
<td>107 92.2</td>
<td>205 90.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hooked on Nicotine Checklist (HONC) score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score (SD)</td>
<td>8.0 (2.1)</td>
<td>8.0 (1.7)</td>
<td>8.0 (1.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean scores for confidence in being able to quit at baseline were 62.4% (out of 100%; SD=22) in the intervention group and 66.5% (SD=22) in the control group. This corresponds to being ‘moderately confident’ in being able to quit on this occasion in both groups.

5.4.4 Primary Outcome

At six months, participants were asked if they had smoked at all since quit day and their responses are shown in Table 5-6. The Russell Standard definition of continuous abstinence was used, which
allows up to five cigarettes (as ‘lapses’) since the nominated quit day. (165) All categories of responses are shown here, then the first two categories are combined to represent continuous abstinence and the final two categories are combined for the purposes of an intention to treat (ITT) analysis. This is the most conservative analysis that is usually recommended in smoking cessation studies, as it assumes that all those who are lost to follow-up will have returned to smoking. This is not necessarily the case and so sensitivity analyses are sometimes performed, although this was not considered necessary here.

**Table 5-6: RCT continuous abstinence outcomes at six months**

<table>
<thead>
<tr>
<th>Have you smoked tobacco at all since Quit day?</th>
<th>Intervention (N=110)</th>
<th>Control (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, not a single puff</td>
<td>12</td>
<td>7</td>
<td>0.2</td>
</tr>
<tr>
<td>Yes, between 1 and 5 cigarettes</td>
<td>17</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Yes, more than 5 cigarettes</td>
<td>46</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>35</td>
<td>26</td>
<td></td>
</tr>
</tbody>
</table>

**Intention to treat analysis**

| Not a single puff or up to 5 cigarettes     | 29                   | 32              | 0.8            |
| Missing or more than 5 cigarettes          | 81                   | 84              |                |

As described earlier, with the low recruitment for this study it was unlikely that a statistically significant difference between the two groups would be able to be demonstrated even if estimated differences between the groups were achieved (i.e. the study was under-powered). Assuming a control group quit rate of 28% as above and with the achieved sample size of 226, a quit rate of nearly 50% would have been required in the intervention group in order to detect a statistically significant effect (90% power/0.05 type 1 error). However it is also possible that there was no effect of the intervention over that of the control.


5.4.4.1 Verification of quitting status

Verification testing was asked of the 61 participants reporting continuous abstinence at 6 months. Ten participants were either not contactable to arrange the mailing of the test-pack or, when contacted, stated they had relapsed since the end of the study period. This was compounded in the initial follow-up period where there was a gap for some participants between finishing the programme and being contacted by the research assistant for verification. Therefore, test-packs were only sent to 51 of these 61 participants (25 in the intervention group and 26 in the control group). Repeated attempts were made to contact these participants to encourage them to return their test-strips and up to three test-packs were sent to those that were contacted but still did not return them. Fourteen quitters in the intervention group (56% of those sent a pack) and 15 in the control group (58% of those sent a pack) returned their test-strips. Their results are shown in Table 5-7.

Table 5-7: RCT salivary cotinine test results to verify self-reported quitting

<table>
<thead>
<tr>
<th>Cotinine level on Nicalert test</th>
<th>Intervention group N=25</th>
<th>Control group N=26</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10 ng/ml †</td>
<td>7    28</td>
<td>11   42</td>
</tr>
<tr>
<td>10-30 ng/ml</td>
<td>6    24</td>
<td>0    0</td>
</tr>
<tr>
<td>30-100 ng/ml</td>
<td>1    4</td>
<td>2    8</td>
</tr>
<tr>
<td>100-200 ng/ml</td>
<td>0    0</td>
<td>1    4</td>
</tr>
<tr>
<td>200-500 ng/ml</td>
<td>0    0</td>
<td>0    0</td>
</tr>
<tr>
<td>500-2000 ng/ml</td>
<td>0    0</td>
<td>0    0</td>
</tr>
<tr>
<td>2000+ng/ml</td>
<td>0    0</td>
<td>1    4</td>
</tr>
<tr>
<td>Missing</td>
<td>11   44</td>
<td>11   42</td>
</tr>
</tbody>
</table>

† indicates non-smoker

Seven participants in the intervention group (50% of those who returned tests, or 24% of total quitters in that group) were confirmed as non-smokers. Eleven participants in the control group (73% of those who returned tests, or 34% of quitters in that group) were confirmed as non-smokers. These verified results can be applied to the primary outcome as in Table 5-8 but remain not statistically significant.
5.4.4.2 *Return to regular smoking*

As a further check on the primary outcome, participants were also asked whether they had gone back to regular smoking at 6 months (Table 5-9). Eighteen participants (16%) in the intervention group confirmed that they had NOT gone back to regular smoking, and sixteen (14%) in the control group.

Table 5-9: RCT participants returned to regular smoking at 6 months: ITT analysis

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (N=110)</th>
<th>Control group (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>No</td>
<td>18</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Missing or Yes</td>
<td>92</td>
<td>84</td>
<td>100</td>
</tr>
</tbody>
</table>

5.4.5 *Secondary Outcomes*

5.4.5.1 *Point prevalence abstinence*

Participants were asked if they had smoked at all in the past seven days at 4 weeks, 12 weeks and 6 months after QD. The results for all three time points are shown in Table 5-10.

<table>
<thead>
<tr>
<th>Verified continuous abstinence</th>
<th>Intervention (N=110)</th>
<th>Control (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>7</td>
<td>6.4</td>
<td>11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Return to regular smoking</th>
<th>Intervention group (N=110)</th>
<th>Control group (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>18</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Missing or Yes</td>
<td>92</td>
<td>84</td>
<td>100</td>
</tr>
</tbody>
</table>
Table 5-10: RCT point prevalence abstinence (no smoking in the past 7 days) at 4 weeks, 12 weeks and 6 months: ITT analysis

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (N=110)</th>
<th>Control group (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No not a single puff</td>
<td>12</td>
<td>10.9</td>
<td>14</td>
</tr>
<tr>
<td>Yes or missing</td>
<td>98</td>
<td>89.1</td>
<td>102</td>
</tr>
<tr>
<td>12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No not a single puff</td>
<td>30</td>
<td>27.3</td>
<td>25</td>
</tr>
<tr>
<td>Yes or missing</td>
<td>80</td>
<td>72.7</td>
<td>91</td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No not a single puff</td>
<td>25</td>
<td>22.7</td>
<td>26</td>
</tr>
<tr>
<td>Yes or missing</td>
<td>85</td>
<td>77.3</td>
<td>88</td>
</tr>
</tbody>
</table>

There were more missing data at four weeks than at the other time points which may make comparisons between time points unreliable and so a responders-only analysis is also shown below (Table 5-11), along with the numbers of missing data at each point.

Table 5-11: RCT point prevalence abstinence at 4 weeks, 12 weeks and 6 months: responders-only analysis

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No not a single puff</td>
<td>12</td>
<td>19.7</td>
<td>14</td>
</tr>
<tr>
<td>Yes ≥ 1 cigarettes</td>
<td>49</td>
<td>80.3</td>
<td>63</td>
</tr>
<tr>
<td>Total responders</td>
<td>61</td>
<td></td>
<td>77</td>
</tr>
<tr>
<td>12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No not a single puff</td>
<td>30</td>
<td>38.0</td>
<td>25</td>
</tr>
<tr>
<td>Yes ≥ 1 cigarettes</td>
<td>49</td>
<td>62.0</td>
<td>62</td>
</tr>
<tr>
<td>Total responders</td>
<td>79</td>
<td></td>
<td>87</td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No not a single puff</td>
<td>25</td>
<td>34.2</td>
<td>26</td>
</tr>
<tr>
<td>Yes ≥ 1 cigarettes</td>
<td>48</td>
<td>65.8</td>
<td>62</td>
</tr>
<tr>
<td>Total responders</td>
<td>73</td>
<td></td>
<td>88</td>
</tr>
</tbody>
</table>
5.4.5.2 Continuous abstinence at 4 weeks

Due to the large amount of missing data for the four week point prevalence of abstinence (no smoking in the past seven days), continuous abstinence at four weeks (no smoking since quit day) is also presented in Table 5-12. This question had fewer missing data.

Table 5-12: RCT continuous abstinence at 4 weeks

<table>
<thead>
<tr>
<th>Have you smoked at all since quit day?</th>
<th>Intervention group (N=110)</th>
<th>Control group (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No or less than 5 cigs</td>
<td>39 48.1</td>
<td>37 39.8</td>
<td>0.3</td>
</tr>
<tr>
<td>Yes more than 5 cigs</td>
<td>42 51.9</td>
<td>56 60.2</td>
<td></td>
</tr>
<tr>
<td>Total responders</td>
<td>81</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>29</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td><strong>Intention to treat analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No or less than 5 cigarettes</td>
<td>39 35.5</td>
<td>37 31.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Missing or more than 5 cigarettes</td>
<td>71 64.5</td>
<td>79 68.1</td>
<td></td>
</tr>
</tbody>
</table>

5.4.5.3 Change in confidence

Participants were asked at baseline to rate their confidence in being able to quit at this attempt. At four weeks and six months, those reporting quitting were asked to rate their confidence in being able to stay quit, and those who had relapsed were asked to rate their confidence in being able to quit again. Confidence in ability to quit was asked with a response scale of 0% (not confident at all), 50% moderately confident, to 100% (extremely confident). There were no statistically significant differences in mean confidence scores between the groups at any time points.
Table 5-13 shows the change in mean confidence scores in those who reported quitting at six months and those who reported having relapsed. Those who reported to have quit at six months had slightly higher confidence scores at baseline (mean 66.6%, SD=22.0) than those who had relapsed by six months (mean 63.2%, SD=23.0). In those who had quit, the mean confidence score increased in both groups by 11.5 percentage points – slightly more in the intervention group (64.8% to 77.4%) than in the control group (68.3% to 78.8%). In those who were smoking at six months, the mean confidence in quitting next time increased in the intervention group (58.7% to 62.0%) and decreased in the control group (66.9% to 62.2%).

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Overall</th>
<th>t-test p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean</td>
<td>SD</td>
<td>n</td>
</tr>
<tr>
<td>Participants reporting having quit at six months: confidence in staying quit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>42</td>
<td>64.8</td>
<td>21.1</td>
<td>42</td>
</tr>
<tr>
<td>Six months</td>
<td>42</td>
<td>77.4</td>
<td>26.6</td>
<td>42</td>
</tr>
<tr>
<td>Participants reporting smoking at six months: confidence in quitting next time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>30</td>
<td>58.7</td>
<td>23.5</td>
<td>36</td>
</tr>
<tr>
<td>Six months</td>
<td>30</td>
<td>62.0</td>
<td>24.7</td>
<td>36</td>
</tr>
</tbody>
</table>

5.4.5.4 Use of any nicotine replacement therapy

Participants were asked whether they had used other assistance to quit and these results are shown in Table 5-14.
Table 5-14: RCT participants’ use of other cessation support, at six months

<table>
<thead>
<tr>
<th>Used pharmacological cessation support (combined)</th>
<th>Intervention group (N=110)</th>
<th>Control group (N=116)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>54</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>78</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15</td>
<td>23</td>
<td>0.2</td>
</tr>
<tr>
<td>%</td>
<td>22</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>41</td>
<td>41</td>
<td></td>
</tr>
</tbody>
</table>

Specific methods:

- **NRT gum**: 8 (12%) in the intervention group and 10 (14%) in the control group.
- **NRT patch**: 9 (13%) in the intervention group and 15 (21%) in the control group.
- **Nicobrevin**: 1 (1%) in both groups.
- **Bupropion**: 0 (0%) in both groups.
- **Nortriptyline**: 0 (0%) in both groups.
- **Quitline**: 4 (6%) in the intervention group and 5 (7%) in the control group.
- **Counsellor**: 2 (3%) in the intervention group and 1 (1%) in the control group.
- **Internet**: 4 (6%) in the intervention group and 0 (0%) in the control group.
- **Other**: 3 (5%) in the intervention group and 3 (5%) in the control group.

Fifteen participants (21.7%) in the intervention group and 23 (30.7%) in the control group (p=0.2) used pharmacological quitting support (nicotine patches, nicotine gum or nortriptyline) at six months.

5.4.5.5 Number of quit attempts

At six months, all participants were asked how many quit attempts they had made during the study period. The proportion of respondents who stated they did not make a quit attempt at all, was 9.6% in the intervention group and 4.9% in the control group, but the majority of respondents in both groups made multiple quit attempts (Table 5-15).
Table 5-15: RCT participants’ number of quit attempts made during the 6-month study period

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (N=73)</th>
<th>Control group (N=81)</th>
<th>Chi-sq p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>None</td>
<td>7</td>
<td>9.6</td>
<td>4</td>
</tr>
<tr>
<td>One</td>
<td>22</td>
<td>30.1</td>
<td>24</td>
</tr>
<tr>
<td>More than one</td>
<td>44</td>
<td>60.3</td>
<td>53</td>
</tr>
</tbody>
</table>

5.4.5.6 Use of on demand features

A report produced from the intervention programme software confirmed that 29 intervention group participants (45%) had used the crave function by sending in a text message with the word ‘crave’. Eighteen intervention group participants (16.4%) had used the relapse function by sending in a text message with the word ‘relapse’.

5.4.5.7 Participant satisfaction

Participants in the intervention group were asked for their feedback on the programme. In general the majority of responders stated they liked the video messages from quitters, and appeared to appreciate the frequency and timing of messages (Table 5-16).
Table 5-16: RCT intervention group participants’ satisfaction with aspects of the intervention

<table>
<thead>
<tr>
<th>Which aspects did you…</th>
<th>like?</th>
<th>dislike?</th>
<th>No comment</th>
<th>Did not use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>That I could relate to quitters</td>
<td>46</td>
<td>69</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>What quitters had to say</td>
<td>44</td>
<td>66</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Video messages from quitters</td>
<td>43</td>
<td>64</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>The timing of messages</td>
<td>41</td>
<td>61</td>
<td>15</td>
<td>22</td>
</tr>
<tr>
<td>Receiving lots of messages</td>
<td>39</td>
<td>58</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td>The website</td>
<td>34</td>
<td>51</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Crave messages</td>
<td>32</td>
<td>48</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>Anti-tobacco industry messages</td>
<td>25</td>
<td>37</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>Animations</td>
<td>23</td>
<td>35</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Intervention group participants were also asked whether the different aspects of the intervention were helpful in their quit attempt, even if they later relapsed. Their responses are shown in Table 5-17. A large proportion of respondents to this question (88%) felt that watching someone like them go through the quitting process was helpful. Also being supported to feel like they could do it and feeling like others were going through the same thing were helpful in their quit attempt (86% and 81% respectively). Three quarters stated that getting messages at the right times was helpful, and 60% said the intervention prompted them to get support from their friends or family. Less than half thought that realising they had been manipulated by the tobacco industry was helpful in their quit attempt, which may align with less positive feedback in the earlier stages of this project about this theme of content. Also only a small proportion (45%, n=29) said the crave messages were helpful, which is exactly the number of participants who actually used this function according to the software.
Table 5-17: RCT intervention group participants’ responses to whether the messages were helpful

<table>
<thead>
<tr>
<th>Did these aspects help you to stop smoking even if you relapsed later?</th>
<th>Yes n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watching someone like me go through the quitting process</td>
<td>59</td>
<td>88</td>
</tr>
<tr>
<td>Being supported to feel like I could do it</td>
<td>55</td>
<td>86</td>
</tr>
<tr>
<td>Feeling like I belonged/like others were going through same thing</td>
<td>52</td>
<td>81</td>
</tr>
<tr>
<td>Things the people in the video clips said</td>
<td>50</td>
<td>76</td>
</tr>
<tr>
<td>Getting messages at the right times</td>
<td>47</td>
<td>75</td>
</tr>
<tr>
<td>The free stuff</td>
<td>44</td>
<td>69</td>
</tr>
<tr>
<td>It was fun</td>
<td>39</td>
<td>61</td>
</tr>
<tr>
<td>Made me get support from my friends or family</td>
<td>39</td>
<td>60</td>
</tr>
<tr>
<td>The website/other people videos</td>
<td>35</td>
<td>57</td>
</tr>
<tr>
<td>Realising I had been manipulated by tobacco industry</td>
<td>31</td>
<td>48</td>
</tr>
<tr>
<td>Messages/games/whatever distracting me from cravings</td>
<td>30</td>
<td>47</td>
</tr>
<tr>
<td>Crave messages</td>
<td>29</td>
<td>45</td>
</tr>
</tbody>
</table>

Participants’ free text responses to what they liked most about the programme could be divided into three main areas:

- Those who reported something about support (29/54, 54%). For example, they reported feeling like they were not quitting alone or were quitting as part of a group, like there was constant support and encouragement, that the messages from real people sharing their experiences were helpful, and that the messages acted as reminders.

- Those whose comments related to the programme (11/54, 20%). For example, they felt it was non-intrusive and there was no pressure, that it was user-friendly and all worked automatically, that it used modern technologies that they liked, and that the messages came every day.

- Those who said ‘all of it’ (5/59, 8.5%).

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When asked what they disliked most about the programme 20 out of 49 (41%) said they disliked nothing. Others commented that:

- They had some sort of technical issue (6/49, 12%)
- They did not feel the content was right or they did not relate to the models (7/49, 14%)
- There were too many messages (5/49, 10%)
- The messages reminded them to smoke (1/49, 2%)
- One had the (false) perception they were being charged for messages (2%).

Participants were also asked for any suggestions to improve the programme for the future. Most said they had no suggestions (23/45, 51%), however suggestions that were made have been categorised below:

- Content improvements (12/45, 27%): these included adding graphic videos of health effects, reference to a self-help book, allowing personal phone calling contact, facilitating group meetings, adding in a social networking aspect, and more tailoring of role models to participants’ contexts.
- Programming improvements (5/45, 11%): these included changing the timing of messages (which participants could already do), adding more text messages, making the intervention longer, and including a link to Quitline.
- Technical improvements (3/45, 7%): these included adding in the use of email, improving the quality of videos, and improving download time.

5.4.5.8 Māori versus non-Māori analysis

Due to small numbers, the Māori versus non-Māori analysis findings are presented only for the baseline characteristics and the primary outcome. There were 54 Māori participants in the trial (24% of participants). Half (n=27) had heard about the study from radio advertisements, and another 22% (n=12) from friends or family.
Table 5-18: RCT Māori versus non-Māori participants’ baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Māori N=54</th>
<th>non-Māori N=170</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Mean age in years (SD)</td>
<td>29 (9)</td>
<td>27 (9)</td>
</tr>
<tr>
<td>Female</td>
<td>35 65</td>
<td>72 42</td>
</tr>
<tr>
<td>Mean number of cigarettes/day (SD)</td>
<td>14 (10)</td>
<td>12 (8)</td>
</tr>
<tr>
<td>Smoke 'roll-your-own' tobacco</td>
<td>39 72</td>
<td>96 56</td>
</tr>
<tr>
<td>Smoke first cigarette within 30 minutes of waking</td>
<td>38 70</td>
<td>112 65</td>
</tr>
<tr>
<td>Mean confidence to quit this time (on a scale from 0%-100%) (SD)</td>
<td>69 (23)</td>
<td>63 (22)</td>
</tr>
</tbody>
</table>

Māori participants were older than non-Māori participants, and there was a higher proportion of Māori female participants than for non-Māori (Table 5-18). A higher proportion of the Māori participants smoked roll-your-own cigarettes compared with non-Māori although this was generally in combination with factory made cigarettes, as only one Māori participant said they did not smoke manufactured cigarettes at all. One third of Māori participants smoked within the first five minutes of waking and 70% within the first 30 minutes, indicating a high level of nicotine dependence. This was similar to the level of dependence seen in non-Māori participants.

Five Māori participants in the intervention group (21%) and seven in the control group (23%) reported not smoking since their selected quit day, but these differences were not statistically significant. (Table 5-19) We also questioned participants on whether they considered they had gone back to daily smoking at six months. Only three in the intervention group (13%, using an intention-to-treat analysis) and two in the control group (7%) reported they had not gone back to daily smoking.

For non-Māori, 15 participants in the intervention group (17% intention-to-treat analysis) and 14 (16%) in the control group stated they had not gone back to regular smoking. These results were not statistically significant.
Table 5-19: RCT Māori versus non-Māori participants’ self-reported continuous abstinence at six months

<table>
<thead>
<tr>
<th></th>
<th>Māori</th>
<th></th>
<th>Non-Māori</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention N=24</td>
<td>Control N=30</td>
<td>Chi-sq p-value</td>
<td>Intervention N=86</td>
</tr>
<tr>
<td>Have you smoked at all since Quit day?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (allows up to 5 cigs)</td>
<td>5</td>
<td>31%</td>
<td>7</td>
<td>29%</td>
</tr>
<tr>
<td>Yes, more than 5 cigs</td>
<td>11</td>
<td>69%</td>
<td>17</td>
<td>71%</td>
</tr>
<tr>
<td>Missing</td>
<td>8</td>
<td>6%</td>
<td>27</td>
<td>6%</td>
</tr>
<tr>
<td>Intention to treat analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (up to 5 cigarettes)</td>
<td>5</td>
<td>21%</td>
<td>7</td>
<td>23%</td>
</tr>
<tr>
<td>Yes or missing</td>
<td>19</td>
<td>79%</td>
<td>23</td>
<td>77%</td>
</tr>
<tr>
<td>Have you gone back to daily smoking?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>27%</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Yes</td>
<td>8</td>
<td>73%</td>
<td>13</td>
<td>87%</td>
</tr>
<tr>
<td>Missing</td>
<td>13</td>
<td>15%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.4.5.9 Adverse events

Five participants in each group reported having a motor vehicle accident during the study period (Table 5-20). Four out of five (in both groups) occurred where the participant was the driver. One such accident in the control group occurred while the participant was using their mobile phone, one within five minutes of receiving a message, and two while the participant was smoking. None of the accidents in the intervention group were reported as being temporally related to mobile phone use or smoking.
### Table 5-20: RCT participants involved in motor vehicle accidents in study period

<table>
<thead>
<tr>
<th>Were you involved in a car crash during the study period?</th>
<th>Intervention group (N=110)</th>
<th>Control group (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>No</td>
<td>67</td>
<td>61</td>
</tr>
<tr>
<td>Yes</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Missing</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>If yes, were you the driver?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>If yes, did the crash happen while using your mobile phone?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>While smoking?</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Within 5 minutes of receiving a message?</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

#### 5.5 Meta-analysis

##### 5.5.1 Objective

To update the systematic review and meta-analysis, described in Chapter 3, on the use of mobile phones in smoking cessation by including the RCT results.

##### 5.5.2 Methods

This RCT does meet the pre-specified criteria for inclusion of studies, namely:

- Types of studies: Randomised or quasi-randomised trials.
- Types of participants: All smokers who want to quit smoking. No age restrictions applied.
- Types of interventions: Studies which examine any type of mobile phone-based intervention.

This included any intervention aimed at mobile phone users, based around delivery via
mobile phone, and using any functions or applications that can be used or sent via a mobile phone.

- Types of outcome measures: The primary outcome of interest was smoking abstinence at four weeks and six months after the start of the intervention, and longer wherever the data were available. Both sustained abstinence and point prevalence abstinence were considered, and both self-reported and biochemically verified smoking status.

### 5.5.2.1 Analysis

As in the original systematic review a meta-analysis was conducted using the Mantel-Haenszel Risk Ratio, fixed-effect method, with statistical heterogeneity assessed by the $I^2$ statistic. (156)

### 5.5.3 Results

The original systematic review included four randomised controlled trials. The STOMP text messaging mobile phone intervention trial in New Zealand; (34) a pilot of this intervention adapted slightly for the UK (txt2stop); (140) and two separate studies of the same mobile phone and internet-based intervention in Norway (Happy Ending). (162, 163) The meta-analysis for this review divided the studies into two separate groups due to the differences in the interventions, that is, into mobile phone-only interventions and mobile phone plus internet interventions. Therefore, for this updated meta-analysis, STUB IT data are only pooled with the other mobile phone-only interventions. The primary outcome in this RCT study was 6-month continuous abstinence (with lapses) and this has been pooled with similar outcomes from the two other mobile phone-only interventions. (Figure 5-5)
These long-term outcomes were not presented in the original review due to significant heterogeneity ($I^2=77\%$). Adding in this RCT reduces the heterogeneity a small amount ($I^2=65\%$) and provides a non-statistically significant increase in quitting with mobile phone interventions (RR 1.21, 95% CI 0.94-1.57). For completeness, since responders-only analyses have been displayed in the results above and had been conducted for the Cochrane review (but not included in the final published article), the responders-only data for six month outcomes is shown here. (Figure 5-6) Pooling this data does give a statistically significant difference in favour of the mobile phone interventions.

**Figure 5-6: Forrest plot of mobile phone-only intervention versus control, 6-month self-reported continuous abstinence: responders-only**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>Free 2008a</td>
<td>15</td>
<td>90</td>
<td>19</td>
<td>94</td>
</tr>
<tr>
<td>Rodgers 2005</td>
<td>64</td>
<td>591</td>
<td>39</td>
<td>674</td>
</tr>
<tr>
<td>Whittaker 10</td>
<td>29</td>
<td>75</td>
<td>32</td>
<td>90</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>756</td>
<td>858</td>
<td>100.0%</td>
<td>1.47 [1.08, 2.01]</td>
</tr>
<tr>
<td>Total events</td>
<td>108</td>
<td>90</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 5.22, df = 2 (P = 0.07); $I^2 = 62\%$
Test for overall effect: Z = 2.43 (P = 0.01)
Only the Free pilot study and this RCT attempted to verify abstinence at six months, and neither of these studies was powered to show a difference. Pooling their data on verified-only abstinence does not demonstrate a statistically significant difference. (Figure 5-7)

**Figure 5-7: Forrest plot of mobile phone-only intervention versus control, 6-month verified quitting**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Odds Ratio</th>
<th>M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Total</td>
<td>Weight</td>
</tr>
<tr>
<td>Free 2008a</td>
<td>8</td>
<td>102</td>
<td>6</td>
<td>98</td>
</tr>
<tr>
<td>Whittaker 10</td>
<td>7</td>
<td>110</td>
<td>11</td>
<td>116</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>212</td>
<td>214</td>
<td>100.0%</td>
<td>0.88 [0.43, 1.82]</td>
</tr>
<tr>
<td>Total events</td>
<td>15</td>
<td>17</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 0.86, df = 1 (P = 0.35); I² = 0%
Test for overall effect: Z = 0.33 (P = 0.74)

In the original review, short-term point prevalence of quitting appeared to more than double with mobile phone interventions (RR 2.18, 95% CI 1.80-2.65). Adding in this RCT increases the degree of heterogeneity but only slightly reduces the RR to 2.05 (95% CI 1.70-2.48). (Figure 5-8)

**Figure 5-8: Updated forest plot of mobile phone-only intervention versus control, short term self-reported point prevalence abstinence**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Total</td>
<td>Weight</td>
</tr>
<tr>
<td>Free 2008a</td>
<td>26</td>
<td>102</td>
<td>12</td>
<td>98</td>
</tr>
<tr>
<td>Rodgers 2005</td>
<td>239</td>
<td>852</td>
<td>109</td>
<td>853</td>
</tr>
<tr>
<td>Whittaker 10</td>
<td>12</td>
<td>110</td>
<td>14</td>
<td>116</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1064</td>
<td>1067</td>
<td>100.0%</td>
<td>2.05 [1.70, 2.48]</td>
</tr>
<tr>
<td>Total events</td>
<td>277</td>
<td>135</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 5.32, df = 2 (P = 0.07); I² = 62%
Test for overall effect: Z = 7.53 (P < 0.00001)
5.6 Discussion of the trial findings

5.6.1 Effectiveness of the intervention

This randomised controlled trial was the first to test video messaging via mobile phones as an intervention for smoking cessation. There was no statistically significant difference between the intervention and control groups in the primary outcome of abstinence at 6 months, nor in any of the secondary outcomes. However, the trial was substantially under-powered due to difficulty recruiting participants. Indeed with the sample size achieved (n=226) and the reported control group quit rate (28%), an intervention group quit rate of approximately 50% would have been needed to achieve statistical significance. The relatively high quit rate in the control group may possibly reflect the effectiveness of brief video phone contact in increasing quit rates, and that adding a more intensive theoretically-based intervention may not have significantly improved quit rates over and above this.

There are other possible reasons as to why we did not observe an effect of the intervention. There was a differential loss to follow-up between the groups, with 32% of intervention group participants and 22% of control group participants having missing data for the primary outcome. In the ITT analysis, all those with missing data were treated as smokers. Therefore, with more missing data in the intervention group, the quit rate in the intervention group is lowered more than that in the control group. This moves the primary outcome from favouring the intervention in the responders-only analysis to favouring the control in the ITT analysis. This is also true of 4 week point prevalence which suffers from even larger loss to follow-up (45% and 34% in intervention and control groups respectively). The other cessation outcomes (4-week complete abstinence, 12-week point prevalence, and return to regular smoking at six months) remain favouring the intervention. It is unlikely to be completely true that all those missing have returned to smoking, as has been shown in one small study of Quitline non-responders.(235) Indeed, discussions with two of our participants indicated that once quit they no longer wished to be reminded of smoking by having anything to do with the study. It is possible that this was a factor for more participants who dropped out.
It was originally hypothesized that one mechanism whereby the intervention could be effective was by increasing participants’ confidence or self-efficacy in being able to quit. However, the study was unable to demonstrate this, with little difference between the mean confidence scores of the two groups at all time points. Gwaltney et al recently undertook a meta-analysis of studies examining self-efficacy and quitting.(228) They concluded that the relationship may have been previously overestimated. Pre-quit measures of self-efficacy only had a modest association with future smoking, and post-quit measures were thought to reflect rather than predict success in quitting. This was because the correlation of self-efficacy with success was much smaller if only abstinent smokers were included. Our results may align with this, in that those who had successfully quit reported increased confidence scores in both intervention and control groups. In those who had relapsed, those receiving the intervention reported smaller increases in confidence, and those in the control group actually decreased their confidence in being able to quit next time.

The intervention also did not appear to prompt more quit attempts than were reported in the control group – another potential mechanism for effectiveness. The control group participants did report using more pharmacological support for quitting (nicotine replacement therapy and nortriptyline) although again this was not a statistically significant difference.

Overall, it is difficult to draw any conclusions about the effectiveness of the intervention. The possibility that there really was no difference between the groups must be considered. That is, that the theory-based complex intervention was no more effective than the less frequent (fortnightly) sending of health related video phone messages. Participants in both groups signed up to a research study to stop smoking (i.e. had serious intentions to quit), both groups set a target quit date, and both groups received ‘novel’ mobile phone contacts from the researchers. Perhaps this was sufficient to support quit attempts, as evidenced by the fact that self-reported quit rates in both groups were high.
(26% and 28% self-reported continuous abstinence at six months). In comparison New Zealand’s Quitline reports 17% self-reported six month continuous abstinence in their recent evaluation and an even lower rate of 10% in 18-24 year olds.(236) Continuous abstinence rates (allowing up to three lapses) in the New Zealand STOMP text messaging cessation intervention were 7.5% and 4.6% for intervention and control groups respectively.(34) The high rates in this RCT are despite the fact that the participants appeared to be quite highly addicted according to their baseline nicotine dependence scores.

Feedback from participants receiving the intervention showed 88% felt that watching someone like them go through the quitting process had helped them to quit, even if they later relapsed. Being supported to feel like they could quit, and feeling as if they belonged and there were others quitting with them, also helped the majority of participants. Over three-quarters of participants in the intervention group liked that they could relate to the role model. This reflects Social Cognitive Theory and the use of observational learning to assist many participants to feel supported in their quitting attempts, to normalise the process and the behaviour change required, and to feel they were part of a group of similar people going through similar difficulties.

Adding in the STUB IT RCT results to the previous meta-analysis made little difference overall. A short-term improvement in quit rates with mobile phone interventions remains. It is envisaged that a definitive answer with respect to long-term outcomes of mobile phone cessation interventions may be provided with the future inclusion in the meta-analysis of the current large (n=5800) randomised controlled trial of the text messaging intervention in the UK.(140) Inclusion of true control groups that do not receive any intervention may also help. However, this is unlikely to occur, as it would be unethical not to offer any assistance to the control participants when we know that effective interventions exist.
5.6.2 Strengths of this trial

The main strength of the study is that it was designed in accordance with CONSORT guidelines in an effort to control systematic error or bias.\(^{(237)}\) The CONSORT checklist for this RCT is shown in Appendix 22. This includes randomisation, allocation concealment, single blinding, using a recognised primary outcome, and appropriate treatment of missing data. Other strengths include the pragmatic nature of the trial and providing information on the use of technological methods for data collection.

In this study, randomisation was used to ensure the balance of factors that may influence outcomes between the two comparison groups. Minimisation was used to further ensure that important factors known to impact cessation outcomes were equally spread, such as ethnicity, age group and level of nicotine dependence. However, randomisation should also take care of any as yet unknown factors. In this study, the majority of baseline characteristics were distributed in a similar manner between the two groups. There were minor baseline differences in sex (53% female in the intervention group and 42% in the control group) and in the proportion who smoked “roll-your-own” (RYO) tobacco (65% and 55% respectively). Gender has not been associated with the success of quitting in New Zealand.\(^{(10)}\) Although RYO cigarettes tend to be smoked differently from manufactured cigarettes,\(^{(238)}\) there are no studies on whether this affects cessation.

Another important factor in randomisation is allocation concealment to ensure there can be no manipulation of the allocation. This study used computerised randomisation, so that on submission of the online baseline data collection form by the participant, the system would automatically allocate that participant to intervention or control group. Therefore, allocation was completely concealed until the point of randomisation and interference with the allocation would not be possible. Participants were also locked out of re-entering forms or re-registering for the trial once initially registered and so were not able to ‘try again’ to get the allocation they desired.
Measurement bias can manifest in several different ways. Data collection in this trial predominantly took place via web-based forms completed by the participant. Participants who did not complete the forms were phoned by the research assistant who completed the questionnaire over the phone and entered the data directly. The research assistant was blind to allocation in these instances in order to prevent any subconscious manipulation of outcomes data according to group. However, participants were aware which group they were allocated to and it is possible that those in the intervention group may have felt extra pressure to report quitting than those in the control group. For this reason all participants were warned at the commencement of the trial that reports of quitting would be verified with a test. This alone has been shown to improve the accuracy of self-reported quitting in research studies.\(^{(239)}\) The fact that similar proportions of self-reported quitters in both groups (56% and 58\%) returned the tests would seem to indicate that the intervention group did not feel any more or less pressure to falsely report quitting.

The trial was designed with the primary outcome representing a strict definition of quitting (continuous abstinence according to the Russell standard \(^{(165)}\)) and for an intention-to-treat analysis of the outcomes. This means that all randomised participants are followed up and are included in the analysis regardless of protocol violations or actual receipt of the intervention. In smoking cessation trials this also means that all missing data are treated as having returned to smoking regardless of last outcome value. This is the most conservative form of analysis (as used by the Cochrane Tobacco Group) as it is unlikely that all those lost to follow-up are actually smokers. Therefore, some researchers favour sensitivity analyses or presenting the raw data so that the assumptions made in the analyses are clear and can be tested by readers. This has been done here by presenting the intention-to-treat analyses along with the responders-only and numbers of missing data. This study also attempted to verify self-reported quitting with mailed salivary cotinine tests. However, despite extensive efforts to get the tests returned (multiple phone calls and re-sending up to three test packs) the response rate was poor.
The pragmatic nature of the trial may be seen as a strength with respect to its generalisability or external validity. That is, the trial examined the effect of the intervention as it might be delivered in a ‘real world’ setting; with direct to consumer advertising to recruit participants, web-based registration processes, and no face-to-face contact with researchers. However, the eligibility criteria may have affected external validity to some extent and this is discussed in the next section under limitations (Section 5.6.3).

Finally, this trial used new technology-based methods for recruitment, informed consent and outcome measurement collection, demonstrating that this is feasible and acceptable to participants. Online advertising was used with direct links to the online registration and eligibility check. Participant information sheets were available online in a variety of formats and were followed up by text message confirmation of consent (with the exact words “I consent” sent by SMS). Automated text message prompts and reminders were set up to direct participants to complete web-based data collection forms at baseline, four weeks and six months post-QD. However, the highest response rates were to simple text message questions: 96% response rate to a question about confidence at QD and 76% response to a smoking status question at twelve weeks post-QD.

5.6.3 Limitations of this trial

The limitations of this trial involve recruitment of participants, generalisability of the findings and the retention of participants.

5.6.3.1 Recruitment of participants

This trial did not recruit the expected number of participants and this impacted on the ability to detect an effect. There are several potential reasons why recruitment was suboptimal. Firstly, recruitment efforts were targeted at young adults (16 years and over). Despite indicating their interest in quitting,
most young people contacted were not actually ready to commit to a cessation intervention. This phenomenon has been demonstrated elsewhere (15, 72, 73) and has been discussed in the literature review (Chapter 2). A Cochrane review of smoking cessation interventions for young people commented that many of the included studies were underpowered, with only 5032 participants from 24 studies. (13) Only two of these studies recruited directly from the community as we did. Lipkus randomised 402 participants despite approaching nearly 40,000 young people in shopping malls. (76) Patten required 42 months to randomise 139 participants to a trial of an internet cessation programme compared with an office-based intervention. (75) Dahm and colleagues found that non-attendees at a smoking cessation trial were more likely to be young, with every year increase in age meaning participants were 4% more likely to enrol (OR 1.04, 95% CI 1.02-1.06). (240) Recruitment to youth smoking cessation services (rather than studies) has also been shown to be problematic. (71, 74)

More successful studies and services have used school-based approaches, which we did not attempt, and internet approaches, which we did. Internet advertising and online magazines did not appear to be overly successful, although this may reflect the sites used. Novel recruitment methods aimed at young adults included ‘social’ advertising on one social networking website and setting up a group on another video-based social networking website. Direct mobile phone advertising, via an organisation with an established client base happy to receive such advertisements, was also used. However, none of these sources delivered many participants.

Secondly, the new multimedia mobile phone technology may have proved too much of a barrier for some. At the time of recruitment, New Zealand mobile phone data charges (or anything other than SMS and voice calling) were expensive. We spoke to two participants who were wary of hidden costs despite being advised the programme was free, and there may have been more who did not register for this reason. Also many people were unaware whether their mobile phone could receive video
messages or not. These factors may have dissuaded people even registering their interest and therefore we have no information on their relative importance in our recruitment.

It is unlikely that low recruitment was related to it being a ‘mobile phone’ intervention. CTRU’s previous study of a text messaging mobile phone cessation intervention recruited 1705 participants in seven months in New Zealand.  

(34) A UK study based on that text messaging intervention recruited 5800 participants in 20 months (personal communication, Dr Caroline Free, principal investigator). Also, the candidate is involved in a current trial of a multimedia mobile phone programme to prevent adolescent depression that has recruited 1200 participants over three school terms (of approximately ten weeks each). Therefore, if poor recruitment was related to a wariness of new multimedia messaging, this may be short-lived.

Thirdly, monetary incentives are thought to be particularly effective in encouraging participation of young people. (241) This trial was initially designed with monetary incentives directly to participants’ mobile phones in mind. However, after commencement it was determined that this would no longer be possible and so monthly prize draws of new mobile phones were instigated instead. The ethics committee did not approve promotional materials that advertised this as they were seen as an inducement to participate in the trial. As soon as recruitment was seen to be falling behind, ethics approval was given to provide all participants with mobile phone, supermarket or petrol vouchers as reimbursements for their participation. The recruitment rate rose in response but not enough at that late stage to make a large difference to overall recruitment within the budget constraints.

Finally, there was competition from other cessation programmes at this time with respect to advertising. In particular, CTRU’s text messaging cessation programme described above was launched as a free national programme (txt2quit) in June 2008 by the Quitline. This programme recruited nearly 4000 participants in its first twelve months. (139) Potential reasons for their relative
success at recruiting participants include Quitline’s greater reach with respect to national advertising (including TV ads) and their reputation as a respected provider of cessation counselling and subsidised nicotine replacement therapy. These services were available to txt2quit clients alongside the text message programme. Also, as a service rather than an RCT, there would be no participant concerns about a 50:50 chance of receiving a potentially less effective ‘control’ programme. The availability of the txt2quit programme at the same time as recruitment to the STUB IT trial is likely to have reduced the number of participants willing to participate in the trial.

5.6.3.2 Generalisability of the findings

The second limitation is predominantly around the eligibility criteria for the trial. Participants were required to be daily smokers as these were considered to be those most in need of cessation support and to reduce any issues with verifying smoking status. Young adults who do not class themselves as daily smokers but who smoke heavily on fewer occasions (e.g. at weekends only) were not included and the findings may not be applicable to this group.

Participants were also required to have a mobile phone on the Vodafone network. At the time Vodafone NZ Ltd were able to show that young adults were more likely to be Vodafone customers than their competitors. It was also thought to be common practice for young people to have two phones to cover the special price deals provided by the two competing networks. The phones also needed to be capable of displaying video messages. This was considered to be a potentially limiting issue and therefore processes were put in place to enable ‘officials’ to refer people wanting to quit who did not have such a phone. These people could be offered a ‘loan’ phone for six months in order to be able to participate. There was some media publicity on this loaning of phones to ‘smokers’ as potentially inappropriate. Several smoking cessation and health services personnel did sign up to be ‘officials’, however only one participant came forward to be loaned a phone. Several others were referred into the trial in this manner, but did not take up the offer or complete registration.
The intervention was actually designed to be appropriate for the ‘lower end’ technology phones and very few participants reported any technical difficulties with viewing the messages. However, these eligibility criteria may have meant that those who registered were more technologically aware, and therefore may have limited the generalisability of our findings to all young adults wanting to stop smoking.

5.6.3.3 Retention of participants

Thirdly, there was a high attrition rate over the duration of the trial and the loss to follow-up differed between intervention and control groups. Overall, our data collection of primary outcomes was lower than expected, despite multiple attempts to reach participants in a variety of ways, including text messages, phone calls, and emails. The automated system of prompts, alerts and reminders to participants and to the research assistant that the final data collection form was due, did not work for several weeks. This resulted in some participants being approached to complete final data collection some weeks after their intervention had ceased. This may have contributed to difficulty in contacting some participants for final data collection. It also affected the ability of the research assistant to arrange verification procedures for self-reported quitters, which did result in some claiming they had relapsed again since the end of the intervention (when they had reported quitting). Therefore, these participants could not undergo verification. This system failure led to an internal CTRU quality audit into the reasons why it occurred. Recommendations were made for new policies and procedures particularly around data management standard operating procedures for set-up and testing.

Perhaps even more importantly, there was a differential loss to follow-up between the groups. There was greater loss to follow-up at six months in the intervention group (32% of intervention group participants did not provide primary outcomes data) than in the control group (22% did not provide data). There was no obvious reason for this difference. Perhaps some in the intervention group grew tired of the more frequent messages from the study and no longer read them. As described above, in
an intention-to-treat analysis for smoking cessation trials, missing data are generally treated as having returned to smoking. Therefore, a greater number of missing data in the intervention group has the effect of perhaps underestimating quit rates in that group in comparison with the control group.

5.6.4 Consistency with other research

There are few other published randomised controlled trials of interventions using mobile phones for smoking cessation. The systematic review found four trials. This RCT demonstrated higher quit rates than all four of these studies, with 26% and 28% self-reported continuous abstinence at six months (intervention and control groups, respectively). The STOMP text messaging intervention trial reported six month self-reported continuous abstinence rates of 7.5% (64/852) and 4.6% (39/853). The six month point prevalence abstinence, described as no smoking in the past seven days, was higher at 25.4% and 23.7% in intervention and control groups respectively.(34) The STOMP trial also suffered from differential loss to long term follow-up, and went from a statistically significant increase in quit rate at four weeks to no significant difference at six months.

Of the international studies included in the review, there was a pilot study of the STOMP intervention in the UK (as txt2stop), which had six month continuous abstinence rates of 14.7% (15/102) in the intervention group and 19.4% (19/98) in the control group.(140) As a pilot study, this was not powered to show a statistically significant difference. A large randomised controlled trial of this intervention has been completed and findings should be available later this year (2010). The other two studies were trials of the same internet and mobile phone based intervention in Norway with statistically significant differences in six month repeated point prevalence abstinence of 22% (44/200) and 13% (26/200) in one study, and 20% (29/148) and 7% (10/148) in another study.(162, 163)

Overall, this trial did demonstrate higher quitting rates in both groups, in comparison with the other trials. This is unlikely to be solely due to over-reporting as participants were advised that verification
would be requested of all self-reported quitters. The Norwegian studies did not attempt to verify quitting status. Rodgers et al attempted to verify a sub-sample of self-reported quitters at six weeks and experienced higher non-return rates than those seen here. Only the UK pilot study attempted verification of all quitters at six months. They found some over-reporting of quitting, as was shown in this trial, but more so in the control group (the current trial had slightly more in the intervention group).

There may also be some differences in participant characteristics. The mean age of participants at 27 years falls somewhere between studies aimed at adolescents or young adults, and those aimed at adults. For example, the mean age in the Rodgers study was 22 years and in the three other studies (in the systematic review) was 36-39 years. Participants also appeared to have high nicotine addiction scores (mean HONC score of 8.0, SD=1.9). Wellman et al in a cohort of more than 1500 adults found that heavy smokers had a mean HONC score of 7.7 (SD=2.4) compared with moderate (mean 5.3) and light (mean 6.8) smokers.(234) Higher HONC scores were associated with a shorter duration of longest period of abstinence from smoking. In another cohort of young adults, Wellman claimed that high HONC scores were predictive of a failed cessation attempt, with each additional symptom doubling the likelihood.(223)

Finally a large proportion of participants in this trial smoked ‘roll-your-own’ (RYO) tobacco (60%), predominantly in combination with manufactured cigarettes (only 8% smoked RYO alone). New Zealand is known to have high RYO usage in comparison with other countries (7-28% in USA, Canada, Australia and UK).(242, 243) Young people in particular are high users of RYO tobacco in New Zealand.(5) This is thought to be predominantly due to cost considerations.(243) RYO cigarettes have been found to be no less, and possibly more, dangerous than manufactured cigarettes, and smoking behaviour to be different with RYO cigarettes.(238) However, there has not been any research on whether that difference has an effect on cessation.
5.6.5 Implications for practice

Support was originally obtained from the Ministry of Health and The Quit Group for this trial, with a view to considering the intervention as an update to the txt2quit service if it was found to be effective. However, this trial did not demonstrate sufficient evidence of effectiveness to support its implementation. It was also not able to demonstrate sufficient interest from those wanting to quit. It is possible that the adoption of multimedia mobile phone technology had not yet entered the ‘upswing’ phase of the ‘S’ curve of diffusion of technology (Figure 2-1, Chapter 2). That is, that the general population had not yet taken up the use of multimedia functions on their mobile phones to a degree that would support widespread understanding and appeal of our novel intervention. Indeed, Vodafone NZ Ltd has now introduced an ‘MMS’ gateway that more easily allows the sending of video in a similar manner to text messages. If it is indeed the case that this intervention was ‘ahead of the curve’ then there may be an opportunity to test the appeal and effectiveness of multimedia mobile phone cessation support in the future.

5.6.6 Implications for future research

This research has demonstrated that it is still difficult to recruit young adults to a smoking cessation intervention trial. Previous research on this topic has suggested that interventions need to be designed specifically for young adults, with respect to ‘fitting in’ with their lifestyles, being convenient and flexible, and recognising some of the social factors that promote continued smoking. This intervention attempted to do this, involving young people in its development and using a delivery method that was already integrated into young adult lifestyles. However, recruitment was still an issue. Further research in this area could usefully examine different methods of promoting study participation in young adults. Possibilities could include a more concerted approach to social networking websites, determining effective reimbursements for young adults, and evaluating the use of recently introduced internet programmes for recruiting research participants by young adults.
This research also demonstrated the feasibility and acceptability of research processes carried out via technological methods. In particular, the use of text message-based data collection methods to increase response rates should be explored in future research studies. This may also be valuable in reducing the participant burden and thereby assisting with the issues of recruitment and retention.

Participants who received the intervention provided encouraging feedback. The majority of respondents liked the intervention, and in particular the video role modelling messages. They reported that watching someone like them go through the quitting process was important in helping them to quit. They also reported feeling supported in their quit attempt, and feeling like they were not alone but were quitting with others. This was important in assisting their quit attempt, even if they later relapsed. This feedback appears to endorse the theoretical basis of the intervention, providing the opportunity for observational learning from ‘ordinary’ role models. This warrants further investigation. For example, there may be the potential to target other population groups. Many participants in this trial were older than was specifically targeted. With older role models and a target audience with more serious quitting intentions, the intervention could be worth testing further. Some in-depth interviews with intervention group participants could provide further information on what aspects were useful, whether the theoretical basis was appropriate, and potential future uses of the intervention.

5.6.7 Summary

This trial was unable to demonstrate a statistically significant effect of the intervention in comparison with a control group. However there was sufficient positive feedback on the intervention to warrant further investigation. A qualitative sub-study, with volunteers from the intervention group, was designed in order to obtain more detailed feedback on the intervention that could inform future developments. This is reported in the next chapter.
6 Qualitative sub-study

“Qualitative methods are useful in the exploratory stages of a research project, where they will often help to clarify or even set the research question, aid conceptualisation and generate hypotheses for later research. Qualitative methods may also be used to interpret, qualify or illuminate the findings of quantitative research and to test hypotheses.”
Murphy et al, 1998 (152)

6.1 Introduction
The sample size of the randomised controlled trial of the ‘STUB IT’ intervention did not reach the estimated number required. Even with the smaller sample size, there was not a trend to suggest that the intervention was more effective than minimal mobile phone contact. To explore why the intervention may not have been effective and to assess what participants thought of the intervention, a qualitative study was designed by the candidate. The study was also designed to explore whether the theoretical approaches underlying the development of the intervention were appropriate. The study involved interviewing participants from the intervention group after the trial had finished, using qualitative research methods.

6.1.1 Summary of theoretical approaches used in intervention development
The main theoretical approaches underlying intervention development were social cognitive theory, effective behaviour change techniques for smoking cessation, and adolescent development principles. Social cognitive theory describes the benefit of observational learning, or watching others perform the behaviour change, to enhance self-efficacy for making that change themselves.(142) Observational learning can be provided by ‘coping’ role models. These are ‘ordinary’ people who describe the difficulties faced and the strategies they used to get through the difficulties of quitting smoking. The second approach was to ensure the use of behaviour change techniques for smoking cessation that
have been effective in past studies such as setting a quit date; identifying cues and triggers and planning to avoid these; providing information on withdrawal symptoms and positive reinforcement.(54) The third approach was the use of adolescent development principles to ensure the involvement of young people in the intervention development process.(202) Finally, consideration was also given to social marketing techniques.

6.1.2 Rationale for the use of qualitative methods

Qualitative research can be defined as “an approach that seeks to understand phenomena in uncontrolled, context-specific settings, in which data are not numbers but text, audio or visual”.(244) Curry describes situations where qualitative methods are useful including:(245)

- Generating data necessary for a comprehensive understanding of a problem (provide detailed descriptions of individual perceptions and experiences, enhance quantitative measures of phenomena);
- Gaining insights into potential causal mechanisms (generate hypotheses about why a given intervention has a specific impact, how the impact occurs, and in what organizational context it occurs).

Curry also describes situations where primary quantitative research is examined in greater depth with a follow-up qualitative component, particularly to corroborate findings, generate more complete data and enhance insights.(245)

In this case, qualitative methods were used to follow-up non-significant quantitative findings with more in-depth information from individuals’ experiences of the intervention. Interviews were therefore chosen as the appropriate qualitative data collection method. This would allow exploration of participants’ experiences, with each participant being able to direct the course of the discussion and identify unanticipated concepts.
6.2 Aims
To gain more detailed understanding from participants about the programme, and whether the theoretical approaches underlying the intervention development were appropriate. Results could inform future adaptations or uses of the intervention programme.

6.3 Methods

6.3.1 Study Population
The study population included participants in the STUB IT trial intervention group.

6.3.1.1 Inclusion and Exclusion Criteria
Participants were eligible for the study if they were:

- Able to provide informed consent
- Able to participate in a phone interview
- Had received the active intervention during the STUB IT RCT and had therefore previously met the inclusion criteria for that trial, namely:
  - daily smokers
  - wanted to stop smoking
  - at least 16 years of age
  - able to provide text consent
  - users of a Vodafone multimedia mobile phone OR users of a Vodafone phone (not multimedia capable) and were referred to the study as a confirmed smoker who wanted to quit by networks established for this purpose

Participants were excluded if they were known to have been un-contactable at follow-up during the RCT.
6.3.2 Recruitment

Participants meeting the above criteria were sent an invitation to participate in this sub-study by email and by text message. This was later followed up by a phone call. Interested participants were mailed or emailed a participant information sheet (PIS) and consent form (Appendix 23), and were asked to return a signed consent form. This included permission to record and transcribe their interviews and to use direct quotes where appropriate. Participants were advised that they would be reimbursed for their time with a $20 supermarket voucher to be mailed on completion of the interview. On receipt of the signed consent form, participants were phoned at a pre-arranged time for the interview. If this had not been pre-arranged, they were phoned to arrange a convenient time for the interview.

6.3.3 Interview

All interviews were one-to-one undertaken by telephone and were audio-taped. The interviews were carried out by Ms Enid Dorey, an experienced qualitative researcher. The interviews were semi-structured, that is using open-ended questions on a number of pre-specified themes but allowing the interviewee to identify unanticipated themes and for a reflexive discussion to take place.(245) The themes that were planned to be explored included: likes/dislikes regarding the intervention; social support; role modelling; self-efficacy/confidence to quit; engagement with the programme; and future ideas. The semi-structured interview guidelines can be seen in Appendix 24. After the first two interviews, the interviewer and the candidate reviewed the process and the discussions. The semi-structured interview guidelines were adjusted at this stage to refine the questions, ensure the flow of the interview and to pursue emerging themes.

The digital recordings of the interviews were transcribed by an experienced external transcriber. The interviewer checked the consistency of the transcripts by listening to two of the digital recordings and checking the transcription was accurate.
6.3.4 Sample Size and Analysis

The candidate set a flexible target of 15 participants for this sub-study, aiming for a mix of demographic and smoking statuses to ensure a broad range of responses. Theoretical saturation, that is the point at which no further new themes/concepts are emerging from the interviews, was the aim of the sampling.\(^{(246)}\)

A general inductive thematic analysis was undertaken.\(^{(247)}\) This type of analysis describes starting with the raw data and deriving themes from the data. The purpose is to allow the findings to emerge from the observations without the restraints or preconceptions inherent in more structured methods. The data analysis involved repeated readings of the transcriptions, the development of categories from the data, organising and classifying the raw data into the categories, and summarising the data into key themes. Themes refer to recurrent unifying concepts or statements about the participant experience.\(^{(245)}\) NVivo8 software was used to facilitate and aid in the organisation of the analysis [http://www.qsrinternational.com/products_nvivo.aspx].

6.3.5 Study Organisation

The candidate led the design of the qualitative sub-study, the ethics application, and the development of the semi-structured interview guidelines. The candidate provided oversight of conduct of the study and reviewed the processes throughout the study with the interviewer, resulting in an update of the semi-structured interview guidelines. As outlined above, the study procedures including recruitment, informed consent procedures, and phone interviews, were carried out by Ms Dorey. The initial thematic analysis was undertaken by Ms Dorey, then verified by the candidate. The final interpretations were developed conjointly.
6.3.6 Bias

In qualitative research the findings are inevitably shaped by the researchers who decide what is more important and less important in the data. (247) In particular, the candidate would have a strong interest in seeing the intervention as appreciated by participants and helping them to stop smoking. The candidate did not undertake the interviews or the initial thematic analysis, which may have reduced this potential bias. However, in designing the study and in the final interpretations, the candidate may have had an effect on the research findings. The interviewer in this study (Ms Dorey) had not been involved in the conduct of the trial although she had contributed somewhat to the original development of the intervention.

6.3.7 Ethics Approval

Application was made to the Multi-Region Ethics Committee for approval of the sub-study as an amendment to the STUB IT study ethics approval. Approval was obtained on 6th August 2009 ref: NTX/06/10/130.

6.4 Results

The study was carried out between August 2009 and December 2009.

6.4.1 Study participation

As many of the participants had completed their study period some considerable time earlier, contact details were not always current and many participants were not able to be contacted. All contacted participants were interested in participating. Twelve participants returned signed consent forms and ten completed the phone interviews. Data saturation appeared to have been reached with no new themes emerging.
6.4.2 Characteristics of participants

Participant characteristics are described in Table 6-1. Participants were fairly evenly spread by sex (six females, four males) and ethnicity (three specified NZ European ethnicity, three Māori, one Indian and three ‘Other’).

**Table 6-1: Qualitative sub-study participants’ baseline characteristics**

<table>
<thead>
<tr>
<th>Age</th>
<th>Ethnicity</th>
<th>Sex</th>
<th>Smoking status at time of interview &amp; relation to the STUB IT intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>NZ European</td>
<td>Female</td>
<td>Quit with STUB IT for 4 months but is now back to smoking.</td>
</tr>
<tr>
<td>18</td>
<td>Other European</td>
<td>Male</td>
<td>Quit with STUB IT and Quitline and is still a non-smoker.</td>
</tr>
<tr>
<td>20</td>
<td>Other</td>
<td>Male</td>
<td>Quit with STUB IT and is still a non-smoker.</td>
</tr>
<tr>
<td>30</td>
<td>Other</td>
<td>Female</td>
<td>Did not quit with STUB IT but quit with a friend after the programme ended.</td>
</tr>
<tr>
<td>31</td>
<td>NZ European</td>
<td>Female</td>
<td>Quit with STUB IT for 3.5 months but is back to smoking.</td>
</tr>
<tr>
<td>34</td>
<td>NZ European</td>
<td>Female</td>
<td>Did not quit with STUB IT. Quit with a smoking cessation book after the programme finished</td>
</tr>
<tr>
<td>35</td>
<td>Māori</td>
<td>Female</td>
<td>Quit with STUB IT and is still a non-smoker.</td>
</tr>
<tr>
<td>37</td>
<td>Māori</td>
<td>Male</td>
<td>Had a few little attempts during the programme but was not successful in giving up. Trying to give up now.</td>
</tr>
<tr>
<td>53</td>
<td>Māori</td>
<td>Female</td>
<td>Did not quit with STUB IT. Still smoking.</td>
</tr>
<tr>
<td>56</td>
<td>Indian</td>
<td>Male</td>
<td>Quit for a little while during the programme but then the text messages made him want to smoke so he started again.</td>
</tr>
</tbody>
</table>

There was a considerable age range from 17 years to 56 years and only three participants were in the ‘young adult’ age range. All participants had tried to quit smoking prior to participating in the trial and made it clear that they were serious about wanting to quit but found it difficult.
“Um, and yeah no smoker ever enjoys being a smoker. I don’t care what they say. It’s not an enjoyable thing to inhale ash and burning embers and you know, it’s just not an enjoyable thing. So we don’t do it because we enjoy it, we do it because we’re addicted. Pure and simple” (56 year old male)

Participants were asked about their smoking status and quitting journey. It was made clear to participants that the interviewer did not have any of their previous information, including what they had reported about quitting during the RCT, in an attempt to ensure participants felt free to respond honestly. Of the five who had stopped smoking, three had quit with the STUB IT intervention and two had quit after completing the intervention. Three others quit with the STUB IT intervention but later relapsed. The final two did not quit with STUB IT. Of the five who were currently smoking, one was trying again to quit.

6.4.3 Thematic analysis

The analysis of the interview data produced the following themes: motivation to quit, ambivalence towards quitting with STUB IT, role model selection, support, engagement with the programme, general likes/dislikes, and future ideas for the programme.

6.4.3.1 Motivation to quit

All participants claimed to have been consistently looking for methods to help them quit. However, five of the participants had had recent events in their lives that had increased their motivation to quit, and the promotion of STUB IT happened to appear at the right time to capitalise on this. These motivations included illness, pregnancy and financial difficulties.

... I got sick during the winter and so I was sick and it was the winter and I was like why am I smoking, this is ridiculous. I’m just going to be sick for the entire winter, so I thought OK well now because I’m sick maybe it’ll be easier to start quitting. So I kind of was able to start quitting easily enough. But I needed the program to keep me focused on doing it. (Female, 30 years old)
I’ve just had a baby boy and um, that was the best thing ever, is to know, my first two children unfortunately I smoked with, but this one was smoke free. It was just wonderful to know that I haven’t inflicted the asthma and the bronchitis and all the problems my other two have because of being a horrible smoker (Female, 34 years old)

Some of the participants commented that seeing the role models struggle or ‘slip up’ made them feel better about their own quitting attempt and actually invoked a sense of competition, that is, they wanted to prove they could do better than the role model. This may have provided some on-going motivation to succeed in the quit attempt.

So did you feel that the people that you were watching quitting…did they make you feel more confident about your own attempt?

Yes, yeah. I thought well, you know, if you can get through that, or you know. If you can do this and still carry on, hey I can do it (laugh). Cos I even think with a couple of the people that I was watching, I was thinking, I could beat you, you know. So I had this competitive side of me started coming out too and I thought, “get outta here, it’s not that hard” (laugh). So it’s really quite funny. Everybody was laughing at me like, “Are you talking to your phone”? I was like, “yeah”, so I’d play it again. “Look at this? I can so do better than that”. (Female, 35 years old)

6.4.3.2 Ambivalence towards the likelihood of success

When asked how confident they had felt that they could successfully quit on this attempt, feelings of ambivalence were unanimously expressed. With all participants having had failed quit attempts and therefore understanding how hard it is to quit smoking, all were very hesitant that STUB IT would work for them. But, as one participant described it, they were “hopeful”.

Did you feel confident that STUB IT might be able to help you?

I was hopeful

You were hopeful, OK

Yeah very hopeful. Um, I mean I’d done all sorts of things. I’d done the patches and the hypnotism and all that sort of thing so I was hopeful that this being different would maybe work. Um, yeah. (Female, 34 years old)
The attraction of the intervention seemed to be the novelty of the concept. Many said that they wanted to try it simply because it was “something different” and that it was not until they were in the programme that they felt a bit more confident that they could actually quit with this attempt.

**So what did you sort of think of the idea of using a phone to help people quit smoking?**

Yeah well at first I was a little bit like oh how is this going to help? Somebody just sending me a text isn’t going to make me not want a cigarette, but you know as it went on and I had programmed the times for me getting messages around times that I thought I might really feel like a cigarette, so it was, you know, there was times that I kind of needed an extra boost and it came through (Female, 30 years old)

### 6.4.3.3 Importance of the role model selection

The intervention consisted of a series of video diary messages from a selection of role models. Participants self-selected the role model they would most like to hear from at the start of the study based on a photo and short biography (including their age, general situation, smoking history). They were able to return to the website and change or add role models during the study period.

Two participants did not pick a role model themselves and so were assigned a role model randomly by the software. The remainder chose a role model either on similarity to themselves where possible or because they felt that person would be interesting to hear from. The factors used to determine similarity included age/stage of life, culture, gender and smoking history (how long they had smoked for and how much they smoked prior to quitting).

*I picked someone similar to me and yeah it was a young Mum. She’d just had a baby. Or she was going. Hold on. Now I’ve got to remember. No she’d just had a baby I think and so yeah, it was the fact that she was a mother and I’m a mother and she was worried about her children and worried about her health, um, affecting being there for her children and yeah that, that is why I picked it, because she was similar to me* (Female, 34 years old)

One participant felt there were no role models whom she could relate to well.
Um, I thought choosing a profile of somebody online I didn’t really find anyone that matched me at all

OK yeah, I was going to ask you about that, that’s interesting
Yeah so I thought, as the videos went on, I just kind of felt more and more distant from the person that I had chosen and yeah so

Did you try changing to someone else or did you just feel that there was no-one that you could really relate to?
Yeah well I did go on-line and try to change to somebody else but then, one was man and one was a Mum with a baby and I was like no neither of those are really me
Yeah. OK
So, maybe if you did it again, now that you have those profiles built up, you could add to them and you know, make it more varied

So what kind of person would you like to listen to, to hear from do you think?
Um, maybe somebody more like myself. Like just working professional. Um, has a number of friends who smoke that you go out with and socialize with and so you smoke together. You know.
Yeah kind of 20’s to 30’s professional person
Mm, OK
Yeah. Who finds social times a bit more difficult because what are options now I’m a non-smoker? What am I going to do? Instead of going out with my friends for a cigarette am I going to be sitting at the bar by myself while everyone goes for a cigarette, you know, that kind of profile a little bit more than. Like I didn’t even smoke during the day, just cos my job, I couldn’t smoke during the day, so, um, I would smoke my first cigarette at 4.00 O’clock. Now that might be a bit different but I think there’s lots of people who are like that
For sure, yeah
Yeah. Who are at work all day. Don’t really even think about it during the day but go for a glass of wine after work and smoke a pack of cigarettes (Female, 30 years old)

Two participants commented that they did not choose someone similar to themselves and that perhaps it would have been better if they had chosen a role model they could relate to.

Um maybe I should have chosen someone that was going to be similar to me and you know quite hard because I’ve been smoking for um, I’m almost 40 now, I’ve been smoking since I was a teenager. Um, like the trouble with me is I looked at, they’re [role models] only young guys, so they’ve probably only been smoking a few years, um, and maybe the hold on them wasn’t as tough as it was for me for whatever reason. (Male, 37 years old)
It became obvious during the interviews that many of the participants did not realise they could return to the website to change role models whenever they wanted.

### 6.4.3.4 Provision of support

Participants reported the most appreciated aspect of the programme as the provision of support, and all felt that even more support could improve the programme further. It seemed that participants felt supported to quit just by participating in a research project, as they knew others were going through it at the same time, and study staff were monitoring them, despite the lack of direct phone or face-to-face contact.

*Yes I thought the programme was helpful. I thought kind of the ‘keep at it’ attitude and there was other people who are going through this as well and you know um, you know that just whole ‘you can do it’ attitude and we’re here to listen if you need or, you know, we’re here for support should you need it, was really good.* (Female, 30 years old)

However, the most commonly mentioned support was that provided by the role models. Watching someone else go through the same thing was considered useful, particularly in comparison to past attempts where many had felt very alone or isolated.

*How did seeing someone else go through that process of quitting make you feel about your own attempt?*

*It makes you feel, um, not alone. Not isolated. Cos you do feel isolated. You feel like you’re doing this all by yourself and um. You. It’s easier to give up on giving up if you’re by yourself. You know what I mean?* (Female, 34 years old)

*No it does help because you kind of, you’re listening to what they’re saying and you’re thinking, yeah OK, maybe it’s not that bad after all and um what they’re putting up with, they’re going through it as well, so, it does make it a bit more easy in a way.* (Female, 31 years old)
There also appeared to be some subtle pressure from the role models who were perceived as holding them to their quit attempt.

Some of the messages directly encouraged participants to seek out support from their own networks. However this did not come through as an important component for these participants, even though some did have good family support for their attempt.

*It didn’t matter what my friends and family said, um, it really had to be up to me. I mean I watch. I definitely watched every single person I love quit smoking before me and it did not encourage me to do it, in fact it dragged me down more because it made me feel like a loser because they were all quitting and I wasn’t. You know what I mean. So even though their support was there, it wasn’t what I needed. I needed to switch my thoughts into doing this* (Female, 34 years old)

Increasing the support further came through as a strong theme for improving the intervention in the future. The suggestions made were: being able to talk to the role model about their quit attempt; chat rooms; a *facebook* page; and face-to-face community support groups where they could swap tips and discuss quitting with fellow quitters.

**6.4.3.5 Engagement with the programme**

The study website did appear to encourage engagement with participants commenting on going to the website to complete forms but also to view clips that they had been previously sent. However, there were other interactive components of the programme – texting ‘crave’ or ‘relapse’ to the shortcode in order to receive further messages and support, and changing/adding in role models to their programme - that the majority of participants said they were unaware of and did not use.
6.4.3.6  Self-efficacy and confidence

This theme was particularly explored with those participants who did not quit or who relapsed in order to determine if the intervention had improved their self-efficacy. These participants did report that they had learnt a lot about what it takes to successfully quit and felt more confident in being able to quit again in the future. Many also reported continuing to watch the video messages even after they had given up on their own quit attempt.

**And when you found out, or when you realized that it wasn’t going to work for you, did you continue watching the messages?**

*Oh yes, yeah. I did the whole programme. Um, hoping that one day it would just click (laugh). Um, but it just didn’t, unfortunately. But yes I did, I went right through the programme.*

**Yep, and what influenced that decision?**

*Oh I didn’t want to give up. I mean I wanted to be a non-smoker, so I thought if anything, you know, this could be it, so I’ll just keep going and hopefully it will work (Female, 34 years old)*

*Yeah it [STUB IT] has been a big help and it’s still in my mind that I’m not finished trying to give up and I think probably if it weren’t for the program I wouldn’t care (laugh). Yeah*

**So do you feel like it’s sort of increased your confidence?**

*It did yeah and because of that too I did have a good crack at it and I know that I can do , so, and I didn’t think that before, I thought there’s no way in hell I can give up*

**Yep**

*I didn’t think, yeah, I just didn’t think I could (Female, 31 years old)*

6.4.3.7  Timeliness of mobile phone messages

Participants commented on some of the benefits of using mobile phones, such as always having the phone with them so messages could come at the right times to distract them from cravings or they could fill in spare time by reviewing messages on their phone. Also, they could have some control over the intervention by viewing the messages when they wanted.
I actually thought it was a really good idea because it gave them something to do with their hands at the same time. And because the messages came in every so often, most of the time I was sitting there thinking about a smoke, my phone went, so it put me off (Female, 31 years old)

And um and what did you think of the idea of you know using phones to help people quit smoking?
I thought it was brilliant

What do you think was good about it?
Oh it was just, because you know everybody has mobiles

Mm hm
So just to have it right there when you needed it, because even being asked how often do you want to be contacted. You know so, knowing that, you know, there’s a call coming through. “Oh here it is” (laugh). You know. I mean unlike other things you could sort of do the “oh I want it on this day at this time and bla, bla”, and it never happens

Mm hm
Whereas yeah the first couple of times it was like “oh, see what happens” and then after that it was sort of got to the stage where it was like “ok, you’ll be coming through, you’ll be on there soon” (laugh) (Female, 35 years old)

And so were there any other things about having it delivered over a mobile phone that you liked or didn’t like?
Oh I liked the consistent like follow-ups and messages and stuff, that was pretty good (Male, aged 18)

...Because you got the text message, you don’t have to read it at the same time. It’s there. You can come back to it again and unlike sort of someone ringing you, the text message just sits on your phone (56 year old male)

Participants were asked their opinions on receiving the messages via email instead of mobile phone. Only one participant said they would prefer email. The reasons for preferring mobile phones included always having them on them and not wanting or being able to watch the videos at work which was predominantly where they accessed email.
One of the other options we’ve been thinking of is potentially giving people the option of being sent their messages over the internet to their email.

I’d prefer a mobile phone

And why is that do you think?

Oh just mainly like I smoke when I’m bored and I’m not doing anything and you know if you’re just sitting there and just like twitter with your phone you can go through your messages and open up some videos and read the texts again and all that kind stuff. OK, might be easier cause your phone’s always on you. (Female, 17 years old)

6.4.3.8   Negative aspects of the intervention

Negative feedback on aspects of the intervention included one participant who remained wary of being charged for viewing messages despite assurances that the programme was free. Another participant found the messages to be a negative reminder of failing at his quit attempt

What did you think about the number of messages per day?

Um, that didn’t bother me um. At first I found them quite good but then after a while because I felt that I was failing at it, it sort of became like a I’m being reminded of how what can you say, how bad I was doing. It went from like a positive to a negative

Right OK

It was within myself I suppose. Yeah cos I’ve had problems with different addictions in the past and I’ve given them up. And they were far worse to me than, in my mind, than smoking itself

Yep

So when I come to give up smoking and I found I was having problems with it I was sort of running myself down a bit about it. It was like hey you can deal with this and that but, when you do this. So yeah so there was a lot of negative feelings towards myself in that respect

(Male, 37 years old)

One participant felt that the STUB IT intervention did not offer any new information to help them to quit.
Unfortunately everything that’s in the programme is great. It is a good programme and I’m really pleased that people are trying to help. Um, but it’s nothing new. Everything that we saw and that was talked about was just nothing new. We know it all. As smokers, that’s the worst part is that we’re not stupid. We want to believe that we’re OK and that we enjoy smoking, but the reality is, is we’re all very aware of what we’re doing to ourselves. We all hate it to pieces and want to be free of the slavery. Um, everything that was said was everything we knew

**How did you find hearing about things that you already knew?**

Um, frustrating that it doesn’t work, you know what I mean. It was very frustrating because I knew you were correct and I knew that um I have to do something about this but I also knew that it wasn’t working, it wasn’t affecting me, enough to stop

**OK**

So I found it very frustrating. Cos you feel stupid, you feel like you’re being stupid because you’re aware of everything and yet you’re still doing it. (Female, 34 years old)

There were some comments about technical difficulties including taking some time to work out how to view the video messages, and occasions where they did not receive messages on some days and then received too many on subsequent days. This latter issue had been known to have occurred on a small number of occasions due to network problems interfering with the scheduling of messages.

### 6.5 Discussion

This qualitative sub-study was conducted to elicit more in-depth information on participants’ experiences of the STUB IT intervention and to help assess whether the theoretical approaches underlying the development of the intervention were appropriate.

#### 6.5.1 Summary of findings

Ten participants agreed to participate in this sub-study. There was a range of participants according to sex, ethnicity, age and smoking status. The main themes identified are classified here according to the theoretical approaches in question that are summarised above in Section 6.1.1:
Observational learning to enhance self-efficacy using role modelling:

- The most commonly appreciated aspect of the programme was the feeling of support provided by watching someone like them go through the quitting process and by feeling that they were not quitting alone
- It appears to be important that participants could select a role model they could relate to, particularly with respect to age/stage of life, sex, and smoking history
- Those who did not successfully quit this time reported feeling more confident to quit again in the future having learnt about what would be required to be successful

Promoting effective behaviour change techniques for smoking cessation:

- Setting a quit date was the only technique specifically commented upon as being helpful
- Some commented that there was not enough new information to help them quit

Adolescent principles of involvement and engagement:

- Many of the interactive/responsive functions of the intervention were not well used due to participants being unaware of (or forgetting) their existence

Social marketing techniques to make intervention appealing:

- Many participants required external motivations to prompt quitting
- There was general ambivalence towards the likelihood of success with the intervention at the start, although they were attracted by the novelty

There were also some general comments about the use of mobile phones to deliver the intervention:

- The timeliness of the messages was appreciated and was seen as a benefit over the possibility of emailed messages. Messages generally came at the ‘right times’ to distract from cravings or could be viewed at appropriate times.
• Negative aspects included that the messages could act as a reminder of failing to quit and there were some minor technical issues.

6.5.2 How do these qualitative findings add to the quantitative findings from the RCT?

6.5.2.1 Support for theoretical basis of intervention

The qualitative sub-study findings appear to corroborate the quantitative feedback from the trial participants (Section 5.4.5.7). That is, that watching someone similar to them going through the quitting process assisted participants to feel supported in their quit attempt. This, in conjunction with their reported increased confidence in being able to quit again, supports the theoretical basis of observational learning to enhance self-efficacy for quitting. During the early pre-testing there was some unfavourable feedback about ‘negativity’ in video messages addressing withdrawal symptoms and the difficulties of quitting. However, this sub-study demonstrated that those going through a quit attempt may actually appreciate hearing from people who are struggling. This aligns with the idea of ‘coping role models’ as people who struggle to undertake the behaviour.(171) This kept some participants going through some difficult times.

Participant use of behaviour change techniques was not recorded in the RCT. It is not clear from the sub-study that participants were prompted to try effective behaviour change techniques by watching the role models (such as identifying cues and triggers to smoke, and planning coping strategies for these). The only technique specifically mentioned by sub-study participants was setting a quit date. Some commented that there was not enough new information to help them quit.

Trial data demonstrated that participants did not interact greatly with the intervention or other participants. This low use of interactive components was confirmed in the sub-study where
participants stated it was mainly due to forgetting about the existence of these features. Interestingly, most of the suggestions to improve the intervention were around increasing interactivity (e.g. talking to the role models, support groups with participants). So although they did not use it in this trial, participants did still like the idea of interaction with the programme.

6.5.2.2 Perceptions of the intervention

There was some feedback that participants felt supported to quit just by being in a research study and by the researchers despite the lack of any real contact. It is possible that this may have been the experience for control group participants, who also received brief mobile phone contact to initiate the study, and further contact to record outcome measures. This could potentially explain some of the high control group quit rate in the trial, and may support the possibility that a simple mobile phone intervention is as effective as a more complex mobile phone intervention. A further factor could be that the only effective behaviour change technique the sub-study participants commented upon was setting a quit date. This featured in both intervention and control groups, and so could have reduced the potential difference in quit rates between the two groups.

It appears that the behaviour change techniques and strategies could have been more obviously promoted in follow-up text messages and frequent reminders. This might have prompted greater use of the techniques, which could have improved quit rates. Similarly, if the interactive functions (e.g. relapse function and changing message frequency on the website) had been better promoted this may have prevented the negative feedback about unwanted messages ‘reminding’ participants to smoke. Better use of the relapse function may have prompted more quit attempts, as was the intention of this feature.
6.5.2.3 Recruitment into the trial

With respect to the appeal of the intervention and the difficulty recruiting participants to the trial, the qualitative sub-study did add some interesting information. Although participants were attracted by the novel approach using technology, they were not at all confident that it would be effective. The promotions and branding were not mentioned by participants. Indeed, half of the participants had a timely external motivating factor that prompted them to sign up. This may point to a need for ongoing and timely reminders of cessation services at these ‘suggestible moments’ in peoples’ lives.

6.5.3 Limitations of the qualitative sub-study

All intervention group participants that could be contacted were invited to participate in the sub-study, however only 9% of participants agreed and participated in an interview. It is possible that those who had a positive view of the intervention were more likely to volunteer to participate. Although, the fact that only three of the ten participants successfully quit with the STUB IT intervention makes this unlikely. The small number of participants may limit transferability (or generalisability) of these findings.(248) The participants did cover the age range, main ethnicity groups and smoking statuses (152) although there were only three interviewees who were in the target young adult age range.

The sub-study was conducted after the ‘STUB IT’ randomised controlled trial (duration of 21 months) had been completed. Therefore, for some participants, it could have been a significant time period since they participated in the intervention. This time lapse may have affected their recall of positive or negative aspects of the intervention.

The RCT was set up to enable participants to complete the research processes and the intervention with no phone or face-to-face contact with researchers. In contrast, this sub-study involved a phone interview. It is possible that participants may have felt the need to respond positively about the
intervention in order not to disappoint the interviewer (social desirability response bias). The interviewer did try to reduce this possible effect by reassuring participants that she did not know any of the information they had previously submitted and that the intention was only to improve the intervention for future users.

The interviewer had had some involvement in the development of the intervention, which may have biased her interpretation of responses. However, the interviewer was less involved in the conduct of the trial than the candidate, so it was thought that the potential for bias was less. Furthermore, some knowledge of the intervention was helpful when interviewing participants about what they thought of the intervention components. Also, Ms Dorey, as an experienced interviewer, was aware of the reciprocal influence of participants and interviewer on the process and on the subjective interpretation of the data. This is termed reflexivity in qualitative research, describing the on-going analysis of personal involvement to make the process open and transparent, and to ensure rigour in the research.(152, 248, 249)

6.5.4 Implications for improvements in future interventions

Many lessons have been learnt from these findings that could be used to improve similar interventions and future developments.

A video messaging mobile phone smoking cessation intervention that is theoretically-based appears to have been appreciated by the participants in this sub-study. Participants did appreciate the support provided by watching people similar to themselves go through the same lifestyle behaviour change. This may be the case particularly for those who have felt isolated during previous quit attempts. It was important that they could select a role model they related to and who was of a similar stage of life. Therefore, it is clear that a greater variety of role models would be necessary, particularly including older adults. Some may also appreciate greater opportunities to obtain support from the role
models, for example with text message contact. More interactivity could utilise the ‘competition’ with the role models that was raised by some participants. However, the RCT results suggested that less frequent video message mobile phone contact and setting of a quit date may have been as effective as the more complex intervention with role models and other behaviour change strategies.

Several of the behaviour change techniques and the interactive features of the intervention were not well used. More frequent text message prompts and reminders of these strategies and available intervention components may help participants to put these proven strategies into action. Stimulating increased use of the interactive features and ability to change their role models and frequency of messages could give participants more control over their intervention. This may help with some of the negative issues raised, such as unwanted messages ‘reminding’ people to smoke. Ensuring that the relapse function provides a clear path once a participant has lapsed may also be important here, and could facilitate further quit attempts.

6.5.5 Implications for research

Findings from this small qualitative study support the relevance of observational learning and role modelling in developing technology-based behaviour change interventions although this was not supported by the results of the trial. Participants’ comments on the use of role modelling will be used to inform the consideration of observational learning within future mobile health interventions. It may be that role modelling via mobile phone may be appropriate for other target groups wanting support to make healthy behaviour change. For example, adults wanting to control weight with diet and physical activity, or wanting to better self-manage chronic illnesses. Some may appreciate learning from others in similar circumstances about how to fit the necessary behaviour changes into daily life. The acceptability and feasibility of such an intervention could be the subject of future research.
There was feedback that some participants felt supported to quit just by being in a research study and being monitored by the researchers despite the minimal contact. This will need to be carefully considered for its effect in future similar trials.

Attempts to bring participants together to support each other have not been well taken up. Despite this, there were many suggestions on increasing support further in interactive ways, such as talking to the role model, chat rooms, a *facebook* page, and community support groups. Further investigation into possible methods for encouraging interactive support that would actually be taken up by different groups of research participants is required. There could be ethical issues with facilitating in-person meetings of research participants. Online social networking could also face issues of connecting people inappropriately. This may need to be ‘moderated’ or monitored by the researchers in order to ensure no offensive material or inaccurate cessation information is posted. Also social networking and other types of online interaction tend to fail if few people are contributing. Exactly how to stimulate this type of networking in a safe and supportive manner requires some work.

6.5.5.1 *Implications for recruitment into research studies*

Half of the sub-study participants required personal external motivation to prompt their participation in the trial. This could influence future recruitment sources to capitalise on moments of increased external motivation. This could include, for example, maternity care providers, antenatal clinics, primary care, secondary care outpatient clinics, Work & Income NZ (social security agency), community organisations and food banks. Participants did confirm that they were on the look-out for something ‘new’ to help them quit. Therefore, it is important to continue to capitalise on the ‘novelty’ factor of technologically-based interventions, while recognising that novelty alone is not enough and must be complemented by proven effectiveness or new practical information and strategies.
6.5.6 Conclusions

The qualitative sub-study findings align with those suggested by the RCT that the role model video diaries were able to convey support for the quitting attempt and make participants feel less isolated. The intervention did appear to improve self-efficacy for quitting again in the future for some of the relapsed participants in this sub-study. It also confirms that the more interactive components of the intervention were not well used due to a lack of awareness of their existence more than a perceived lack of usefulness.

The intervention may be improved with more choice of role models (particularly older role models), clearer instructions about the interactive components, and more control over the intervention particularly for those who have lapsed. Future research could investigate the intervention’s effectiveness with an older target age group, and new methods for greater and more interactive support from role models and other participants in the programme. The development of future healthy behaviour change interventions will draw heavily upon these findings.
7 Discussion

The aim of this thesis was to determine whether mobile phones could be effective in delivering smoking cessation support, particularly for young adults. This was achieved by conducting a systematic review of the literature on mobile phones in smoking cessation, developing a theory-based multimedia smoking cessation intervention using mobile phones, and testing the effectiveness of the intervention in a randomised controlled trial.

7.1 Findings of the literature review

The background literature review confirmed that young adult smoking rates are high in New Zealand, particularly in young Māori. Young adults often say they want to quit but it does not appear to be a priority. For them, smoking is linked to social and lifestyle factors that make it difficult to quit, on top of the physiological addiction to nicotine. It is important that new smoking cessation support interventions are developed that appeal to and are effective for young adults. In New Zealand, it is particularly important that any new cessation interventions are appropriate and effective for young Māori.

Mobile phones are ubiquitous and integrated into the daily lives of young adults in New Zealand and internationally. They provide a potential method of delivery for health behaviour change support programmes. The systematic review found evidence of short-term benefit of mobile phone smoking cessation interventions, but there is currently not sufficient evidence of long-term benefit of mobile phone-only smoking cessation interventions; although there is evidence of long-term benefit of a mobile phone and internet smoking cessation combined programme.(154) Further high quality studies are required particularly to determine the long-term effectiveness of mobile phone-only interventions.
Findings of the systematic review were based on only two different interventions (in four different studies). The first intervention was a text messaging (SMS) mobile phone intervention that has since been implemented as a free national programme in New Zealand.(34) A small pilot of this intervention in the UK was included and a much larger randomised controlled trial of this is now underway.(140) The second intervention was an internet and text message and IVRS calling intervention in Norway.(162, 163) There were no published trials of multimedia or video-based mobile phone smoking cessation interventions identified in the systematic review.

### 7.2 Findings of the intervention development process

The development process found that observational learning could be provided using role models via videos. In this way, the intervention could be guided by Social Cognitive Theory, and effective behaviour change techniques for smoking cessation. Engagement with the intervention was guided by adolescent development principles and techniques from social marketing. This included significant input from young adults into the development of the intervention itself. This input from young people was that the role models must be similar to them, ‘real’ and ‘credible’, and their messages must be believable. Other important issues were the quality of the videos, confidentiality, and respect for young people’s choices. The pilot study confirmed that a video messaging mobile phone intervention was feasible and acceptable to participants. The final intervention was developed based on all of these findings.

### 7.3 Findings of the randomised controlled trial

The study enrolled 226 participants. One hundred and ten were randomised to the tailored smoking cessation video and interactive messaging intervention (STUB IT intervention) and 116 were randomised to receive less frequent general health mobile phone video messages (control). Both groups set a quit date. At six months, 26% of the intervention and 28% of the control group (p=0.7) had quit (five or less cigarettes since quit date), using an intention to treat analysis. In a responders-
only analysis excluding those lost to follow-up, 39% and 36% had quit in the intervention and control groups respectively (p=0.2). Therefore, no significant difference was found between the two groups in the primary outcome.

The trial found recruitment of young adult participants to be more difficult than expected, and had to be stopped due to budget considerations despite the number enrolled being below the target sample size. Therefore, the trial was not well powered to detect a small difference between the groups as statistically significant. There was no obvious trend in the difference in the primary outcome to suggest that the STUB IT intervention was more effective than the control programme. It is possible that the infrequent mobile phone contact plus setting a quit date was as effective as the more intensive and tailored content of the intervention. The relatively high quit rates in both groups, in comparison with other studies, suggest this may the case. A ‘true’ control may have produced positive results, but such a group would have been unethical, given the existing evidence that brief mobile phone contact is effective in improving short-term quit rates.(154)

There was also no significant difference between the two groups in secondary outcomes of point prevalence and continuous abstinence, and change in confidence at different time-points. For example at 4 weeks, 36% of the intervention group and 32% of the control group reported continuous abstinence (p=0.6). Again, quit rates were high in both groups compared with usual quit rates without intervention.(10)

Participant feedback about the intervention was mostly positive. A high proportion of participants receiving the STUB IT intervention reported that watching someone like themselves go through quitting was helpful during their own quit attempt.
Adding these results into the meta-analysis of high quality studies of mobile phone interventions in smoking cessation made little difference to the overall findings. A short-term benefit of mobile phone cessation interventions was demonstrated. The long-term findings favoured the intervention groups but were still not statistically significant.

7.4 Findings of the qualitative sub-study
The qualitative study of a sample of participants who received the STUB IT intervention suggested that the theoretical basis of the intervention’s development was appropriate. Participants felt supported and less isolated in their quit attempts, and those who failed to quit had greater self-efficacy for future quit attempts. The intervention could potentially be improved with more choice of role models (particularly older role models), clearer instructions about the interactive components, and more control over the intervention particularly for those who lapsed.

7.5 How these findings add to the literature
These findings add to the literature in the areas of multimedia mobile phone health interventions, the use of role modelling to support social cognitive theory for behaviour change, recruiting young adults into smoking cessation studies, and using technology-based data collection methods.

7.5.1 Using multimedia mobile phone interventions for population health
The findings from the systematic review of at least short-term benefit were consistent with other reviews of the use of mobile phones to support healthy behaviour change. Recently, Fjeldsoe et al reviewed 14 studies using SMS/text messaging in health behaviour change interventions and concluded that they had positive short-term effects.(29) Krishna et al have reviewed 25 studies using
mobile phones in health care and self-management.(128) They concluded that enhancing standard care with mobile phones can improve health outcomes and care processes.

To date, there have been no published studies of the use of multimedia mobile phone interventions in health. Although these trial results were not positive, this is the first multimedia mobile phone intervention to be described in the literature. The trial demonstrates that it is feasible to deliver theory-based content in video messages sent directly to participants’ mobile phones. This was acceptable to the participants in the trial and there were almost no technical difficulties with the delivery of the intervention. It also demonstrates that it is feasible to conduct a rigorous randomised controlled trial on novel technology-based interventions. This adds to the small but growing body of knowledge for those using mobile phones in health. Other researchers and programme developers may be interested in using the richer and more in-depth content that can be delivered by video than that delivered by text message. Video messaging allows a personalised intervention that does not require participants to have smartphones, making it more universally available.

7.5.2  Using video role modelling to put social cognitive theory into action

This is one of the few trials reporting on the use of role modelling as the basis for a smoking cessation intervention. Role modelling has been recognised as important in influencing adolescents to initiate smoking by observing family, peers, and friends undertaking this behaviour.(181-184) To date, there has been little research on the observation of role models quitting smoking in order to enhance self-efficacy for smoking cessation behaviour. In the small number of interventions where role modelling has been included as part of a wider intervention, the effectiveness or acceptability of this has not examined separately,(186, 191) has not been published,(192) or the focus was on motivating to participate (76, 185) or on education only.(187, 188)
This trial has demonstrated that role models can be used to provide observational learning opportunities around quitting smoking although the added benefit over brief intervention has yet to be demonstrated. The majority of participants reported finding it helpful in their quit attempt to watch someone like them also going through the quitting process. A sample of participants reported that this helped them to feel supported to quit, less isolated, as if they were quitting with others, and increased their confidence in quitting next time.

7.5.3 Recruiting young adults to smoking cessation

This trial has added to the body of literature on the difficulty of recruiting young adults to smoking cessation intervention studies. Surveys in many countries have found high smoking prevalence rates in young adults and high proportions of young adults who smoke expressing the desire to quit.(5, 12, 68) However, smoking cessation studies (75, 76) and services (12, 52, 70, 74) have found it difficult to recruit young adults. This research project took the advice of previous studies’ authors into account in the design of the intervention.(15, 16, 60, 72, 74, 90-94) This was done by:

- Developing the intervention with the input of many young people (15)
- Attempting to ‘fit in’ to young adult lifestyles by proactively using a delivery method that was already integrated into their daily lives and with them at all times (15, 250)
- Being flexible and convenient, and not requiring attendance at a clinic or sessions with a counsellor, but allowing them to participate when and where they wanted (15, 71, 74)
- Delivering the intervention via young adults like themselves, who displayed their understanding of the issues involved in quitting smoking (15, 200)
- Recognising social factors involved in quitting and contexts that might trigger lapses, such as stress, drinking and boredom (14, 96, 98)

However, this novel and convenient cessation intervention alone was not sufficient to attract young adults to participate, and the trial did not recruit its target number of participants. Much of the current
literature on how to improve recruitment rates in young people has concentrated on school-based approaches and incentives, (241, 250) or university-based approaches, (86, 251) In the Cochrane review of cessation interventions for young people, only two studies used direct community-based approaches, and both experienced difficulty recruiting sufficient numbers of participants. (75, 76) Only one study has described the effectiveness of similar methods to this trial. In a web-based smokeless tobacco cessation intervention, Gordon et al found that targeted media releases and Google ads were effective but placing links on websites, paid advertising, and direct mailings were not. (207) Graham et al used the internet in a different way with active user sampling from internet search engines to invite individuals to be screened and enrolled in a cessation intervention. (252) They eventually enrolled 7% (n=764) of those who expressed initial interest (n=11,147).

This trial used a variety of methods that were specifically designed to target young adults, including contracting a youth-oriented media company, radio advertising, internet advertising, online magazines, social networking site advertising, cafes, tertiary institutions, and music magazines. None of these methods appeared to be particularly effective, although radio advertisements were the most common recruitment source for those registering interest in the study.

Perhaps the greatest challenge remains to assist young adults to make quitting a more urgent priority in their lives. Although most young people who smoke intend to give up at some stage, the majority will actually continue to smoke into their sixties and beyond. Quitting before the age of 35 years is likely to return the individual to the health risks of a non-smoker. (43) More investigation is needed into how to transmit this sense of urgency to quit to young people.

7.5.4 Using technology-based data collection methods for research with young people

Retention of young adults in research studies is another recognised issue. (15, 75, 85) This may be in part related to the participant burden of data collection. In the intervention development phase of this
research, difficulties were experienced in contacting young adults to speak to researchers over the phone. It was hypothesized that data collection via web-based forms may be more successful than by phone calls. However, it was noted that internet-based studies appear to suffer particularly from attrition of participants. (75, 138) Therefore, a system of text message instructions with a link to the web-based form, and daily text message reminders were established. Also two data collection questions were asked solely by mobile phone.

Data collection by mobile phone has recently become popular with interventions collecting real-time frequent assessments of mood, cravings, substance use, and physical activity. (118-122) These studies were small and required participants to report via mobile phone for short periods of time (e.g. daily for seven days), however they all reported high compliance with reporting requirements. The text message questions in this trial (at quit day and 12 weeks post-QD) had higher response rates (96% and 76% respectively) than the web-based forms at 4 weeks (49% completed online). As part of the informed consent process took place via text message, participants in this trial were obviously comfortable with this method of communication with researchers. It may be worth considering using this form of data collection more in similar studies with this target audience.

7.6 **Strengths of this research**

The strengths of this research include the use of theory, the involvement of young people in designing the intervention, the involvement of Māori at all levels, and the testing of the intervention using a randomised controlled trial design. Qualitative methods were also used to corroborate findings and explore reasons why the intervention may not have been effective.
7.6.1 The role of a theoretical basis and principals for intervention development

Reviews of smoking cessation interventions for young people have concluded that a theoretical basis is important. (13, 77) A review of technology-based behaviour change interventions also demonstrated the importance of a theoretical background in identifying theoretical constructs to be targeted, mechanisms underlying particular behaviour change techniques, or selecting participants most likely to benefit. (167) In this article Webb reviewed internet-based interventions for healthy behaviour change and found that more extensive use of theory tended to have larger effects on behaviour.

In developing a multimedia mobile phone cessation intervention it was found useful to have a theoretical basis and principles to refer to in order to ensure the intervention was consistent and evidence-based. This development used social cognitive theory and known effective behaviour change techniques for smoking cessation. Feedback from participants appears to support the use of social cognitive theory, in that participants felt supported and less isolated in this quit attempt and those who relapsed reported greater self-efficacy for quitting next time.

Participant feedback did not mention any of the specific behaviour change techniques (e.g. goal setting, identifying and planning for their cues and triggers) as being particularly helpful. Setting a quit day was mentioned by some, although this occurred in both intervention and control groups. It is possible that merely setting a quit date and receiving infrequent general health video messages (the control group programme) was sufficient to help some people to quit. This is suggested by the high control group quit rate in comparison with usual unassisted quit rates.

7.6.2 Involvement of young people in the intervention development

Youth development principles and social marketing techniques guided the involvement of many young people in the design phase of the intervention development to ensure that it would appeal to, and retain the interest of, young adults. Nearly 250 young adults were involved in the year-long
process from initial focus groups and online survey, submitting video content, pre-testing different styles of video, rating and commenting on role models, to a pilot study. All of this input was used in the development of the final intervention. Without this input it is likely that the intervention would have looked different, with a different style, and certainly with different role models. The intervention could continue to be improved further with the feedback from participants in the trial and the more in-depth feedback from the qualitative sub-study.

7.6.3 Participation of an indigenous population in intervention design and randomised controlled trial conduct

As outlined in the background literature review, Māori suffer disproportionately from the adverse health effects of tobacco smoking.(42) Young Māori have high smoking prevalence rates compared with other young adults.(5) Therefore it was important that the developed smoking cessation intervention would be appropriate and effective for young Māori adults.

To ensure responsiveness to Māori in research, Māori must be given the opportunity to participate at all levels from question design through to dissemination.(253) This research attempted to involve Māori in the development of the intervention and in the randomised controlled trial to test its effectiveness. The levels of involvement in this research were: governance, involvement of partner organisations, input into the development of the intervention from early stages, ensuring the intervention is culturally appropriate, prioritising recruitment methods, appropriate analyses, and feedback and dissemination.

Governance: The Clinical Trials Research Unit’s Māori Research Advisory Committee provided early input into the overall intervention and study design. A Māori co-investigator (Dale Bramley) was involved on the Trial Steering Committee and provided oversight with regards to Māori cultural integrity and protection of Māori participants and their data.
Partnering with Māori organisation: Mai Media Ltd, a media company that was at the time owned and led by Māori, came on board with the research as a recruitment partner. They were contracted to provide radio advertising and other promotional work to assist in recruiting particularly young Māori and Pacific adults. They also assisted with naming the intervention, scriptwriting, selecting the role models, and advising on the ‘look and feel’ of the videos with young Māori role models.

Input into the intervention development: At all stages of obtaining young adult input into the development of the intervention recruitment sources were selected in order to maximise the involvement of young Māori. This included the focus group school which had high proportions of Māori students, and using Mai FM’s website to advertise the online surveys and pilot study.

Designing a culturally appropriate intervention: Input from the Māori co-investigator, Mai Media Ltd and young adult Māori, were all instrumental in ensuring an appropriate intervention for Māori. Specifically, three of the six role models in the programme were Māori. When the first two were interviewed and were found to not have many traditional cultural aspects to their stories, the third role model was selected purposely to represent a more whanau (extended family) oriented lifestyle. These aspects were emphasised in the strategies the role model used to quit smoking and stay smoke-free.

Recruitment methods: Recruitment into the randomised trial attempted to prioritise sources that would particularly target young Māori. This included the radio station with a high proportion of young Māori listeners, websites and print magazines that claimed a Māori audience, and approaches to Māori cessation and smokefree services.

Data collection and analysis: Ethnicity was self-selected by participants in baseline data collection forms using Statistics New Zealand standard classifications. Participants were allowed to select more than one ethnicity and in this case the Statistics New Zealand prioritisation system was adopted in all analyses. That is, if Māori was one of the selected ethnicities it was prioritised over all other ethnicities. A Māori versus non-Māori analysis was undertaken on baseline characteristics and the main outcomes. The results of these analyses were interpreted in consultation with the Māori co-investigator.
Feedback and dissemination: The findings of the Māori versus non-Māori analysis have been presented to relevant Māori organisations and have been presented as a separate article submitted for publication.

This has been an inclusive approach that has attempted to involve Māori from the start of the project through to the end. It is hoped that this has ensured a more culturally appropriate intervention for young Māori. Although 24% of participants in the trial were Māori, the target sample size was not reached. The failure of recruitment (of Māori and non-Māori young adults) into this trial is discussed further below.

7.6.4 Appropriate use of research methods

This research used a mixture of quantitative and qualitative research methods. The authors of a Health Technology Assessment (HTA, UK) report on the use of qualitative research concluded that the choice (or combination) of methods should be made on the basis of what type of research would answer the question most effectively and efficiently.(152) Several authors have described the utility of qualitative methods in the exploratory stages of research, and for “developing or optimising interventions”.(152, 254) In this research qualitative methods were useful in the intervention development phase, such as the focus group discussions providing input from young adults into intervention development.

However, rigorous research evidence is required before an intervention can be seen to be effective and considered for implementation. Randomised controlled trials are considered to be the highest level of research evidence of effectiveness. This is because random allocation should produce two groups that are comparable in known and unknown risk factors that may affect outcomes. Therefore, any differences in outcomes between the two groups should be due to the intervention received by one group and not the other. The trial described in this thesis was conducted according to CONSORT
guidelines for high quality randomised controlled trials. This includes: complete allocation concealment, researchers blind to allocation in data collection, use of standard outcome measures, appropriate treatment of missing data, and an intention-to-treat analysis.

Qualitative research methods were then employed again in order to “interpret, qualify or illuminate the findings of quantitative research”.(254) Semi-structured interviews were used to assist in determining what aspects were useful and whether the theoretical basis of the intervention was worthwhile. Technology-based interventions like this are often quite complex interventions with many factors influencing their uptake, appeal and effectiveness. A review series in the British Medical Journal (BMJ) recommends that complex interventions require the use of both quantitative and qualitative evidence.(151) Qualitative research examining participants’ views on the various factors is likely to be important in improving future interventions and finding ways of being used so that they might be effective.

“(W)here qualitative research is conducted properly and data analysed thoroughly, this approach can provide valuable information on the implementation and impact of health technologies on both health professionals and patients.” (152)

7.7 Limitations of research

The main limitations of this research are around the recruitment and retention of participants in the randomised controlled trial (RCT).

7.7.1 Recruitment

The RCT recruited fewer than the target sample size. As discussed above in Section 7.5.3, problems with recruiting young adults to smoking cessation interventions are not new. Despite developing this intervention specifically for young adults and trying multiple recruitment methods, this trial was no
more successful at recruitment than many others. The ambivalence and lack of priority placed on cessation by young adults has been discussed, and there is little research on how to better motivate young adults to serious quit attempts. Other potential reasons for poor recruitment specific to this trial include: competition for participants from the national text messaging cessation service (txt2quit) with more extensive advertising and without the participant burden of ‘research’; prize draws being considered insufficient reimbursements for participation in a research study; and a perception of high costs associated with ‘new’ mobile phone functions.

In particular, this research attempted to integrate a health programme with new technology of video messaging that was not yet widely used. This may have been ‘ahead of the curve’ or too early in the upswing of the ‘S’-shaped curve of diffusion of technology (see Figure 2-1). The previous text-messaging mobile phone smoking cessation intervention (STOMP (34)) appeared to work well in coinciding with the rapid increase in use of text-messaging. The STOMP intervention was developed when text messaging was new, was tested when it was becoming very popular (so participants were happy to receive multiple text messages daily) and then was implemented once the technology was in widespread use. At the time of the initial discussions on this project Vodafone NZ Ltd were confident of a similar pattern occurring with video messaging and video calling, due to imminent changes in the network and reductions in costs. However the new MMS gateway (for multimedia messaging) was not introduced, costs were not reduced, and the ‘upswing’ did not appear during the study period. This may have affected the overall appeal and perceived usability of this novel intervention, and thereby affected recruitment into the trial.

The result of the poor recruitment was that the trial was under-powered to detect a difference in effect between intervention and control groups. Power represents the probability of avoiding a false-negative conclusion – that is, the probability of not detecting a statistically significant difference when a difference of a given magnitude in reality exists (known as type II error). With the actual
sample size this trial had less than 10% chance of detecting a significant difference on the given primary outcome at a two sided 0.05 significance level. In a review of negative trials, Moher and colleagues found that most did not have large enough sample sizes to detect a 25% or 50% relative difference.\(^{(256)}\)

Low recruitment may also have affected the generalisability of the findings of this research. If less technologically proficient individuals were wary of participating in this study as suggested above, then feedback on the use and satisfaction with the intervention may not be representative. Other factors potentially affecting the generalisability of the findings to the population, were that the participants had high nicotine addiction scores and a very high proportion smoked roll-your-own cigarettes in comparison with other studies.

### 7.7.2 Retention

Loss to follow-up was also high in the RCT and was differential between the two groups with a higher loss to follow-up in the intervention group (35/110, 32%) compared with the control group (26/116, 22%). The high loss of outcomes data may have been contributed to by an error in the system that saw some participants followed up later than expected. However, this does not explain the differential loss to follow-up between the intervention and control groups. It could be that more people in the intervention group relapsed and did not want to admit so. Alternatively it could be that more people in the intervention group had quit and did not want to be reminded about smoking by continuing to be associated with the study. It could also be that intervention group participants grew tired of the higher level of messaging from the study and no longer bothered to read them. The outcome of the higher loss to follow-up in the intervention group was that the direction of the effect actually changed in the intention-to-treat analysis, from favouring the intervention to favouring the control (although these were not statistically significant differences).
7.8 Implications for practice

There is no evidence to support the implementation of STUB IT into cessation practice at this time. Indeed, while mobile phone cessation interventions have been found to be effective in the short-term,(154) the addition of this trial’s findings to the meta-analysis of these studies did not make the long-term effect significant. A very large trial currently underway in the UK should contribute to a definitive result.

It appears that text messaging mobile phone interventions are being introduced into practice around the world. The txt2quit text messaging cessation programme in New Zealand’s Quitline service is based on previous research (34, 161) and is subject to a three-year evaluation. Internationally, text messaging programmes are being introduced as adjuncts to current services. For example, the UK National Health Service stop smoking service’s ‘Together programme’ includes text message alerts along with self-help materials, emails and phone calls (see http://smokefree.nhs.uk/what-suits-me/support-at-home/). They also have a free NHS quit smoking application for Apple iPhones (see http://smokefree.nhs.uk/quit-tools/quit-app/). While others are being introduced by commercial organisations such as GlaxoSmithKline’s Clicktoquit 2.0 text messages to support those using their cessation treatments (see http://niquitin.co.uk/help-stopping-smoking/text-messages).

While not being able to prove that this multimedia intervention is effective, it has been demonstrated that role modelling of cessation is feasible and that this can be delivered via mobile phones. Quit rates in this trial were high in both intervention and control groups. It is possible that the control programme of setting a quit date and receiving infrequent video messages on general health topics was sufficient to help some people to quit. It is likely that the use of multimedia mobile phone functions may become more common in the future. If this is the case, there may be future opportunities for testing a multimedia mobile phone smoking cessation intervention.
7.8.1 Issues for multimedia mobile phone health programmes

This section outlines some extra considerations regarding the use of multimedia mobile phone interventions for health services in general. These include the stand-alone nature of the interventions, mobile phone network guidelines, the complex nature of the interventions, and data collection on the use of (or adherence to) the interventions.

While it is important to research such interventions alone to determine their effectiveness, in their later implementation it is likely that they may be considered as adjuncts to other services. For example, the txt2quit text messaging smoking cessation intervention has been implemented within Quitline services so that it can be used alone or with other Quitline services such as phone counseling, subsidised nicotine replacement therapy or online support. Mobile phone interventions may be even more effective in conjunction with other effective therapies. Related to this, the amount of information provided by mobile phone-based interventions is limited by the size of text messages and the length of video messages. While this is not necessarily an issue, some participants may want to access more information as can be provided by a website or from a helpline.

It is important to be aware that there are mobile network industry guidelines protecting against unsolicited messages to mobile phones. This means that participants must sign up to receive messages and must be regularly advised how to stop the messages. In this trial participants were able to text ‘stop’ to the shortcode and the messages would be automatically stopped within 24 hours. From participant feedback there is a small group of people who, once successfully quit, do not want to be reminded about smoking at all and may find any ongoing messages from the programme distressing. Therefore it is important that these requests to opt out are dealt with in a timely manner.

As yet, there has been very little research reporting which components or aspects of such mobile phone behaviour change interventions are most effective. Interventions are often developed as a
whole package of complex components and are tested as such. This research has attempted to add to
the currently available knowledge by publishing the development process, (215) and will attempt to
publish the participant feedback from the trial and the qualitative sub-study. Unfortunately, this trial
did not collect data on how many of the videos were actually viewed by participants. This may be
considered the ‘dose’ of the intervention that was actually taken by the participants, or their
‘adherence’ to the intervention over the study period. This may be useful information in the future to
determine exactly what the effective components of interventions are. It is important that intervention
developers add to the understanding about what has been tested already so that others can build on
this to develop effective interventions in the future.

7.9 Implications for future research
Although the trial was unable to prove that the intervention was effective, feedback from participants
did appear to support the theory behind the intervention. Participants felt supported in their quit
attempt, and said that watching others like them attempt to stop smoking helped them in their quit
attempts. Further research on this intervention could include targeting other specific audiences with
role models appropriate to those audiences. In particular, an older age group who may be more
committed to quit, have tried multiple times and are looking for something new to help them. As this
type of mobile phone function becomes more commonplace in the future an older age group may be
more open to trying such an intervention.

Some of the suggestions for improving the intervention would also require further investigation.
Some participants suggested more interaction with other participants via setting up face-to-face
groups or online social networking. Both of these methods have potential pitfalls. Exactly how to
stimulate this type of networking in a safe and supportive manner, and as a part of a research project,
requires further investigation and testing.
How to recruit young adults not just into cessation studies but also to use any sort of cessation support requires further research. In the example of this trial there are some suggestions on how recruitment could possibly have been improved. The input of young adults into the intervention development phase was invaluable however the input ceased at this stage. It has been suggested that a more formal youth advisory group, established at the start of the project for a more involved and long-term relationship with the research, could have been useful. This group could have continued to advise on study design, recruitment processes and retention of participants. This would align more with a youth participation framework.(257, 258) This would also be consistent with more effective relationships with young Māori in research, allowing more involvement with the whole process from the start and building their capacity to contribute and develop skills.(253)

Other suggestions for the recruitment of young adults that have arisen out of this research are the use of social networking and motivating events or times. The serious use of social networking to recruit young adults is unlikely to be able to be done by researchers. This would need to be done by young people themselves and using their current networks and networking sites. This aligns with the importance of friends and family as a source of recruitment information for Māori participants. A finding of the qualitative sub-study was that many participants had current external motivators to participate. Further work could be done on how to identify young people at such times of financial difficulty or illness and capitalise on these moments as motivation to quit.

Research with young adults should consider data collection via text message where possible. That is, where questions are able to be asked in less than 160 characters and are easily answerable by yes/no (“Have you smoked in the past 7 days?”) or numbers (“How many cigarettes have you smoked in the past 7 days?”). This would reduce the participant burden, possibly assisting with the retention of participants, and may reduce missing data.
The findings of this research can be used to guide the development of new interventions for delivery by mobile phone. In particular, the extensive input and feedback from young adults could help design future mobile phone-based health interventions. This research could be of interest to those developing interventions in other areas of healthy behaviour change support, such as weight management, increasing physical activity, healthy eating, mood management, stress management, controlling problem drinking behaviour and other addictions. These areas could align with a social cognitive theory based approach using role modelling to enhance self-efficacy for the necessary behaviour change. They also may align with the direct, proactive, time-sensitive and tailored approach possible with mobile phones.

7.10 Conclusions
There is a need for smoking cessation interventions that can both motivate and support young adults to quit smoking, in order to prevent lifelong addiction to nicotine and adverse health effects of tobacco smoking. There is also a need for any new smoking cessation interventions in New Zealand to be appropriate and effective for Māori. Mobile phones are a part of everyday life and have potential as a delivery method for health interventions. A systematic review demonstrated short-term benefits of using mobile phones for smoking cessation interventions. A novel multimedia mobile phone cessation intervention (STUB IT) was developed using social cognitive theory, effective behaviour change techniques for smoking cessation, and with the input of over 250 young adults in the development process.

A randomised controlled trial of STUB IT in young adults was unable to demonstrate a statistically significant effect in comparison with infrequent general health video messages. The main limitation of the trial was the inability to recruit participants, which could indicate that the intervention was not considered appropriate by the target audience at the time. Indeed, the use of multimedia mobile phone technology has been slow to be adopted in New Zealand, possibly due to cost. If the use of such
functions does undergo an ‘upswing’ similar to that which occurred with text messaging, this type of intervention may become more appealing.

There does also appear to be a wider issue of lack of urgency or priority around quitting for young adults who smoke. This has been demonstrated in many other studies and surveys. Despite following recommendations from those previous authors regarding the intervention design, this was not sufficient to prompt participation in the trial. Clearly, further research is still required on methods to prompt quit attempts in young adults and incentives for young adults to participate in research studies.

Poor recruitment resulted in a lack of statistical power to be able to demonstrate an effect. Both intervention and control groups reported high continuous abstinence rates at four weeks and six months. Therefore, it may be that the minimally intensive general health multimedia mobile phone control programme, plus setting a quit date, was as effective as the theoretically-based intensive interactive programme. However, participant feedback supported the theoretical basis of the intervention, in that watching someone like them go through a quitting attempt was seen as helpful.

This was the first video messaging mobile phone population health intervention to be conducted. As the use of multimedia mobile phone functions becomes more widespread in the future, this intervention may be worth further investigation with a wider audience. This research will provide useful information for others developing technology-based interventions for smoking cessation and other healthy behaviour change support.
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# List of Outputs Arising from this Research

## Publications

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<tr>
<th>Topic/title</th>
<th>Journal</th>
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<tr>
<td>Whittaker R, Dorey E, Bramley D, Bullen C, Denny S, Elley CR, Maddison R, McRobbie H, Parag V, Rodgers A, Salmon P. STUB IT: randomised controlled trial of a theory-based video messaging mobile phone smoking cessation intervention</td>
<td>JMIR</td>
<td>Accepted for publication</td>
</tr>
<tr>
<td>Opinion paper on the recruitment of young adult smokers to quitting programmes</td>
<td>HCIRIO</td>
<td>2010</td>
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<tr>
<td>Whittaker R, Bramley D, Bullen C, Dorey E, Parag V. Māori participation in intervention development and trial design: the STUB IT video messaging smoking cessation trial.</td>
<td>Tobacco journal</td>
<td>Draft</td>
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<td>Qualitative sub-study paper</td>
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### Presentations

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<tr>
<td>Development of video content for a mobile phone smoking cessation intervention. <em>Presentation: R Whittaker</em></td>
<td>The 2007 Oceania Tobacco Control Conference, Auckland</td>
<td>2007, 4-7 Sept</td>
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<tr>
<td>Mobile phone-based smoking cessation programmes for young people (STOMP &amp; STUB IT). <em>Presentation: R Whittaker</em></td>
<td>Centre for Youth Health, Manukau, Auckland</td>
<td>2007, 16 Aug</td>
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<tr>
<td>The use of mobile phones in delivering interventions to young people. <em>Presentation: R Whittaker</em></td>
<td>Lets Get Connected’ Workshop for adolescent health &amp; development workers on use of technology, Auckland</td>
<td>2007, 22 May</td>
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<tr>
<td>Mobile phone smoking cessation research at CTRU. <em>Presentation: R Whittaker</em></td>
<td>Smokefree North Hui, Auckland</td>
<td>2007, 11 April</td>
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<tr>
<td>CTRU Tobacco research programme and STUB IT. <em>Presentation: R Whittaker</em></td>
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<td>Recruitment for the STUB IT study: using video mobile phones to help young people to quite smoking. <em>Presentation: R Whittaker</em></td>
<td>Auckland Regional Smoking Cessation Network, Greenlane Clinical Centre, Auckland.</td>
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<td>STUB IT: multimedia mobile messaging for smoking cessation. <em>R. Whittaker</em></td>
<td>PhD in progress seminar, School of Population Health, University of Auckland</td>
<td>2009, 14 August</td>
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<tr>
<td>2. Using communications technology for data collection.</td>
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<td><strong>Poster Whittaker R, Parag V</strong></td>
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<tr>
<td>STUB IT: An RCT of a multimedia mobile phone smoking cessation intervention. <strong>Presentation: R Whittaker</strong></td>
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<td>Person centred healthcare: Using mobile phones to deliver person-centred population health programmes. <strong>Presentation: R Whittaker</strong></td>
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<td>Case studies in mobile health. <strong>Invited Presentation: R Whittaker</strong></td>
<td>Pre-conference workshop, HINZ 2009 Conference</td>
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<td>Working collaboratively: example from a mobile phone depression prevention programme. <strong>National Keynote Speaker: R Whittaker</strong></td>
<td>m-health NZ Conference</td>
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<td>Qualitative evaluation of a theoretically based mobile phone smoking cessation intervention, <strong>Presentation: E Dorey, R Whittaker</strong></td>
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Appendix 1: Chapter 4: Focus Group Participant Information Sheet

To: Students

I am a researcher employed at the Clinical Trials Research Unit, University of Auckland. We are inviting all students in Years 11 and 12 at your school, who are aged 16 years and over, to participate in research focus group discussions. Participation in this research is entirely voluntary and you do not have to take part.

This research aims to help us design a programme that will help young people deal with the stressors of everyday life. This will involve a group discussion (with about 8 others from your school who are the same sex as you) about some of the ideas we have for this programme. We will ask your opinions about the ideas we have. The things you tell us will help us to design a programme that will appeal to young people.

This research is being funded by the Oakley Mental Health Foundation, and we will be providing a summary report of the focus group research to this organisation.

If you want to join in a focus group discussion, we will arrange a day that suits you to meet after school hours. The discussion will take about 1.5 hours, and will be held on school grounds.

Your school principal has given us permission to approach students and to use school grounds for this research. Your choice to participate or not, will not affect your grades or your relationship with the school in any way.

If you decide to join in, you will be free to change your mind and withdraw from the project at any time without giving reasons. However, due to the nature of focus groups, you will not be able to withdraw information you provide in the discussion after it has taken place.

We intend to audio-tape the discussions to help us take notes and learn from your discussion. The tapes can be switched off at any time at your request. The audiotapes will be erased after transcribing (into written form) has been completed. The focus group transcriptions and discussion notes and will be stored securely on University premises in an anonymous electronic format for a period of 6 years for use by the research team. No identifying information will be stored with focus group data. Any identifying information in the focus group discussion or any contact details you have...
provided will be destroyed at the end of the project (e.g., by deleting the electronic documents).

Due to the nature of focus groups confidentiality cannot be guaranteed on behalf of the group, but your anonymity will be respected in any reporting or write up.

The staff helping with the focus groups and transcribing the discussions have signed a confidentiality agreement.

If you decide you would like help dealing with stress during the course of the focus group discussions, the school guidance counsellor, …., will be available to help you.

All personal information will remain strictly confidential and no material that could personally identify you will be used in any report on this study.

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<th>Researchers name and contacts</th>
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<td>Dr Robyn Whittaker&lt;br&gt;Public Health Physician&lt;br&gt;<a href="mailto:r.whittaker@ctru.auckland.ac.nz">r.whittaker@ctru.auckland.ac.nz</a>&lt;br&gt;09.3737599 x84766</td>
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<td>Puti Wilson&lt;br&gt;Māori Researcher&lt;br&gt;<a href="mailto:p.wilson@ctru.auckland.ac.nz">p.wilson@ctru.auckland.ac.nz</a>&lt;br&gt;09.3737999</td>
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For ethical concerns contact: The Chair, The University of Auckland Human Participants Ethics Committee, Office of the Vice Chancellor, Secretariat, Room 005, Alfred Nathan House, 24 Princes Street, Auckland. Tel: 373-7599 extn. 87830.

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 16 AUGUST 2006 TO AUGUST 2009 FOR THREE YEARS REFERENCE NUMBER 2006/306
Appendix 2: Chapter 4: Focus group discussion guidelines

Format
Arrival, refreshments, name tags
Introductions, ground rules
Warm up
Work through topics as below
Conclusion
Finish, thanks, reminders of rules, koha

Topics:
1. Use of mobile phones
   - How many of you use mobile phones?
   - What do you use your mobile phones for? What sorts of things do you like to do with your mobile phone?

   Prompts: Listen to music, play games, surf the net, download ringtones, video calling, watch videos/TV, look at cartoons, text, call

   - What other sorts of things would you like to use your mobile phone for if you had the functions available?

   Prompt: Listen to music, play games, surf the net, download ringtones, video calling, watch videos/TV, look at cartoons

   Prompt: What would you like about video calling, etc.? Or not like about it?

   - Do you switch your mobile phones off? When?

   - What new stuff would you most like to be able to get on your mobile phone?

   - Do you own/use an IPOD or similar MP3 player as well?

2. Relaxation and distraction

   - What sorts of things do you like to do to relax?

   - What sorts of things would you most like to receive over your mobile phone to help you relax?


   Prompts: What sorts of videos, instalment-type stories, games, cartoons?

3. Life Problems/Social Support

   - What do you do when you’re dealing with a big problem? How do you deal with things?
Prompt: **Who** or **what** is most likely to help you with this? Friends, family/whanau, someone don’t know well, expert, anonymous person (e.g., youthline or similar) school counsellor/teacher?

Prompt: What does he/she/they do? How do they help?

Prompt: If not a person, what helps?

Prompt: How does this help?

- What do you do when you feel you need/want **social support**?

Prompt: Who do you go to? (who is most likely to provide support?)

Prompt: How do they support you? What do they do to support you?

- Could/are mobile phones useful in getting social support? How?

Prompts: Calls, text, video, about the problem or about something unrelated just to know they are there

- Do you think mobile phones are a good way of getting support from the other sources mentioned?

4. **Problem solving**

- What do you think would most help you to deal with an important issue/problem you were having:
  - at school?
  - with friends?
  - with family?

  Prompts:
  - Having someone else to talk to about it? Who?
  - Talking to someone confidentially/anonymously? How would you like to do this? E.g., via text messaging, calling?
  - Watching a video of someone else going through a similar problem and how they deal with it?
  - Reading about others with similar problems (like in a cartoon) and seeing how they deal with it?

- Who would you most like to watch working through similar problems to see how they cope?

  Prompts:
  - People like you (same age/circumstances)?
5. Our programme

“A lot of young people have problems with feeling really down or feeling really worthless or hopeless at times. Researchers are thinking about developing a programme for people your age to help them to deal with problems they might face to try to prevent things getting really bad in this way for them. The programme they want to develop would be delivered via your mobile phone.”

- Out of some of the things we have already talked about, what aspects of mobile phones do you think would be useful in such a programme? (E.g., texting, video messaging etc.)
- Some of the things that could be a part of the programme are: …

- What do you think of each of these?
  - video clips of other young people facing difficult situations, how different people handled them and what were the consequences
  - cartoons of people trying to solve their problems
  - games to distract you from your problems
  - games that show you different ways of handling certain situations and what might result
  - receiving positive reinforcement messages, e.g.
  - receiving text messages to motivate and remind you of things you can do
  - receiving text messages with information about specific topics that you request
  - links to other sources of help when you get stuck
  - things to relax you

- These are some examples of ‘styles’ of graphics that could be used in the programme.

- Which ones do you like?

- Why do you like those ones?

- It is sometimes useful to practice some particular techniques, such as thinking positive thoughts about yourself. How do you think we could get people to practice these through mobile phones?

- What else would be good/would you like to see in a programme like this?
Appendix 3: Chapter 4: Online survey questionnaire

Mobile Phone Usage Survey

If you live in New Zealand, are over 16 years old and use a mobile phone, complete this 5min survey & go into the draw to WIN a cool 2GB iPod nano!

Your participation is entirely voluntary (you chose) and you do not have to take part.

We stress that taking part in the survey is not obligatory. Should you choose to complete the survey, we ask that you read the information sheet and then tick the box at the bottom of the page which indicates your agreement to complete the survey.

The National Institute of Alcohol and Drug Research (NIARDR) is undertaking a study to obtain valuable information about the type of content and format that appeals to young people, to assist in the design of nationwide mobile phone health programmes for young New Zealanders. This study is being funded by the Digital Strategy Unit of the Ministry of Economic Development.

The National Health and Medical Research Council (NHMRC) also endorses this research as very important and the results are expected to influence future public policy.

We are hoping that this research will be useful for those interested in the design and implementation of future mobile phone health programmes, and will be developed after 15 years according to standard research practice. We expect the online survey to take 5 minutes of your time.

The results of this survey will be reported in a journal which will be distributed to the health profession and researchers.

All personal information will be confidential and participants' responses will be anonymous as data collected from this survey is done so in a secure online survey tool.

If you have any questions or would like to contact the study manager prior to completing the survey, email them at office@niardr.co.nz.

Agree to complete the short online survey now?

Yes 100%
Mobile Phone Usage Survey

2) What is your mobile number? (required to contact the iPod nano winner)

3) How old are you?

4) What is your ethnicity?

- New Zealand European

If you selected other, please specify:

5) Can you receive video messages on your phone?

Yes

This online survey is powered by WebSurveyor.
Mobile Phone Usage Survey

9) How many times per day do you make video calls?
   [ ] Once
   [ ] Twice
   [ ] Three
   [ ] Four
   [ ] Five
   [x] Six

10) Do you play games on your phone?
   [ ] No
   [ ] Yes

   Previous Page  | Next Page
Mobile Phone Usage Survey

12) What sort of things do you like to do on your mobile phone? you can select more than one

☐ Call
☐ Text
☐ Listen to music
☐ Play games
☐ Surf the net
☐ Download stuff
☐ Video calling
☐ Watch videos
☐ Look at cartoons
☐ Text page
☐ Enter competitions
☐ None of these
☐ Other (please specify)

If you selected other, please specify:

13) Do you ever switch your mobile phone off?

☐ Yes
☐ No

The online survey is powered by WebSurveyor.
Mobile Phone Usage Survey

14) Can you specify when you turn your phone off? (eg in a lecture or from 10pm-7am)

15) When you get sent something good like a joke or a picture, do you send it on to your mates?

Yes

No
210) Do you own an iPad or other MP3 player?
- Yes
- No

211) What would you most like to receive over your mobile phone to help you to relax? you can select more than one:
- Music
- Videos
- TV shows
- Games
- Cartoons
- Jokes
- Competitions
- Nothing
- Other (please specify):

212) If you were to sign up to receive video messages over your phone to help you be healthier (e.g. stop smoking, exercise more), how many such messages would you want to get each day?
- Less than 1

213) If you were part of such a programme, how would you like to interact with others going through the same programme with you? you can select more than one:
- Writing a personal internet blog
- Reading other people's blogs
- Contributing to a message board
- Reading messages on a message board
- Being introduced to a ‘buddy’ participant going through the same programme
- Involving contact with other participants

214) We are currently doing research looking at various ways to motivate young people to quit smoking. If you recently stopped smoking, and live in Auckland would you be interested in contributing your QUIT story to our study? (If yes, we will contact you by mobile to set up a time)?
- Yes

215) To conclude the survey on a lighter note, we need your help in choosing a catchy name for our Quit Smoking with 3G Mobile Phones study. Do you like the name ‘Takahia’?
- Yes
- No
Appendix 4: Chapter 4: Pre-testing study questions

PART A:

1. Agree to complete & submit the online survey now?
   - Yes (takes them forward to the demographic questions)
   - No (returns them back to the MaiFM website http://www.maifm.co.nz)

2. If you agree to complete this survey, you will be shown 5 short video clips which you will be asked to rate. Each of the clips is under 600 KB, however, we highly recommend a broadband connection. Do you still want to continue?
   - Yes (continues)
   - No (takes them back to MaiFM website http://www.maifm.co.nz)

3. What is your mobile number? (required to contact the iPod shuffle winner)
   (Free textbox)

4. How old are you?

5. Are you:
   - Male
   - Female

6. Which ethnic group do you belong to:
   - NZ Māori
   - NZ European/ Pakeha
   - Pacific Islander
   - Asian
   - Indian
   - Other, please specify….. (Free textbox)

7. Are you a daily smoker?
   - No
   - Yes

   ➔ The ‘next page’ button at the bottom of this webpage will lead the participant to the next page with the link which opens up a popup window with the video clip.
   ➔ The participant will have to click the ‘next page’ button to continue on with the survey and answer the following standard questions:

PART B:

7) Please give the video clip you just watched a rating out of 10 (1=really hated it, 10= really enjoyed it)
   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
8) Please write a few words explaining why you rated this video clip this way? (E.g. because it was/ was not funny, because I liked/ did not like the person/people in the video clip) (Free textbox)

9) How did you find the length of the video clip?
- Too short
- Okay
- Too long

10) Could you understand this video clip?
- Yes
- No

11) Please explain why you could not understand this video clip? (E.g. I couldn’t understand the words they used or the people in the video clip talked too fast etc.)
[Free textbox]

12) Were you offended by this video clip?
- Yes
- No

13) Please explain why you were offended by this video clip?
[Free textbox]

14) Could you relate to the person/people in this video clip?
- Yes
- No

15) Please explain why you could not relate to the person/people in the video clip?
[Free textbox]

→ Conditional breaks are in place here and the participant is lead to the open ended questions when necessary

[The questions for each video clip are exactly the same as those above in PART B.]

[After the last video clip questions are answered, the link at the bottom of the webpage should lead to a general questions section]

PART C:

43) Please rank the video clips you just watched in the order of which one you liked the most. (1= liked the most, 5=liked the least)

1) ANIMATIONS
2) MIXES
3) CASUAL INTERVIEWS
4) STUDIO INTERVIEWS
44) In general, what style of video clip do you prefer watching?
- ANIMATIONS (like the SMOKING NINJA)
- MIXES (like the GREEN DAY MIX)
- CASUAL INTERVIEWS (like the ones on the PARK BENCH and NEAR A TREE)
- STUDIO INTERVIEWS (like the one about WHAT IS NOT HOT)
- OTHER (Please specify)
  (Free textbox for the other)

45) Is there anyone else that you would find more appealing to watch in our video clips? (e.g. someone more like me, someone older/ someone younger, someone famous etc) [Free textbox]

46) If there was a free programme that sent video clip messages to your mobile phone (like the ones you just saw about stopping smoking or about something else, like dealing with mood, about decreasing the amount of alcohol or drug use) would you sign up?
- No
- Maybe
- Yes

47) Hey! Do you think you can do better video clips than ours?
- Yes, please contact me!!
- No, don’t contact me.

48) Do you have any suggestions that you think might help us improve the video clips? Please give us your ideas here in the box below:
[Free textbox]

49) Would you like us to send you the results of this survey?
- No
- Yes

*Page break here

50) If yes, please enter your email address here:
[Free textbox]

Hey, thanks for your help today, just click the "Submit Survey" button & you will be in the draw to win the latest Apple iPod shuffle 1G 2nd Generation! We will be in touch by calling your mobile if you are a lucky iPod shuffle winner!

Participant is automatically redirected back to http://www.maifm.co.nz
Within 5 seconds upon submitting the survey.
Appendix 5: Chapter 4: Questions to inform the role model video clips

1. When did you start smoking?
   14-15 years old

2. Why did you start smoking?
   socialising, started drinking alcohol, friends smoked – just seemed to be what you did.

3. How much do/did you smoke a day?
   now smokes 1-2 cigarettes a day.
   when she started she was only smoking socially – weekends, evenings working in hospo she got up to nearly a pack a day

4. What do you like about smoking?
   having something to do with your hands, smoking gets you out of awkward conversations, the emotional attachment to it, uses it to distress

5. why do/did you smoke?
   habit, stress and thinks/thought it was cool

6. What do you hate about smoking?
   the guilt of knowing that it is doing horrible things to your body, giving tobacco companies money

7. Who else in your family smokes (what did you think about this when you were growing up)
   older brother (8 years her senior) when she was young she thought he was the coolest person in the world

8. Do your friends smoke?
   some do

9. Have you tried to quit before?
   yes

10. how many times?
    maybe twice seriously

11. how long was the longest time?
    a few months

12. why do/did you want to quit?
    unless you want to smoke forever you’re gonna have to quit sometime. It’s better to quit earlier in life than later
    wants to quit this time

13. what do you think is the hardest thing about quitting
breaking the psychological connections ie. stress, booze, coffee, friends that smoke. Separating things so you can enjoy them without smoking.

14. what did/could you do to get over this particular thing/s totally change your lifestyle for a while ie. sit inside when studying, don’t have coffee with smoker friends, don’t go out to bars/clubs if you know you’ll have a smoke

15. which are the hardest cigarettes in the day to give up after dinner cigarette, afternoon/evening, anytime you’re drinking alcohol

16. what did/could you do to plan for this time of day be aware, choose not to have one, do something else instead

17. what has worked/s for you in quitting advice from dad – if you want to quit, smoke while you’re not doing anything else. Smoke the whole cigarette from beginning to end and try and detach any emotional feeling you have

18. have you used any gum/patches/anything else to help stop smoking? no

19. what do you think of them? they’d help with the physical addiction of nicotine but might not help with the emotional attachment

20. have you ever had any withdrawal symptoms (grumpiness, irritability, poor concentration, anxiety, problems sleeping) yes – irritable, poor concentration, grumpy, on edge

21. how did you get over these? distraction – herbal tea, read a book, know that the cravings will pass

22. have you ever had cravings for cigarettes – how long did they last yes, ages

23. what are some of the things you did/could do to beat the cravings exercise helps, go for a run, swim etc – you don’t feel like smoking during and after exercise

24. do/did you have any major concerns about quitting (failure, weight increase) used to worry about weight gain now the major worry is that she will still want to smoke

25. if you have quit and then started smoking again – why did this happen/what were the circumstances stress

26. what did/could you do in stressful times when you want to smoke yoga
27. what did/could you do when out with your mates and want to smoke
get into an interesting conversation with a non-smoker, don’t go outside with
smokers, stay inside, don’t go out drinking for a while

28. What were your cues to smoke that were hard to beat? (drinking, coffee, lunch
   break)
sitting down with a friend who’s smoking, drinking alcohol

29. what do you think you could do to prepare for quitting (planning ahead,
   keeping busy)
work out/pin point your weakest times, have a firm plan of attack, think of
alternatives, always have a plan to so something else instead of smoking

30. how did you change your habits when you quit
   exercised more, started valuing health more, enjoyed the idea of being good to her
   body

31. how did/would you celebrate quitting
   something lowkey, because when she thinks of big celebrations she thinks of
   smoking

32. how did/could friends help
   smoker friends shouldn’t offer her cigarettes or smoke around her
generally be supportive, some smokers find it hard to be supportive because they
may be jealous that you’re quitting

33. how did/could family help?
moral support, not being judgemental

34. are you feeling better for stopping?
when she quit before she liked waking up with a nice taste in her mouth, she felt
like she was treating her body better

35. what are the benefits of stopping smoking?
   more money, clothes smell nicer, less dependant, nothing controlling her actions,
   liberating

36. how do you keep up the motivation to stay quit
don’t know

37. did you quit with a friend – how did/would this help
   no – would help but you have to choose the right friend, good for process but you
can’t rely on someone else to make you quit.
Appendix 6: Chapter 4: Example of a role model script

Notes for Caohime:

- We can shoot the clips one of two ways:
  - to look like MySpace, i.e. your quitting video diary shot in your house
  - or like an interview with someone who is off-screen asking the questions
- It will be like you have just quit (we will be sending to participants just in advance of the stage they are at).
- We will give you prompts/bullet points for each clip but we want it to be as much your words as possible
- Clips are roughly 30 seconds long and they need to have a beginning, middle and definite end

On the day of video shoot,
- Please bring in some things for backdrop like art/photo/poster/rugs
- Should look comfortable – bring about 8 different comfortable tops.

Clips

Countdown to quit day:

38. Have decided to stop smoking
- Smoking since 14-15 years old
- But hate giving tobacco companies money and the guilt of knowing that it is doing horrible things to your body,

39. Smoking credentials
- Started smoking because my older brother (8 years older) smoked and I used to think he was the coolest person in the world when I was growing up
- started just smoking socially – weekends, evenings
- but working in hospo got up to nearly a pack a day

40. I’ve been thinking about why I smoke…
- because socialising, started drinking alcohol, friends smoke – just ‘what you did.’
- having something to do with your hands, smoking gets you out of awkward conversations, the emotional attachment to it, uses it to distress
- habit, stress and thought it was cool

41. I know I can do it because …
- Have quit before – lasted a few months one time
- Know it will be hard but I can do it – try what worked last time

42. Why I want to quit
- unless you want to smoke forever you’re gonna have to quit sometime.
  It’s better to quit earlier in life than later
- worried about the physical damage that smoking causes, don’t want to have wrinkled grey skin, and yellow teeth by the time I’m 30!
43. The hardest thing about quitting
   - breaking the psychological connections ie. stress, booze, coffee, friends that smoke.
   - So need to separate things so can enjoy them without smoking.
   - Planning really important

44. Preparing for quitting
   - work out/pin point my weakest times, have a firm plan of attack, think of alternatives, always have a plan to so something else instead of smoking

45. So some of the things I have planned are…
   - Perhaps write a list of all the reasons I want to quit and pin it up somewhere so that I can refer to it when the going gets tough!
   - Tell as many people as possible that I am going to quit so that I feel I owe it to them to follow through.

46. So some of the things I have planned are..
   - Be aware of hardest cigs in day to give up and plan something to do instead – for me, afternoons/evenings hardest so for first few days gonna plan sthg everyday like exercise, movie…
   - For the first month I plan to have a facial or a pedicure at the end of each week I remain quit ?

47. So some of the things I have planned are …
   - I know some of smoking is about the physical addiction to nicotine – lots about other stuff too like habit & emotional attachment to cigs – but using gum/patches could at least help with the physical stuff. So gonna think about getting some gum and having it handy to try when the cravings get really bad. Might try the quitline website and find out more about it

48. Told all my friends and family that Im gonna quit
   - Got this advice from dad – if you want to quit, smoke while you’re not doing anything else. Smoke the whole cigarette from beginning to end and try and detach any emotional feeling you have

49. Tomorrow is the day Im gonna stop
   - Quite nervous, worried about not being able to do it, will still want to smoke
   - Good to get people’s support – all my family and lots of my friends telling me they will help if they can

50. Quit day!
   - Yay! Got my whole day planned out so can try to avoid usual smoke times/habits – told xxxx cant have a coffee with them today cos know we always smoke – gonna go to xxx at lunchtime instead

51. End of Quit day
   - Been good cos been busy
   - Really feel like a smoke now but I know I can do it – first day nearly over!
52. first day as non-smoker!
• Think its important to see myself in that way – thinking positively!
• Definitely feel like an old friend is missing but I know I can do it as I am highly motivated when I set my mind to something … so feel pretty upbeat really.

53. cravings
• know that the cravings will pass in a short time – do something else til it does
• when I get a craving I try to close my eyes and visualise myself licking an ashtray – I find this helps!

54. withdrawal symptoms
• irritable, poor concentration, grumpy, on edge
• drink herbal tea, read sthg

55. how got through the first few days
• after dinner cig hardest
• be aware, choose not to have one, do something else instead

56. funny how good smoking seems now when just a few days ago I was wishing I had never ever started, I really feel like a smoke
• but I know just got to take it one day at a time, each day is one more step

57. cant believe how emotional I am at the moment
• its so embarrassing

58. how got through the first few days
• found Ive had to totally change my lifestyle for a while ie. sit inside when studying, don’t have coffee with smoker friends,
• I just took each day one at a time so that it was in manageable chunks.

59. how got through the first few days
• really hard when drinking alcohol
• don’t go out to bars/clubs if you know you’ll have a smoke

60. what are some of the things to beat the cravings
• exercise helps, go for a run, swim etc – you don’t feel like smoking during and after exercise

61. Ive gotta break some of those habits that always used to go with smoking
• Coffee and smoking don’t have to go together
• Started drinking hot chocolate instead of coffee and going to different places

62. any major concerns about quitting
• used to worry about weight gain but not any longer because?

63. So pleased with myself that Ive managed to stay smokefree so far
- Was hell for those first few days but starting to get a bit easier, fewer cravings, sleeping better

64. I know that I used to smoke when stressed
- But have realised that it doesn’t help there are better things I could do to relieve stress like yoga, music & turn up loud….
- The ciggys just provide a temporary stress release….after the ciggy was finished the stress was still there but on top of that there was the guilt about smoking! I ended up just feeling weak and powerless.

65. going out with mates tonight, been thinking how to handle the temptations
- get into an interesting conversation with a non-smoker, don’t go outside with smokers, stay inside,
- one thing that I know will be cool is not stinking of smoke when I get home – the next morning stench on my clothes is just revolting.

66. I had a slip-up last night and had a few puffs
- Makes it even harder, just wanted to buy a whole packet
- But I didn’t, and I have made it through today without any more

67. Cues to smoke that are hard to beat
- sitting down with a friend who’s smoking, drinking alcohol, going shopping and seeing everyone else smoking – doing other things with friends were you cant smoke like movies, sports?

68. like I’ve said I have changed lots of habits & that’s making me feel good because
- exercising more, started valuing health more, enjoying the idea of being good to my body

69. I think I’ve done really well to stay smokefree so far
- Might celebrate with something low key, because when I think of big celebrations think of smoking, like facial with a friend, haircut?

70. Its good to have friends who help & support
- smoker friends shouldn’t offer me cigarettes or smoke around me
- some smokers find it hard to be supportive because they may be jealous that I’m quitting
- Friends can help by giving heaps of hugs, heaps of room, and unfailing support for as long as it takes

71. Family is really important
- moral support, not being judgemental – examples from your own family?
- It’s a really great feeling to know that your family are proud of you. It’s incredibly satisfying.

72. What Im really enjoying about being quit…
- like waking up with a nice taste in my mouth,
- feel like Im treating my body better
73. Other benefits of stopping smoking?
   - more money, clothes smell nicer, less dependant
   - nothing controlling my actions, liberating

74. This has just been the hardest thing I've done
   - I no longer have cravings and everything smells better
   - Still remember those first few days and just amazed I have made it her

75. I can exercise for longer without taking a break now
   - So proud of myself
Appendix 7: Chapter 4: Functional Requirements Document

The purpose of this document is to set out the requirements for the system to support the multimedia mobile phone smoking cessation research project: STUB IT.

Overview of the system

The developed systems will completely support the administration of the multimedia mobile phone smoking cessation study. This study is a randomised controlled trial, which aims to compare the effect on smoking quit rates in those receiving a multimedia-based mobile phone intervention with those in a control group.

The processes involved include:
- registration of interest in participating in the study via email, web or text
- completion of eligibility criteria
- provision of informed consent
- collection of baseline data
- randomisation into intervention or control group
- establishment of shortcodes, gateway and processes for sending and receiving messages
- selection of appropriate messages for each individual
- selection of times for sending messages to each individual
- sending text & video messages to participants
- receiving text & video messages from participants
- changing phases of intervention (frequency & selection of messages) and status of participants
- collecting further data from participants
- text & video messages pulled on demand
- public website
- website for study management
- website for participants
- producing reports to enable study/participant administration & management
- reporting on the system
- producing data for analysis

Participants will be in the study for six months, and the intervention/control programmes will continue for this 6-month duration, until the final data collection point. The intervention programme will be based primarily on pre-recorded video clips of others going through the quitting process (observational learning). There will be elements of selection of message type by participants, and of assigning messages automatically based on data collected. There will be a time-sensitive element so that the messages are relevant to the stage of quitting of the participant. There will also be a mix of other messages (developed around a small number of themes) that will be included in each individual's programme. These may include text, video, audio, and url links. There will be the ability for participants to request messages on demand.
## Schedule of assessment and intervention

<table>
<thead>
<tr>
<th></th>
<th>Eligibility</th>
<th>Randomisation</th>
<th>Quit date (QD)</th>
<th>4 weeks post QD</th>
<th>12 weeks post QD</th>
<th>24 weeks post QD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection</strong></td>
<td>Eligibility criteria</td>
<td>Baseline data: contact details, demographics, smoking, etc</td>
<td>Confidence</td>
<td>Smoking status, confidence, NRT use, withdrawal sx</td>
<td>Smoking status, confidence, withdrawal sx</td>
<td>Smoking status, verification, relapses/cpd, attempts</td>
</tr>
<tr>
<td><strong>Collection method</strong></td>
<td>IVRS or online Or phone</td>
<td>Online Or phone</td>
<td>Txt or phone</td>
<td>Online Or Phone</td>
<td>Txt or phone</td>
<td>Online Or phone</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>Start programme: countdown to QD 1 messages/day</td>
<td>Start Intensive programme: QD to 4 weeks 2 messages/day</td>
<td>Start maintenance programme: 4 weeks to 24 weeks. 1 message every day, then every 2 days, then every 4 days Relapse cycle: another 4 weeks of 2 messages/day then maintenance programme</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>Start programme: one video clip/text message each fortnight</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Verification</strong></td>
<td>Reported quitters sent verification pack</td>
<td>Random sample arrange visit by RA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Post-RCT study: At RCT completion timepoint, relapsed smokers in control group offered participation in qualitative study – re-randomised to receive Intervention programme of 4 weeks duration or random mixture of multimedia messages, and complete detailed questions on content & aspects of programme.
Users of the system

Participants: Study participants expect to sign up to join the study easily, and to receive the programme that is described to them with no errors. Study participants are expected to provide information at several points during the study.

Study Management: Study management need to be able to manage participants, access participants’ information and message calendars, view incoming and outgoing messages, manage the participants’ webpage, send text messages, view reports, enter data, edit participant information, …

Research Assistants: Research Assistants will be collecting data from participants and entering data into the system.

Gateway company: The Gateway company will send and receive messages to/from study participants and the system.

Vodafone: Vodafone will allow access to its network for the system to send and receive messages to/from study participants at no charge. Vodafone will supply one/two shortcodes for the exclusive use of the study.

IT: IT will develop and manage the system to support the study. IT will provide support for the study regarding any IT issues.

DM: DM will review systems specifications and will test the developed system. DM will approve forms and design CRFs for the study. Assisting with trouble-shooting and data extraction during the study.

Print & Web Design: PWD will design CRFs for the study. PWD will be involved in the design of the website for the study.
Recruitment

Recruitment will be managed by Study Management and Mai Media Ltd. This will be undertaken predominantly by advertising by Mai Media Ltd [see advertising schedule]. Ads will include information about this being a randomised research trial. Interested people will be advised to register their interest by sending a text message to 5552, by calling free 0800STUBIT (0800 778248), or by going to the website www.stubit.co.nz.

Registration

From the point of registration onwards, the Vodafone mobile phone number will be used as the potential participant’s unique identifier.

Text Message Registration of Interest

Those sending a text message will receive an automated response advising they need to check eligibility for the study online (www.stubit.co.nz) or by calling free 0800 778248. (“Thx 4 your interest in our study. U can check if u r eligible at www… or on your phone…”). This will be sent to all unrecognised mobile phone numbers texting the shortcode (i.e. all numbers that have not previously completed an eligibility form).

A report of all text registrations of interest will be required. If recruitment is slow, the RA will call all those who have sent a text but have not proceeded to check eligibility online or by phone.

Online and 0800 Phone Registration of Interest

Those participants who go straight to the public webpage or the 0800 free phone will go straight to the eligibility questionnaire. Therefore there will not be any record of registration of interest by these means. A real-time report on the number of visits to the website, and to the eligibility questionnaire specifically, will be used for this (i.e. to determine the number of visits that did not end in a completed eligibility form – see Reports).

A report from the IVRS system will include the total number of calls, number that resulted in ‘ineligible’, number that resulted in ‘eligible’, and the number of uncompleted calls.

Eligibility

The study public webpage will include an eligibility questionnaire (Form A) for potential participants to self-complete. If potential participants phone the 0800 number to register their interest an IVRS system will ask for their mobile phone number and then will take them through the eligibility questions.

Both methods will submit data directly into the system. Mobile phone numbers will be the unique identifiers for each registrant and participants will only be able to register once.
If they are ineligible on any response they will be advised “Sorry you are not eligible to participate in this study. If you would like further help stopping smoking call quitline on 0800…….”

If eligible, they will be advised “Thanks you are eligible to enter this study…” and will be advised to read the Participant Information Sheet and that they will be receiving a consent text message.

Once eligibility criteria have been entered, the participant’s status will be automatically updated to either Eligible or Ineligible. Ineligible participants will not be able to re-register.

Those registering interest by text message that do not complete either online or 0800 eligibility questionnaires may be phoned by a Research Assistant. This requires a report to be available of all registrations of interest. Eligibility questions will be asked over the phone, with manual data entry directly into the form.

Eligibility questions are shown in Appendix A.

Potential participants who state they are unable to receive videos on Form A will be ineligible. Should any of these participants upgrade their phone and try to register again, the system will recognise their number as ineligible and therefore will not allow them to complete Form A again. Therefore there will be a message on the public website “If you have recently upgraded your mobile phone so that you can receive videos and think that you should now be eligible for the study, the system may not let you re-try. If this is the case please call us on 0800 778 248 and we will register you for the study.” SM/RA will need to be allowed to change the status of these participants from ineligible to eligible where appropriate.

Informed Consent & Participant Information

All those classified as eligible will be advised to read and keep a copy of the participant information (PIS) on the study. They will be advised by recorded message (0800 number) or textbox (online) that this is available on the website (in an easily downloadable/printable version), but if they prefer they can receive the information via email or mail.

Online participants will have to click on a button for ‘mail’ or ‘email’ option, and will be taken to a screen to type in their name/mailing address or email address. 0800 number participants will have to push “1” to indicate their preference and will be prompted to speak their email address or name and postal address.

The system will automatically send out requested emails with the PIS attached. A report will be required where emails have been returned due to invalid email addresses, for RA to follow-up. A report will be generated for the SM of all participants requiring PIS to be mailed, in order that this can be done manually as soon as possible.

Participants will also be told that they have to provide consent before the programme can start, and that they will have to respond to our consent message in order to provide this. The system will automatically send the consent video message which will advise them to reply in text with the words “I consent”. Those without video capable phones will be unable to open the video consent message will therefore be
excluded from entering the study (instructions for different handsets will be available on the website for those unsure how to open the clip).

On receipt of the reply with “I consent”, the system will automatically change the participant’s status to Consented. If the reply is not recognised by the system (i.e. if they text something else in response) it will be filed into the SMS Not Recognised report for the study manager. SM will review this report regularly and deal with these messages individually (e.g. “I nconsent” will be moved directly to ‘recognised’ as a positive response so that system can change their status to Consented; or SM will read and respond individually to other requests).

The system will continue to automatically send the request for consent text message every day until a response has been received or 4 days has passed with no response.

Verification of eligibility

Once eligible and consented a random sub-sample of 75 participants will be selected [this is exclusive of those in the phone upgrade group as below]. A report will be produced and the RA will phone these participants to advise that they have been selected to help us by undertaking a saliva test. The RA will obtain name and mailing address, and send a NicAlert teststrip pack. The RA will manage this process, collecting returned teststrips and manually sending reminders to those who do not return their teststrips. Participants may also be offered an in-person visit to collect the saliva sample. An administration page on the website will be set up to manage all NicAlert verification processes. [See Website requirements]

All NicAlert test strips will be read at the CTRU independently by two staff members. Where there is disagreement, a third party will be asked to verify the result. Results will be entered by the RA into the NicAlert verification administration page.

This will occur immediately on completion of Form A and recognised as consented - however status of those participants selected to undergo verification will be ‘Eligibility verification’, and they will not proceed through the system until a result has been entered. RA/SM will enter numerical result of test and will also enter another field to confirm as a smoker – or confirm as non-smoker in which case they become ‘Ineligible’. An automated text message will be sent advising they are ineligible for the study.

After recruitment is completed, a report will be required of all participants undertaking baseline verification of eligibility and their results.

RA/SM will be able to change status from Eligibility Verification to Withdrawn prior to baseline for those who are not going to progress further.

Phone Upgrade Group: Alternate Pathway

Referral pathways are being established for potential participants who may require a loan upgrade 3G phone for the duration of the study. This will only be possible via approved referrers. Approved referrers will be able to make registrations of interest for potential participants (vouching for their smoking status and lack of video-message capable phone – we need to provide them with a list of models). They will be able to make these registrations of interest via pathways agreed between
themselves and Study Management – these may include the website, email to the info@stubit.co.nz address, text message to the Study Manager (rather than to the system), or phone the 0800 number (with a separate option just for this process).

A database (excel) of approved referrers who have signed the terms of agreement will be maintained by Study Management. Registrations in any form will require the potential participant’s mobile phone number and their name.

Registrations of interest for these loan phone potential participants need to be handled separately from other registrations, with a flag at the registration stage or a separate registration list.

The SM/RA will work through this list of registrations by calling the potential participants, completing eligibility criteria over the phone on a paper Form A. The potential participants will have to meet all eligibility criteria except for having a video-capable phone. Those who are considered ineligible on these criteria will be recognised as such by the system and will not be accepted again. Those who are found to have a video message capable phone at this stage will be switched back to proceed through the usual process (rather than this alternative process) and will not be able to receive a phone upgrade.

Those who are eligible will be advised of a time to attend a study centre to pick up their loan phone. They will mailed or emailed the Participant Information (PIS) to read prior to their visit.

RA/SM will be able to change status from Phone Upgrade Group to Withdrawn prior to baseline for those who are not going to progress further.

Verification of eligibility

All potential participants on this alternate pathway will be advised to attend a study centre to uplift their loan phone. At this time they will provide a biological verification of their smoking status – tested on the spot by the RA using NicAlert test strips [also confirmed later by a second independent reading]. If the test confirms smoking status the visit will continue. If it does not confirm smoking, the participant will be advised that they are ineligible for the study.

A further Information Sheet regarding the terms and conditions of the loan arrangement will be provided and a Loan Agreement form will be signed by the participant. The phone will then be given to the participant. A hardcopy file will be kept of the signed Loan Agreements and handset details for each participant. A data entry point is required for RA to confirm we have received the signed Loan Agreement.

At this time the RA will complete the eligibility Form A online (as can now confirm that they are a smoker) which will include an extra box to flag that this participant is receiving a phone upgrade. The participant will then receive the consent message as usual and will be required to respond to it on the spot to allow the process to continue. The participant will then complete baseline data collection forms online. These clinics will therefore require access to the system.

Participants will need to have completed:

- eligibility questions
- informed consent
• verification of eligibility – NicAlert test
• baseline data collection forms
• phone loan agreement

before the end of this visit.

Baseline data collection

On receipt of an appropriate consent text message, eligible participants will be sent an automated text asking them to go back to the website to complete registration details (Forms B/C). Potential participants will be able to complete baseline data collection forms online. If participants status has been changed to eligible within the system (completed online, by IVRS or by RA directly), and consent obtained, they will be able to enter their mobile number on the public website and then a baseline data collection form will become available for them to complete.

On completion of this form, the participant will push the submit button to enter the data into the system.

If eligible and consented participants do not complete baseline data collection, they will be sent text message reminders automatically daily. After 5 days the participant will be phoned by the RA and asked to complete data collection over the phone. Once the participants’ status has been changed [randomised, control, intervention, ineligible, withdrawn prior to baseline] they will no longer be sent automated reminders.

Baseline data collection will include the setting of a target Quit Date which will be used to anchor the participant’s calendar and their follow-up data collection.
Figure 9: Summary of registration and baseline procedures

Ptpt texts registration of interest to 5552

Automated response – Go to website or 0800

Self-completion Form A on website

Ptpt calls 0800 – IVRS

Automated data entry

ELIGIBLE

Automated blurb advises to read PIS, if select mail/email contact details are collected

RA alerted & rings IVRS voicemail for contact details, enters in Form C

Automated consent text message sent

Automated email PIS

RA mails PIS

Ptpt responds “I Consent”

System recognises – CONSENTED

Or RA changes to CONSENTED

Automated text message – Go to website

Website login with mobile number

Self-completion Forms B/C

RANDOMISED

Programme starts

Automated reminders if don’t respond

- report

- RA rings

Automated reminders if don’t complete

- report

- RA rings & completes

INELIGIBLE – automated blurb refers to quitline, cant resubmit Form A

ELIGIBILITY VERIFICATION

Random selection of 75 ptpts

- Report

- system pauses

- RA sends pack out

- Automated reminders to return

- RA enters result, & confirms as

ELIGIBLE or INELIGIBLE

(may need an automated text?)

Once a mobile number has been registered in the system, and before that ptpt reaches RANDOMISED, the RA/SM may manually change the status to WITHDRAWN PRIOR TO BASELINE
Approved referral source signs agreement to refer only known smokers, want to quit, Vodafone non-video capable phone

Referrer faxes, emails, texts, calls with ptpt name and mobile number to RA

RA phones ptpt for eligibility check with paper Form A

RA considers eligible – study site visit arranged

Video-capable phone – refers to website

INELIGIBLE – refers to quitline

Attends study site:
- NicAlert test eligibility verification – RA enters result & confirms
- Signs phone loan agreement
- Given loan phone – change SIM card
- Confirm eligibility – online Form A
- RA ticks Phone Upgrade Group
- Given PIS
- Automated consent text message sent
- Responds to consent message
- Completes Forms B/C online

ELIGIBLE
PHONE UPGRADE
CONSENTED

RANDOMISED Programme starts

Once a mobile number has been registered in the system, and before that ptpt reaches RANDOMISED, the RA/SM may manually change the status to WITHDRAWN PRIOR TO BASELINE
Randomisation

Once the system recognises that complete baseline data has been entered into the system, the participant will be randomised. Participant status will be changed to Intervention or Control. Randomisation will take place by stratified minimisation by variables likely to be important in cessation as listed below. The probability that the participant is allocated to the treatment with the lowest count will be 0.9.

Variables:

<table>
<thead>
<tr>
<th>Age</th>
<th>&lt;26yrs</th>
<th>26yrs and over</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity</td>
<td>Māori</td>
<td>All other ethnicity categories (incl. Other)</td>
</tr>
<tr>
<td>Phone Upgrade</td>
<td>No – Own phone</td>
<td>Yes – Loan phone</td>
</tr>
<tr>
<td>Nicotine Dependence</td>
<td>Form C: Q2.08 Time to first cigarette: categories</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 6 - 30mins</td>
<td>- 31 – 60mins</td>
</tr>
<tr>
<td></td>
<td>- Within 5mins</td>
<td>- After 60mins</td>
</tr>
</tbody>
</table>

After randomisation a message will be sent to participants welcoming them to the study and outlining what will happen.

NB. Those who select Other Ethnicity and then specify an obvious Māori ethnicity in the free text box – these will be treated as a Protocol Violation, however randomisation will not be held up to deal with this but will continue as specified above.

Data Collection

<table>
<thead>
<tr>
<th>Data</th>
<th>Method</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility criteria – Form A</td>
<td>Online –ptpt or RA, IVRS –see below Online - RA</td>
<td>At registration of interest or anytime after this</td>
</tr>
<tr>
<td>Phone upgrade status – added to Form A for RA only</td>
<td>RA to enter online</td>
<td>At verification of eligibility clinic visit</td>
</tr>
<tr>
<td>Eligibility verification result</td>
<td>RA to enter online</td>
<td>At verification of eligibility clinic visit</td>
</tr>
<tr>
<td>Phone loan agreement signed &amp; received</td>
<td>TAx automated</td>
<td>Once eligible</td>
</tr>
<tr>
<td>Consent</td>
<td>Online –ptpt or RA</td>
<td>After eligibility &amp; consent completed (&amp; eligibility verification if required)</td>
</tr>
<tr>
<td>Baseline data collection, quit date, contact details – Forms B &amp; C</td>
<td>TAx automated or RA phones</td>
<td>On selected quit date set at baseline data collection</td>
</tr>
<tr>
<td>Confidence in quitting on Quit Day 4 weeks – Form D</td>
<td>Online –ptpt or RA</td>
<td>4 wks post quit date</td>
</tr>
<tr>
<td>Smoking status at 12 wks</td>
<td>TAx automated or RA phones</td>
<td>12 wks post quit date</td>
</tr>
<tr>
<td>24 weeks – Form E</td>
<td>Online –ptpt or RA</td>
<td>24 wks post quit date +/-</td>
</tr>
<tr>
<td>Quitting verification</td>
<td>RA to enter online</td>
<td>After 24 weeks data collection –</td>
</tr>
</tbody>
</table>
Baseline data collection has been described above.

IVRS: predominantly automated data collection via push button – data transferred to our system electronically by IVRS set-up. Data will be submitted via webservice immediately. Achieve will also provide master list at regular intervals. All data to be included (e.g. all available information on non-eligosibles and non-completers).

Information to be reported:
- Number of calls – total
- Number of calls – by incomplete, eligible and ineligible
- Incomplete calls – by mobile number
- Reasons for ineligibility – responses to questions
- Where they heard about the study

IVRS Voicemail is to be available to CTRU study staff to access the following information as required:
- messages can be left for study staff
- where participant selects mail or email for PIS, postal address or email address are recorded over the phone.

At selected Quit Date (collected on Form C at baseline) an automated text message will ask about confidence in quitting. A numerical response will be required and entered into the database. A reminder msg will be sent daily for 5 days until a response has been obtained. After 5 days participant is added to a real-time report (No response to data collection message) for RA to follow-up. RA needs to be able to manually enter response to question.

At 4 weeks post Quit Date an automated text message is sent requesting participant to complete Form D online. Automated text message reminders are sent daily for 5 days. After 5 days participant is added to real-time report (No response to data collection message) for RA to phone and complete Form D over the phone.

At 12 weeks post Quit Date an automated text message is sent asking about smoking status and requiring a numerical response. This response is entered into the database. The question will continue to be sent daily for 5 days until a response is obtained. After 5 days participant is added to a real-time report (No response to data collection message) for RA to follow-up. RA needs to be able to manually enter response to question.

At 24 weeks post Quit Date an automated text message is sent requesting participant to complete Form E online. Automated text message reminders are sent daily for 5 days until completed. After 5 days participant is added to real-time report (No response to data collection message) for RA to phone and complete Form E over the phone. On submission of Form E, all quitters will be advised that a Test pack will be sent to them and needs to be returned to the study centre.

On submission of Form E all those reporting quitting (Question 1.01 selected: No not a single puff OR Yes between 1 and 5 cigarettes) will be added to a real-time report
(NicAlert Test Pack to be sent). Those not returning the Test Pack within 7 days will be added to a real-time report (NicAlert Test Pack not returned).

On submission of Form E a random selection of 10% of those reporting quitting will be made and will be added to a real-time report (NicAlert Visit Required). These participants will receive both a mailed NicAlert Test Pack as above, and a NicAlert Visit. This could be done by selecting 1 in every 10 quitters starting with the first participant to successfully quit.

All NicAlert Test results will be entered by the RA or SM on the NicAlert Verification Administration Page (see Website requirements). Results will be entered into the database.

**Intervention**

The intervention will consist of a 6-month package of video and text messages to be sent to participants. This includes:

- a selection of messages from the Intervention Message database
- data collection-related messages at set time points from Quit Date (as for all participants)
- phone loan agreement-related messages for those with a loan phone at set time points, e.g. reminders towards the end of the 6-month study period about the return of phone

**Phases and frequency of messages:**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Frequency</th>
<th>Message Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Randomisation to 7 days prior to Quit Date</td>
<td>1 message every 2nd day</td>
</tr>
<tr>
<td>Phase 2</td>
<td>Countdown 7 days prior to 1 day prior to Quit Date</td>
<td>1 message/day</td>
</tr>
<tr>
<td>Phase 3</td>
<td>Intensive Quit Date to 4 weeks post QD</td>
<td>2 messages/day (up to 4 messages if RMs added)</td>
</tr>
<tr>
<td>Phase 4</td>
<td>Weaning 4 weeks post QD to 6 weeks post QD</td>
<td>1 message every 2 days</td>
</tr>
<tr>
<td>Phase 5</td>
<td>Maintenance 6 weeks post QD to 24 weeks post QD</td>
<td>1 message every 4 days</td>
</tr>
<tr>
<td>Completed</td>
<td>Maintenance 24 weeks post QD</td>
<td>Nil further</td>
</tr>
</tbody>
</table>

*N.B. This is excluding data collection-related and phone loan agreement-related messages*

**Timing of messages:**

Participants will select the two best time periods to receive messages each day. These will be set at a default unless changed at baseline data collection (Form C) to be within 2 hours either side of:

- 10am (i.e. 8am-12pm)
- 6pm (i.e. 4pm-8pm)

Messages will be sent at a randomly selected time within these time periods.

Form B will allow them to change the selected times for each day of the week.
The system will allow all possibilities – including overlapping time periods. Allow hour or half-hour time selections, but not others (i.e. 11am or 11:30am but not 11:24am).

The system will select a random time within the allowed time periods for all messages due to be sent that day – EXCEPT where there is a pre-specified order in the programme, such as the core role model story in the intensive phase (Phase 3) where the two clips/day are in a pre-specified order (generally text to follow video).

**Selection of messages for Core Programme:**

In general, there will be a pre-specified programme of messages (rather than random selection of messages from databases as in previous STOMP study).

There are however a small number of variables selected by the individual participant at baseline (on Forms B/C) which will determine the individual's programme. These variables are:

- selected Quit Date (to determine phase)
- selected role model (if no RM selected randomly select RM 1-6)
- selected times for messages to be sent (as described above).

Also changes are able to made to the programme by the participant (from Quit Date on) which are described further below.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Length of phase</th>
<th>Frequency of messages</th>
<th>Programme specified or selected variable</th>
<th>Message times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1: Random to 7 days prior to QD</td>
<td>Variable length depending on selected Quit Date – 0 days to 14 days</td>
<td>1 clip every second day</td>
<td>Specified order of clips but only get those required to fill required number of days</td>
<td>Randomly within selected time periods</td>
</tr>
<tr>
<td>Phase 2: 7 days to 1 day prior to QD</td>
<td>6 days</td>
<td>1-2 clips per day</td>
<td>Specified order of role model story</td>
<td>Randomly within selected time periods</td>
</tr>
<tr>
<td>Phase 3: QD to 4 weeks post QD</td>
<td>28 days</td>
<td>2 clips per day (up to 4)</td>
<td>Specified order of role model story – order that the 2 role model clips/day will be sent is specified</td>
<td>Randomly within selected time periods – keep to specified order of role model story</td>
</tr>
<tr>
<td>Phase 4: 4 weeks post QD to 6 weeks post QD</td>
<td>14 days</td>
<td>1 clip every second day</td>
<td>Specified order of role model story</td>
<td>Randomly within selected time periods</td>
</tr>
</tbody>
</table>
The Core Programme message database has two main themes.

1. Video clips of role models. There will be a series of video clips from seven different role models that will progress in order through the quitting process. Participants will select at baseline which model they wish to receive clips from (Form B/C - only one model allowed initially). The programme for each model will be in a pre-specified order that will be sent in Phases 2 and 3.

2. Other intervention content. This may include other video clips, such as anti-tobacco industry/politicalisation content, motivational messages from celebrities, music, links to websites, and text messages.

Changing timing, frequency and content of messages

If possible participants will be able to change the timing, frequency and some content of the programme they are receiving. This should be able to be done on the participant webpage after randomisation.

- Participants will be able to reset their selected message times.
- Participants will be able to change role models during the intervention by adding an extra role model to their selection or changing from one role model to another. In both cases, the role model programme continues according to their day from QD and the appropriate day in the role model pre-specified programme (i.e. it will not start again from the beginning, unless they add role model clips in Phase 4 when the original role model story has finished, or in Relapse Phase)

A report on all changes made will be required.

Changes allowed to messages in each phase:

**Phase 1**
Change selected message times only

**Phase 2**
Change selected message times only (1 RM only, can change RM)

**Phase 3**
Add another role model

Rules:
- only by adding another role model story (by selecting one on the website) – will add another 1 RM video clip/day
- new role model stories start from beginning Phase 3 & run for 4wks
- can increase up to 5 messages per day by adding further role models spread evenly over selected time periods

Change role model

Rules:
- stop current role model story
- change to another role model story according to the appropriate day from QD (i.e. not from beginning of RM story)
- frequency of messages stays the same

**Phase 4 & 5**
Increase frequency of messages per day

Rules:
- only by starting a role model story from start of Phase 3 (have to select a
role model on the website) will add 1 clip/day (on top of current Phase 4/5 programme) for the duration of the 4wk role model story (or until participant reaches the end of their programme – QD+24wks) can do this as many times as they want Change selected message times

Regardless of any changes, the programme never extends beyond QD+24wks for any participant.
Figure 10: Examples of programmes and potential changes

Ptpt A:
Sets QD as Day 14, selects RM X

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
<th>Phase 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>/…7 days……../……6 days……./……28 days………………………………./……14 days…./……126 days………………………………/</td>
<td></td>
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<tr>
<td>4 messages</td>
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<tr>
<td>RM X story starts</td>
<td>6 messages</td>
<td></td>
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<tr>
<td>QD</td>
<td></td>
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<tr>
<td>RM X story continues – 56 messages</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RM X stops</td>
<td>7 messages</td>
<td></td>
<td>32 messages</td>
</tr>
<tr>
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<td></td>
<td></td>
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<tr>
<td>Adds RM Y story</td>
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<td></td>
<td>RM Y stops</td>
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<tr>
<td></td>
<td>Adds RM Z</td>
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<td></td>
<td></td>
<td>- goes for 4 wks then stops</td>
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<tr>
<td></td>
<td></td>
<td>Increases messages</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- adds RM A only til end of prog</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Rating of messages**

A process will be set up for participants in the Intervention Group to rate the messages they receive. This has to be a very simple system for participants to use.

This could be done on the participants’ webpage with a history of the clips from the participants programme available to view and tickboxes for data collection.

Results will be collated by the system and presented in a report.

**Compulsory Messages**

As well as the Core Programme, there will be a database of compulsory text messages, such as data collection questions and instructions for the phone upgrade group. These messages will be sent on specified days to specified groups of participants, and will always be compulsory according to these rules. They should be sent at a randomly selected time within the participant’s selected time periods.

**Data collection-related messages**

- for all participants of all Status except (Completed & Withdrawn prior to baseline)
  - **QD** Confidence question
  - **QD + 4wks** Go to website and complete short questionnaire
  - **QD + 12 wks** Smoking status question
  - **QD + 24wks** Go to website and complete short questionnaire
  - **Verification** Reminder about returning NicAlert pack or inperson visit
  - **Reminders for non-response** Automated reminder messages – to be sent daily until response or for 4 days, then goes to report for SM/RA to call
  - **Day before prog due to end**

**Phone loan agreement-related messages (TO BE DONE)**

- for all participants with Status = Phone Upgrade Group
  - **QD + 22 weeks** Just reminding u that phone loan finishes in 2 wks…
  - **QD + 23 weeks** Just reminding u that phone loan finishes in 1 wk. Have u got old/another phone 2 put sim card in?
  - **QD + 24 weeks** Tx 4 taking part in study. We need to get phone back from u…
  - **Reminders** We have been unable to get hold of you to get loan phone back. Pls contact us on 5552, 0800 …..

**Relapse**

At any time in Phases 3,4&5 participants in the Intervention Group can notify the system (by texting ‘RELAPSE’ to 5552) that they have relapsed. The main aim here is to avoid sending “well done, keep it up”-type maintenance messages to people who are smoking again.

In response the system will send three automated responses in sequence. The first message will be sent immediately, the second 30minutes later, and the third 30mins later. These messages have been written in sequence – the system can randomly
select which sequence to send each time. Once all messages have been sent to an 
individual participant, they can be repeated.

This does not require a change of status, but does require a report of all those who 
have notified of relapse, their quit date and the date on which this occurred.

These participants will be advised to go to the website to select another role model 
story to follow. The participant will in effect add a role model story to their programme 
as described in the changes to the programme above, for the 4week duration of that 
story (or until the end of the participant’s programme at QD+24wks). The participant’s 
programme never extends beyond QD+24wks.

There is no limit to the number of times a participant can text RELAPSE for 
automated responses.

**Messages on demand – CRAVE function**

Participants in the Intervention Group will be able to request/’pull’ messages on 
demand at any time from Quit Day to the end of their programme. This will be set up 
as assistance to address cravings – “when you are craving a cigarette, pick up your 
phone and text ‘CRAVE’, we will send you an immediate message with advice on 
how to beat the craving”. This provides distraction as well as practical advice on how 
to deal with cravings or high risk situations. Response messages will be selected 
from a Crave Database.

Ideally Crave will be context-specific. All messages in the Crave Database will have 
Keywords describing the context – participants would have to be advised of the 
contexts/correct words – they text in e.g. CRAVE bar or CRAVE alcohol etc to get a 
message that relates to experiencing cravings when in a bar drinking with your 
friends.

**Suggested contexts:**
- Drinking – text CRAVE DRINKING
- Stress – text CRAVE STRESS
- Boredom – text CRAVE BORED
- General – text CRAVE

The Crave message database will be categorised and within each category there will 
be a set order for the messages to be used (to ensure best ones are sent first). Once 
a participant has used the full number of messages within a category, the system will 
default to the General category. Once the participant has used the full number of 
general messages and continues to text CRAVE (with no suffix) the system can 
randomly select any unused messages. (experience from STOMP is that only a small 
number of people used full quota of crave messages).

There will be a limit on the number of times crave can be used – which will be equal 
to the full number of messages in the crave message database. Once these have 
been used there will be an automated text message advising the participant they 
have used their full quota of crave messages and directing back to the website.
A report will be available on the use of the crave function, by mobile number, quit date, and the number of times they have requested messages (in each category) by date requested.

**Control Group**

The control programme will consist of a 6-month package of text and video messages to be sent to participants. This includes:

- fortnightly messages selected from the Control Message database. All control participants will receive all the messages in a sequential order.
- Compulsory messages: data collection-related messages at set time points from Quit Date (as for all participants); and phone loan agreement-related messages for those with a loan phone at set time points, e.g. reminders towards the end of the 6-month study period about the return of phones

Control group messages will be sent at a randomly selected time between 10am and 6pm.

**One-off messages to participants (TO BE DEVELOPED)**

RA and SM will be able to create new messages and send one-off messages to any selected participants from the website. This may be required individually (to individual participants) or in groups according to status (most likely to Intervention Group, Control Group, Phone Upgrade Group – however there may be others required – please check with Study Manager).

RA and SM will be able to send regular polls, collate responses and send results out to respondents (as per STOMP).

**Withdrawing from the programme**

Participants will be able to automatically withdraw from the programme – meaning they will no longer receive the Core Programme but **will** still receive the Compulsory text Messages (data collection and phone upgrade-related). Participants will be advised to text the word STOP to the shortcode. They will receive an automated response advising that the change may take 24hours to come into effect, and advising that we will still be contacting them at the end of the study. The system will update their status to Withdrawn.

If a participant wishes to fully withdraw and no longer receive any contact from us, they will be advised that they must speak to Study Management. SM will be able to allocate Lost to Follow-up, however it is hoped that most participants will remain as Withdrawn (i.e. still provide 24wk followup data).

**Database requirements**

*Personal profile*

- Mobile phone number (Vodafone) as unique identifier
- Quit Date
- username (if required)
Participant status

<table>
<thead>
<tr>
<th>ID</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Active</td>
</tr>
<tr>
<td>2</td>
<td>Withdraw</td>
</tr>
<tr>
<td>3</td>
<td>Lost to follow-up</td>
</tr>
<tr>
<td>4</td>
<td>Completed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consent not requested</td>
</tr>
<tr>
<td>2</td>
<td>Consent requested - awaiting response</td>
</tr>
<tr>
<td>3</td>
<td>Consent received - unknown response</td>
</tr>
<tr>
<td>4</td>
<td>Consent received - Participant Consented</td>
</tr>
<tr>
<td>5</td>
<td>Consent received - Participant Declined</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unregistered</td>
</tr>
<tr>
<td>2</td>
<td>Registered – Eligible</td>
</tr>
<tr>
<td>3</td>
<td>Registered - Not Eligible</td>
</tr>
<tr>
<td>4</td>
<td>Registered - Eligibility Verification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID</th>
<th>NAME</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Unrandomised</td>
</tr>
<tr>
<td>2</td>
<td>Randomised – Active</td>
</tr>
<tr>
<td>3</td>
<td>Randomised – Control</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Incomplete</td>
</tr>
<tr>
<td>2</td>
<td>Complete</td>
</tr>
</tbody>
</table>

Message databases

Programme messages will be stored on 5 databases:

- **Control Messages**: Compulsory core programme for all Control Group participants from registration to end of programme.
- **Intervention Messages**: Core programme for all Intervention Group
Relapse Messages Automated response to texting RELAPSE. One compulsory and two randomly selected from database.

Crave Messages Pulled on demand by Intervention Group participants only. Categorised by keyword and specified order.

Compulsory text messages

Data Collection-related Messages Compulsory for all Participants (except Completed, Withdrawn prior to baseline)
Phone Upgrade-related Messages Compulsory for all participants with Phone Upgrade Group status

These messages will come from:
- Study management creating new content from existing files or internet
- New content from Richard Smith (video production)
- Content submitted by participants (need to capture: who sent it, date sent, competition 1/2/3 etc. A report will be required on submitted content in order to manage any competitions)

New messages will go through the following process:
- Be saved as All Incoming Content (*submitted version*)
- Be reviewed by Study Management and categorised as
  - Not for use
  - For further consideration
  - Approved for use (*approved*)
- Be moved to website folder once Approved for use
- Be compressed and formatted appropriately for use (*formatted*)
- Be saved as Final Version (*final*)
- Have rules for use confirmed by Study Management (date to be uploaded, duration of use, space on website?)
- Be uploaded to website
- Be saved as Posted to website (*posted*)

RA and SM will be able to create new messages and send one-off messages to any selected participants from the website (individually or in groups).

Incoming messages

The system will need to be able to receive text messages from participants and store them.

Some incoming SMS messages will be expected (Crave, data collection, answers to questions) and will be dealt with automatically by the system. Incoming messages will be sent to the short code. As there are only one or two short codes some expected incoming messages will need to be prefixed with keywords in order to be recognised by the system. Participants will need to be advised of these keywords on the website and in text messages (keep as short as possible).

Text messages (SMS):
- I Consent
- Crave
- Stop
- General registration of interest
- ?data collection questions: Q1, Q2....

Some incoming SMS messages will not be expected by the system and will be reported in real-time as Unrecognised Incoming SMS. The SM/RA will work through this report daily and change assignment to recognised, for the system to deal with (as in the STOMP programme), or will deal with them manually. RA/SM will be able to remove/archive messages from this report once dealt with.

Incoming video messages will be stored for review as described above. For each message the information required is: sender mobile number, date & time received, whether in response to a competition/request (as below).

**Messaging logistics**

Vodafone is supporting the study by providing access to their mobile phone network. One short code will be provided by Vodafone (5552). All messages will be sent to/from these short codes at no cost to the participants or the study.

Video messages are to be sent via embedded text messages with a link to the WAP site. Therefore participants receive a text message with a URL address as a hyperlink. By clicking on/scrolling over/selecting this link, the video is automatically downloaded on to the phone from the WAP site. This takes <1 minute, and then the video plays. The WAP site is also zero-rated by Vodafone, meaning that there is no charge to the participant or the study for downloading these videos.

For participants who are unsure how to select the link and download the video on their phones, a link to the Vodafone website Users guides is provided on the STUB IT website. Participants can be directed to look up the User Guide for their particular model of phone.

Participants are advised not to save the messages to their phones as this would soon use up available memory. The text messages can be saved and the clips downloaded a couple times, after which time the participant will be directed to the website to view them again. (This will limit the opportunity for the clips being forwarded and viewed by others not on the study).

All messages will need to be sent via a Gateway company that is approved by Vodafone. RuntheRed have been selected as the Gateway provider.

*All participants will be Vodafone customers. Vodafone will need to be informed of participants in the study in order that they can set up the necessary changes to billing for those participants – at this stage this is not required, unless it may be required for the incentives provided by Vodafone which are yet to be determined.*
Data validation

Data keyed by the participant or RA using web-based forms will be validated for gross errors and inconsistencies using Java script checking. Immediate display of any data problems will allow the user to correct in real-time.

Answers arriving by TXT responses to TXT questions sent will be validated during regular batch ‘revalidation’ jobs, or immediately upon receipt. Queries arising from batch revalidation will be stored and an ‘alert’ message will be sent to the SM to follow-up the participant with a phone call to clarify the queried data, or they can be reported in batches, as required.

Website requirements

Public page

This needs to appeal to the target population (particularly 18-24 year olds) with appropriate look and language. Wording is provided in the Appendix document. Functionality:

- Public info about the study: benefits of quitting, benefits of joining study, possibility of randomisation to control group, contact details for study management, privacy information, send SMS message to a friend/smoker about study, contact information.
- Click through to eligibility questions: dropdown boxes/tick boxes, immediate response provided to eligibility, participant status updated in system (eligible/ineligible)
- Participant Information Sheet: easily downloadable and readable format/s, request for sheet to be emailed/mailed
- Link to The Quit Group webpage
- Log in for participants by mobile phone number/study management by username and password
- Log in for referring officials to send us mobile phone number and name of referred potential participant?

Participants page – Intervention Group only (My Room and My Lounge)

Specific wording is provided in the Appendix document. Functionality:

- Log in from public page with mobile number – Intervention group only
- A shared participants’ page but customisable to individual. Can view history of video clips in their programme
- Rate the video clips in their programme.
- We post participants submitted video clips (review for best ones to be posted)
- They can rate or comment on posted videos (ours and submitted ones)
- Ability for participants to ‘talk’ to each other on the website - Chat room with Moderator?
- Send us an email
- Send us a video clip by email
- Process for participants to change their message frequency or selection of models
• FAQs about the study (How do I stop receiving any messages? Crave instructions. Relapse instructions. How to send us video clips.)

**Study administration pages**

Log in from public page with allocated user name and password – access according to role (SM, RA etc)

Data collection forms
Participants’ details
Reports

Study Manager functions:
• Change participant status
• Change participant details
• Create new messages
• Remove messages from database
• Send one-off messages to selected participants (individually or in groups)
• View all reports
• All data collection forms and NicAlert Administration page

RA functions:
• All data collection forms
• Selected reports
• NicAlert Verification administration pages

RA and Coder should remain blind to allocated group.

**NicAlert Verification Administration page**

This page to be accessed from relevant reports (see Reporting requirements 6, 11, 12, 13) or routinely by RA and SM. An identical page available for every participant selected (Eligibility Verification, Phone Upgrade Group, All Quitters on Form E). Page allows the following data to be entered:

1. **Eligibility Verification**
   Test Pack ID number (compulsory)
   Date Pack Sent
   Date 2nd Pack Sent and 2nd Pack ID number
   Date of Reminders (allow up to three dates to be entered)
   Date Pack Returned
   Date Visit arranged and Date/Time/Venue of arranged visit
   (allow up to three visits to be arranged)
   Visit Test Pack ID number
   Date Visit completed
   Test Result (compulsory once this page has been started for any participant)
   Test Read by (initials, allow up to two sets of initials)

2. **Quitting Verification (24wks)**
   Test Pack ID number (compulsory)
   Date Pack Sent
   Date 2nd Pack Sent and 2nd Pack ID number
   Date of Reminders (allow up to three dates to be entered)
Date Pack Returned
Date Visit arranged and Date/Time/Venue of arranged visit
(allow up to three visits to be arranged)
Visit Test Pack ID number
Date Visit completed
Test Result
Test Read by (initials, allow up to two sets of initials)

RA to be blinded to intervention/control group allocation – people logging in under this role will not see participant’s allocated group or calendar

Reporting requirements

Internet Statistics

1. numbers of visitors to the public website over time
2. numbers of visitors who open the eligibility questionnaire over time
3. numbers of visitors to the 0800 IVRS – completed questionnaire and not completed questionnaire

Reports Required

1. Recruitment reports for real-time monitoring of recruitment including:
   • numbers of 'eligible’s over time
   • numbers of 'eligible's by Q9 Form A – where they heard about study
   • numbers of randomisations over time – daily, weekly, cumulative
   • randomisations by Māori /all other responses (Form C Q 1.02)
   • randomisations by Income (Form C Q 1.07)
   • randomisations by Phone Upgrade Group/all others

2. registrations of interest (by incoming text messages) with current status of participant (to show those who have progressed)

3. Status report – report of all those in each status at any one time.

4. PIS Letter which will accompany the PIS which will be posted

5. Tasks Outstanding Report (will be used in conjunction with Tasks Outstanding Screen) – the main feature of the report is that tasks will be sorted by urgency and the Research Assistant will process the tasks in the order they are displayed in the Tasks Outstanding Report

6. Baseline Eligibility Verification results – all those who were randomly selected and their results or incomplete. Weekly updates

Tasks Outstanding Screen

1. Eligible participants wanting PIS mailed (by name and mailing address) – daily updates. Tick box for RA/SM to indicate when sent and remove from list.
2. **invalid email address** – participants wanting PIS to be emailed, email returned due to invalid email address. Include mobile number, date email sent, email address. Allow email address to be updated manually by RA/SM and system re-sends PIS email message.

3. eligible participants **not completed baseline data collection forms** B/C after 4 days time period from becoming Consented. Including incomplete forms B/C. Mobile phone number, space to enter dates contacted by RA/SM. Remove from report once forms B/C completed or after two attempts at contact recorded.

4. **not responded to consent text** after 4 days (system sends reminders for 4 days then goes to report). Mobile phone number, space to enter dates contacted by RA/SM. Remove from report once Consented or after two attempts at contact recorded (present report by number of contacts attempted i.e. no attempts at contact at top, then 1 attempt at contact, then two attempts and so on)

5. **Baseline Eligibility Verification.** 75 participants (not in phone upgrade group) randomly selected (1st of every 10 participants) on becoming consented [status = Eligibility Verification]. Real-time report to include name and mobile phone number. Click through to NicAlert Verification Administration page to enter details. Once Test Results have been entered participant removed from report. [status changes to Eligible or Ineligible]

6. No response to **data collection message.**
   - Five days after data collection question sent (at Target Quit Date and 12 weeks) and no response, goes to a report with mobile phone number, date question sent and TQD / 12wk. For TQD/12wk allow response to question to be entered – response to then be entered into database, and participant removed from report. Needs space to enter date/time contacted (allow up to 3 contacts). Once third contact entered, consider this particular data collection point to be unobtainable and therefore participant removed from report however if data received at later point then can access data entry point through participant screen. (present report by number of contacts attempted i.e. no attempts at contact at top, then 1 attempt at contact, then two attempts and so on)
   - Four days after data collection message sent (at 4 weeks and 24 weeks post Quit Date) and Form D (4wks) or E (24wks) has not been completed, goes to a report with mobile phone number, date question sent and 4wk / 24wk. Needs space to enter date/time contacted (allow up to 3 contacts). For 4wk/24wk, RA will complete Form D/E over the phone and participant removed from report once this has been submitted. Once third contact entered, consider this particular data collection point to be unobtainable and therefore participant removed from report however if data received at later point then can access data entry point through participant screen. (present report by number of contacts attempted i.e. no attempts at contact at top, then 1 attempt at contact, then two attempts and so on)

7. **NicAlert Test Pack to be sent.** On submission of Form E, all those reporting quitting (definition Q 1.01 selects No not a single puff OR Yes between 1 and 5 cigarettes) added to this report with date Form E completed, access to
mailing address, and click through to NicAlert Verification Administration page for details to be entered. Once Pack ID number and Date Pack Sent completed, participant removed from report.

8. **NicAlert Test Pack not returned.** Seven days from Date Pack Sent and no Date Pack Returned entered, participant added to report in chronological order. Click through to NicAlert Verification Administration page for details to be entered. Once Test Results have been entered participant removed from report.

9. **NicAlert Visit Required.** On submission of Form E, a random selection of 10% of reported quitters (definition Q 1.01 selects No not a single puff OR Yes between 1 and 5 cigarettes) added to report with date of Form E completion, mobile phone number, and click through to NicAlert Verification Administration page for details to be entered. Once Visit Test Results have been entered participant removed from report.

**Other functionality**

7. Use of Crave. Report by mobile phone number including total uses of Crave, use each week (from Quit Date).

8. Relapse: Report on those texting RELAPSE – mobile phone number, quit date, date Relapse text received (may be more than once).

9. Number of unique visits to website over time (daily)

10. Changes made to role models via My Room. Participants requesting changes made to programme by mobile number, date and change requested.

11. Ratings of content in My room. Report on participants ratings of selected messages in My room.

12. Prize draws (4):
   - Regular report: Monthly draw on completion of Form E (only once per participant)
   - Regular draw: Each randomised participant goes into a monthly draw for each month they stay in the study (max. 6 draws pp). Can only win once.
   - One off report: Draw for completing saliva collection at baseline (drawn at end of recruitment)
   - One off report: Draw for completing saliva collection if quitter (drawn at end of study)

**Testing**

The entire system needs to be fully tested prior to going live. This should include IT (to look at all aspects of system functioning) and DM (to run ‘dummy’ participants through all questionnaires and test data collection) and SM (to test actual receipt of the programme messages on multiple mobile phones).

A testing plan and timeframe needs to be set up by DM.

**Security and access**

- Ensure one user per phone number – mobile number is unique identifier
• Passwords and usernames for all users of the system
• Backups to be taken nightly
• There will be an audit trail kept

Performance

• System up-time 99.5%
• System processing capability to support simultaneous access by ten systems users (study management, research assistants, IT, DM etc)
• System processing capability to support 1300 participants
• The database will need to generate and track up to 1950 messages per day
• The database will accumulate message tracking information, (who for, which message, time sent) on approximately 130,000 messages during the study
• System alarms
  o Content/messages due but not sent
  o Too many messages sent
  o Connectivity to Vodafone not working

Support

IT support will be required during the running of the study.
0800-1800: full IT support required, problems fixed as soon as possible, study management notified of major issues
1800-0800: on-call for major issues that have been reported, triage issues for immediate fix or wait until the next day.
  • Connectivity down or messages due but not sent: can wait til the next morning and fixed with high priority at that stage
  • Too many messages sent (or other issues that will severely impair study relationship with participants) need to be fixed as soon as possible

Longterm data storage

The computer data files and any paper records must be kept securely for a period of 5 years after the study finishes.

Data extraction for analysis

Standard extraction files from Oracle to SAS will be set up.
Appendix 8: Chapters 4&5: Form A

(Online screen)
Are you eligible?

RA screen:
The purpose of this form is to register all interested people, collect some baseline data, and determine if they are eligible to participate in the study.

RA:
Hello, thanks for your interest in the STUB IT quit smoking study. This world first study involves sending video messages to your Vodafone mobile phone to support you on your quitting journey. It may also include checking a saliva sample at some point. I need to check that you meet our criteria for entry into the study – this should take about 5 minutes. Is now a good time to do this?

RA screen only

1.01 Are you in the phone upgrade group?
Yes
No

1.02 If Yes, have you read the phone loan agreement?
Yes proceed
No ineligible

For online and RA screens

1.03 Are you a Vodafone customer?

1.04 What is your Vodafone mobile phone number? Make sure it is the phone number you will be using for the study.

1.05 Can you play video messages on your phone?
Yes
No

1.06 Do you live in Auckland?
Yes
No /don't know
1.07 What is your date of birth? (dd/mm/yyyy)

1.08 Do you smoke cigarettes every day?
   Yes
   No

1.09 Which of the following statements best describes your current situation? (Drop down list, select one only)
   A. I would like to try quitting within the next three weeks.
   B. I would like to try quitting - not within the next three weeks but within 6 months
   C. I smoke but I have no intention of quitting in the next 6 months

1.10 Are you enrolled in any other internet or mobile phone-based stop smoking programmes?
   Yes
   No

1.11 Where did you hear about the study? (drop down list of options, select one only)
   Radio advert
   Internet
   Friend/relative
   Magazine/Newspaper
   Quitline
   Television
   Other

Submit

**To be eligible, must respond accordingly to all of the following questions**

<table>
<thead>
<tr>
<th>Question</th>
<th>Examples of ineligible answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.03</td>
<td>No</td>
</tr>
<tr>
<td>1.04</td>
<td>No or missing</td>
</tr>
<tr>
<td>1.05</td>
<td>Less than 16 years of age</td>
</tr>
<tr>
<td>1.06</td>
<td>B, C</td>
</tr>
<tr>
<td>1.07</td>
<td>Yes, only smoke on weekends</td>
</tr>
<tr>
<td>1.08</td>
<td>Yes (STOMP via quitline,</td>
</tr>
<tr>
<td></td>
<td>internet smoking cessation</td>
</tr>
<tr>
<td></td>
<td>programmes like smokestop,</td>
</tr>
<tr>
<td></td>
<td>quitcoach)</td>
</tr>
</tbody>
</table>
If Not Eligible (RA spiel & online blurb)

Unfortunately, due to our strict entry criteria, you are not eligible to take part in the STUB IT study. If you require assistance with quitting please visit the Quitline website for further assistance - www.quit.org.nz. We appreciate your time today.

RA spiel only:
If participant asks why not eligible: For the purpose of this study you weren’t eligible due to the strict entry criteria. Because this is a research study, we can’t tell you exactly what the entry criteria are, but once again thank you for your time today. and end call.

If Eligible
Thanks for answering these questions – Congratulations! You are eligible to take part in our multimedia quit smoking study. We would like you to read some information about the study, so that you can decide for sure whether you want to be involved. You can view the info at www.stubit.co.nz, or we can send it out to you.

2.01 How would you like to read the study information? (Select one only)
- Dropdown list
- Read online
- Email it to me
- Post it to me

If selected online, direct immediately to PIC online, after displaying…

You will now receive a video clip asking for your consent, we cannot progress your application until you reply to us with a txt message saying the exact words ‘I consent’ (txt to 5552). Your handset will need to be capable of downloading and opening the video clip for you to be in the study. All the video clips you receive from us will be downloaded free of charge to you.

We ask that you read all the study Information on the homepage before you send back your consent message. After we receive your consent txt msg we can personalise your program.

Hope to have you on board and ready to quit soon. If you have any further queries you can email us at info@stubit.co.nz.

If selected email or post, link to Form B fields
2.02 Please type in your email/postal address (free text)

Confirmation box appears:
2.03 You wrote ………………………….. Is this correct?
- Yes (continue)
- No (allow to edit then continue)
Appendix 9: Chapter 4: Pilot study participant information sheet

PARTICIPANT INFORMATION SHEET
Principal Investigator: Dr Robyn Whittaker 09 3737599 x 84766
Study Manager: Mary Ellis-Pegler 09 373 7599 x 89008
You are invited to take part in a small pilot study to test a new intervention to help young people stop smoking using text messages and video clips over a four week period. Your participation is entirely voluntary (your choice). You do not have to take part in this study. If you choose not to take part in this study you will not be affected in any way. If you agree to take part in this pilot study, you may withdraw at any time, without having to give a reason. To assist you in making a decision about participating, we ask that you read this information sheet.

Who is coordinating this study?
The study is co-ordinated by the Clinical Trials Research Unit (University of Auckland).

What is the aim of this study?
To test the content and delivery systems of a newly developed intervention to assist young people to stop smoking. This pilot study will involve a small number of young people going through the mobile phone based multimedia (video clips/txt messages) quit smoking programme. At the end of the programme we will seek your opinion on the content, what was/was not helpful, and what changes you would suggest particularly with regards to style of content, volume/frequency of messages and quality of clips.

Why have I been invited to take part?
You have been invited to take part in this pilot study because:
- you are aged 16yrs or older
- you use a video capable mobile phone on the Vodafone network.
- you are English speaking
- you have agreed to receive this shortened one month programme and to complete a questionnaire providing feedback at the end of this period.

Where will the study take place?
The study will take place at the Clinical Trials Research Unit in Auckland.

How long will the study take?
Each participant will be involved in the study for one month.

What is involved if I take part?
If you decide to take part in this study you will be sent a text message asking for your permission to be involved. You will then be asked to complete some baseline questions either online or with a research assistant over the telephone. You will receive two messages per day for four weeks and at the end of four weeks you will be asked to complete an online questionnaire (or be called by an interviewer if you do not have internet access). This will include questions about: your enjoyment of the programme; features used/not used and liked/not liked; types of content that were considered not/helpful; any issues with receiving the messages; appropriateness of the duration of the programme; suggestions for improvements to the programme.

Will there be any costs involved?
There is no cost for receiving the programme.

What are the risks and benefits of this study?
There are no risks in being involved in the study. If you found the shortened pilot programme helpful and would like to be involved in the main study which is
recruiting from Sept 2007, you will be given this opportunity provided you are eligible to take part.

**Compensation**
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by the Accident Compensation Corporation (ACC) legislation. ACC cover is not automatic and each case is assessed by ACC, according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are a wage earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, please contact your nearest ACC office or ask us for more information before you agree to take part.

**Confidentiality**
The study files and all other information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study. The information will be kept securely at the Clinical Trials Research Unit, University of Auckland and destroyed after 15 years according to national research guidelines. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act. All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

**Results**
The pilot study results will be available on our website @ www.stubit.co.nz by the end of 2007.

**Ethical Approval**
This study has received ethics approval from the Northern X Regional Ethics Committee on 19/04/2007.

**Your Rights**
If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health and Disability Advocate on 0800 555 050. You are encouraged to ask questions at any time during the study. You can contact the study manager, Mary Ellis-Pegler on:

0800 STUB IT (0800 788 248)
info@stubit.co.nz

Please keep this sheet for your information. Thank you for taking the time to read about this study.

**INFORMED CONSENT FORM**
Principal Investigator: Dr Robyn Whittaker 09 3737599 x 84766
Study Manager: Mary Ellis-Pegler 09 373 7599 x 89008

I understand the information sheet for volunteers taking part in this study dated April 3 2007 Version 2, which has been read and discussed with study researchers, and designed to test the content and delivery systems of a new video-based multimedia mobile phone programme being developed to help young people quit smoking. I have had the opportunity to discuss this study with a Research Assistant and I am satisfied with the answers I have been given.
I have had the opportunity to use whanau/family support or a friend to help me ask questions and understand the study.  
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without having to give a reason.  
I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.  
I understand the compensation provisions for this study.  
I have had time to consider whether to take part and I know whom to contact if I have any questions about the study.  
I agree to complete the feedback questionnaire online at the end of the one month study period.  
I understand that there will be no personal details that identify me (such as my name, date of birth, address) on any forms.  
I agree to update study staff with my contact details should they change during the one month pilot study.  
I understand that any data collected as part of this study will be stored securely for 15 years at the Clinical Trials Research Unit, University of Auckland in accordance with the Privacy Act, 1994. After this time the information will be safely destroyed.  
I understand that any information collected, as part of this study will not be used for any other purpose, without my permission and ethical approval, nor given to any other third party outside of the research team.  

**Consent to take part**  
If you agree to these statements and would like to take part in the study, txt the exact words ‘I consent’ to 5552 now.  
If you do not wish to take part, txt the exact words ‘I do not consent’ to 5552.  
If you need more information to help you decide do not hesitate to contact the study manager on:  
0800 STUB IT (0800 778 248)  
info@stubit.co.nz  

This study has received approval from the Northern X Regional Ethics committee.
Appendix 10: Chapters 4&5: Form B

FORM B: Baseline Data Collection - Contact Details

Reg num: (4 boxes) Initials:(3 boxes)

Participant ID: (mobile no, up to 14 boxes more)

DOB: (10 boxes e.g. 01/10/1980)

_____________________________________________________________________

The purpose of this form is to collect as many contact details from eligible participants as possible.

Hello and welcome back to STUB IT, thanks for agreeing to take part, you won’t regret it!
You are nearly there, we just need to ask you to complete this form so that we can personalise your quit smoking programme. It will take 10 minutes so please ensure you have the time to do it now as you will need to finish the form once you have started it (i.e. in one sitting).

1. Contact details:
   1.01 First Name…………….
   1.02 Surname……………..
   1.03 House number and street ………………………………………
   1.04 Suburb …………………………………………..
   1.05 Town/City ………………………………………….. (optional)
   1.06 Postcode……………………………………… (optional)

   If your postal address is different from that above, please supply here
   1.07 ………………………………………………………… (allow up to 4 fields)
   (may be prepopulated from Form A)

   1.08 Home phone number ……………………………… (optional)

   1.09 email address …………………………………….. (optional)
   (may be prepopulated from Form A)

Work contact details: (optional)

   1.10 Company ……………………………………………
   1.11 Number & Street ………………………………
1.12 PO Box/Private Bag....................................................
1.13 Town/City ..............................................................
1.14 Postcode ................................................................
1.15 Work telephone number ..........................................

2. Secondary contact details: (someone NOT living at the same address)
2.01 First Name.............
2.02 Surname...............  
2.03 Relationship (e.g. friend, mother).............................
2.04 Secondary contact: phone number..........................
2.05 Secondary contact: alternative number (e.g. mobile)....
2.06 Secondary contact email address............................
FORM C: Baseline Data Collection - Randomisation

Reg num: (4 boxes)  Initials: (3 boxes)
Participant ID: (mobile no, start with 6421 then up to 14 boxes)
DOB: (10 boxes e.g. 01/10/1980)

RA screen
The purpose of this form is to collect the remainder of baseline data from consented participants, in order to randomise participants to Intervention or Control group. If they do not complete the form, the Research Assistant will call them and complete over the phone.

(Form to have frequent points where data is submitted in case participants don’t fully complete the form online)

For RA screen only:
Is this a good time for you?
01 Yes
02 No

02 If No, when would be a better time for me to call you back? (pop up calendar, participant selects date then time box comes up (“please enter a time between 8am-8pm”) Thank-you, a researcher will be in touch at the requested time.

1.01 Can I check that you have read the information about the study and you are a daily smoker with a Vodafone mobile phone who wants to try quitting in the next three weeks?

Yes – continue with 1.02

No - If No, change their status to ineligible

Ineligible:

Unfortunately, due to our strict entry criteria, you are not eligible to take part in the STUB IT study. If you require assistance with quitting please visit the Quitline website for further assistance - www.quit.org.nz. We appreciate your time today.

End here.

1. Participant Details:

1.02 Which ethnic group do you most identify with?
(Select one only)
NZ Māori
NZ European
Other European
Samoan
Cook Island Māori
Tongan
Niuean
Chinese
Indian
Other

1.03 If other (please specify) .............................................

1.04 Are you: (select one only)
Male
Female

1.05 What is your current employment status? (Select one only)
Fulltime employment
Part-time employment
Home-maker
Retired
Social security
Student
Unemployed
Don’t wish to answer
Other

1.06 If other (please specify) .............................................

1.07 What was your total income in the previous 12 months? (Drop down list, select one only)
Less than 15,000
Between 15,000 and 30,000
Between 30,001 and 45,000
Between 45,001 and 60,000
Over 60,000
Don’t wish to answer

About your cigarette smoking

2.01 At what age did you start smoking cigarettes? yrs (2 boxes)

What sort of cigarettes do you smoke? (can answer yes to more than one)

2.02 Ready-made (or manufactured or tailored) cigarettes
Yes
No

2.03 How many cigarettes do you smoke on average?
Per day (2 boxes)

2.04 Roll-your-own cigarettes (or loose tobacco)
Yes
2.05 How many ryo cigarettes do you smoke on average? 
   Per day (2 boxes)

If Yes to 2.04

2.06 How much loose tobacco do you use on average? For example,
   a 30gram pack every 5 days ..........gram pack every .......days
   (2 boxes)

2.07 How much do you spend on your smoking on average? $(6 boxes) per week

2.08 How soon after you wake up do you smoke your first cigarette? (Select one only)
   Within 5 minutes
   6 – 30 minutes
   31 – 60 minutes
   After 60 minutes

2.09 Have you ever tried to quit smoking, but couldn’t? (Select one only)
   Yes
   No
   (If No go to 2.12)

2.10. Approximately how many times have you tried to quit before? (3 boxes)

2.11 If you have quit before, what is the longest time you have stayed off cigarettes?
   ....... (2 boxes) plus dropdown list for units days weeks months years

2.12 Do you smoke now because it is really hard to quit? (Select one only)
   Yes
   No
   Don’t know

2.13 Have you ever felt like you were addicted to tobacco?
   Yes
   No

2.14 Do you ever have strong cravings to smoke?
   Yes
   No

2.15 Have you ever felt like you really needed a cigarette?
   Yes
   No

2.16 Do you find it hard to keep from smoking in places where you are not supposed to?
   Yes
   No

When you have tried to stop smoking (or if you haven’t used tobacco for a while),
did you feel...(please answer all questions)

2.17 it was hard to concentrate? Yes  No
2.18 more irritable? Yes  No
2.19 a strong need or urge to smoke? Yes  No
2.20 nervous, restless or anxious? Yes  No

System calculates HONC score
2.09 Yes = 1 No = 0
2.12 Yes = 1 No/don’t know = 0
2.13 Yes = 1 No = 0
2.14 Yes = 1 No = 0
2.15 Yes = 1 No = 0
2.16 Yes = 1 No = 0
2.17 Yes = 1 No = 0
2.18 Yes = 1 No = 0
2.19 Yes = 1 No = 0
2.20 Yes = 1 No = 0

Add up to get total score out of 10 & store in database as HONC score

Have you ever used any of the following medications to help you stop smoking? (please answer all questions)
2.21 Nicotine gum Yes No
2.22 Nicotine patches Yes No
2.23 Nicobrevin Yes No
2.24 Zyban Yes No
2.25 Nortriptyline (or Norpress) Yes No
2.26 Other Yes No
2.27 If other please specify

2.28 Have you ever used Quitline to help you stop smoking? Yes  No

2.29 How confident are you that you can quit this time? (Select one only)
☐ 0% - not at all confident
☐ 10%
☐ 20%
☐ 30%
☐ 40%
☐ 50% - somewhat confident
☐ 60%
☐ 70%
☐ 80%
☐ 90%
☐ 100% - completely confident

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2.30 Why do you want to quit at this time? (select one only)
Because this programme will be fun or interesting
Because I believe it will be good for me
Because I feel that I have to/ I don’t have a choice
I will do the programme but I am not sure it is worth it
I don’t know

2.31 In the past week, how much of the time have you felt the urge to smoke?
(Select one only)
Not at all
A little of the time
Some of the time
A lot of the time
Almost all of the time
All of the time

2.32 How strong have the urges been? (Select one only)
No urges
Slight
Moderate
Strong
Very strong
Extremely strong

3. About your mobile phone usage

3.01 On average how much do you spend on (all) your mobile phone(s) per month?
$10 or less
$11 - $30
$31 - $50
$51 – $100
$101 – $150
$151 – $200
$200 or over
Decline to answer

Do you use (please answer all questions)

<table>
<thead>
<tr>
<th></th>
<th>video calling</th>
<th>video messaging/MMS</th>
<th>games on your phone</th>
<th>music on your phone</th>
<th>downloads from the web onto your phone</th>
<th>browse the internet on your phone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes  No</td>
<td>Yes  No</td>
<td>Yes  No</td>
<td>Yes  No</td>
<td>Yes  No</td>
<td>Yes  No</td>
</tr>
</tbody>
</table>

One of the most effective ways to give up smoking is to set a day when you will give up smoking, this is called a Quit Day. We will be sending you messages to prepare you for your Quit day so we suggest that you select a day, not within the next 7 days but in the next 1 – 3 weeks.
4. About your Quit day

4.01 My Quit Day is…
Pop up calendar that shows today’s date and only allows dates between 7 and 21 days from today to be selected

(Validate it is within 7 to 21 days of today’s date)

So, to confirm, your Quit Day will be starting from when you wake up on that day. You will be sent messages to help you get ready for your Quit Day and to remind you when it is.

If participant tries to move on without setting a quit date:
We realise it can be hard to set a date, but your chances of quitting are much higher if you set a date yourself, and we will use this date to send you the most appropriate messages. Think about a day when you are less likely to be stressed or tempted to smoke. Would a weekend be easier or a weekday? Which day would be best for you?
Go back to question

Do not allow randomisation without a quit date
Report on participants who leave the form at this point without setting a quit date

5. Programme Details

Are you concerned about any of the following during your quit attempt? (please answer all questions)

5.01 Putting on weight Yes No
5.02 Peer pressure Yes No
5.03 Feeling isolated Yes No
5.04 Stress Yes No
5.05 Family pressures Yes No
5.06 Failing at your quit attempt Yes No

In general we will send you messages within an hour of the following times. However if you would like to change these times you can do so now – consider when you might most need some extra support from us, such as the time you usually have the hardest cigarettes to give up – first thing in the morning or after work?).

5.07 Monday – 9:00am and 5:00pm
Tuesday - 9:00am and 5:00pm
Wednesday – 9:00am and 5:00pm
Thursday - 9:00am and 5:00pm
Friday – 9:00am and 5:00pm
Saturday - 9:00am and 5:00pm
Sunday - 9:00am and 5:00pm

[Rules: Must have two times. Two times must be at least one hour apart.

5.08 What username would you like to be known by for the study? (Compulsory question, allow up to 12 characters including spaces)
You made it! good work, you have now completed all our questions which means you will start receiving your STUB IT program later today. The computer will randomly select which group you are allocated to. The first messages you receive will tell you about the programme that you will be receiving. As we mentioned earlier, we will be in touch with you regularly to find out how you are going, until the end of the 6mth programme. It is really important that we can check in with you at the end so if you change any of your contact details please let us know (www.stubit.co.nz). Everyone who stops smoking during the programme will be asked to take a test to confirm whether or not they are smoking. Keep in touch and good luck with quitting smoking!

STUB IT team

System randomises to group - Form can be edited by RA/SM but not by participant

Intervention Group only

Now you can select some of the features of your programme.

6.01 You will be sent video messages from other people who are quitting smoking. You can choose one or two people to receive messages from now. You will be able to add others later if you want. If you don’t want to choose now, we will select one person for you. (Select one or two)

[Video stills or clips to view and select. Disallow more than 2 models selected]

Which of the following would you be particularly interested in having sent to you as part of this programme? (please answer all questions)

- 6.02 Cartoon/animation  Yes  No
- 6.03 Games  Yes  No
- 6.04 Music  Yes  No

If yes, 6.05 What sort of music do you like best? (select one or two only)

Dropdown list
Hiphop
Rap
Rock
Pop
Metal
Funk
Electronica
Ska/reggae/dub
Jazz
Classical
Country
Ethnic/folk
### Appendix 12: Chapter 4: pilot study programme schedule

**STUB IT PILOT**

<table>
<thead>
<tr>
<th>Registration process</th>
<th>12pm on appropriate day</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>txt -Consent</td>
<td>ID txt1</td>
<td>once become ‘Eligible’</td>
</tr>
<tr>
<td>txt -Consent reminder</td>
<td>ID txt2</td>
<td>next 2 days at 12pm if hasn’t responded or become ‘Consented’</td>
</tr>
<tr>
<td>txt -Consented response</td>
<td>ID txt3</td>
<td>on receipt of proper consent response</td>
</tr>
<tr>
<td>txt -complete forms reminder</td>
<td>ID txt4</td>
<td>next 2 days at 12pm if hasn’t completed Forms B/C</td>
</tr>
</tbody>
</table>

**Once submitted Forms B/C programme commences as below:**

<table>
<thead>
<tr>
<th>Day before QD</th>
<th>ID</th>
<th>First message - random time between 8:30am-9:30am (or ptpt selected period)</th>
<th>ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day before QD</td>
<td>RTquitday1</td>
<td>- 11:34am</td>
<td>49</td>
</tr>
<tr>
<td>Quit Day</td>
<td>RTpostquit3</td>
<td>– patches</td>
<td>100</td>
</tr>
<tr>
<td>Day</td>
<td>RTquitday2</td>
<td>- evening</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>RTpostquit5</td>
<td>- 1st cig of day, gym</td>
<td>101</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day</th>
<th>ID</th>
<th>Second message - random time between 4:30pm-5:30pm (or ptpt selected period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>on submission Forms B/C</td>
<td>32</td>
<td>welcome video clip</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>text message (ID txt 5) (34)</td>
</tr>
<tr>
<td>countdown 1</td>
<td>35</td>
<td>Crave instruction video clip (35)</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>text message (ID txt 6) (37)</td>
</tr>
<tr>
<td>countdown 2 optional</td>
<td>39</td>
<td>RTcountdown2 - 2nd time, cravings 1st few days</td>
</tr>
<tr>
<td>countdown 3 optional</td>
<td>41</td>
<td>RTcountdown5b - why quitting family reasons</td>
</tr>
<tr>
<td>countdown 4 optional</td>
<td>43</td>
<td>RTcountdown4 - relapsed last time, stress</td>
</tr>
<tr>
<td>countdown 5 optional</td>
<td>45</td>
<td>lungcancer.3pg - voiceover, ashtray coffin</td>
</tr>
<tr>
<td>countdown 6 optional</td>
<td>47</td>
<td>RTcountdown8 - tomorrow is the day</td>
</tr>
<tr>
<td>Day</td>
<td>49</td>
<td>RTquitday1 - 11:34am</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>RTpostquit3 – patches</td>
</tr>
<tr>
<td>QD+1</td>
<td>102</td>
<td>RTpostquit6 - morning ritual, coffee</td>
</tr>
<tr>
<td>QD+2</td>
<td>104</td>
<td>RTpostquit1 - shitty</td>
</tr>
<tr>
<td>QD+3</td>
<td>106</td>
<td>RTpostquit4 - lunchtimes</td>
</tr>
<tr>
<td>QD+4</td>
<td>108</td>
<td>RTpostquit2 - hard to concentrate</td>
</tr>
<tr>
<td>QD+5</td>
<td>110</td>
<td>txt - send us yr best quitting tips (ID txt 9)</td>
</tr>
<tr>
<td>QD+6</td>
<td>112</td>
<td>smoking_ashtray.mpg - voiceover contents cigs</td>
</tr>
<tr>
<td>QD+7</td>
<td>114</td>
<td>RTpostquit9a - stress relief, music walk</td>
</tr>
<tr>
<td>QD+8</td>
<td>116</td>
<td>RTpostquit9b - slip</td>
</tr>
<tr>
<td>QD+9</td>
<td>118</td>
<td>RTpostquit10 - friends &amp; family support</td>
</tr>
<tr>
<td>QD+10</td>
<td>120</td>
<td>txt - send us yr best quitting tips 2 (ID txt 10)</td>
</tr>
<tr>
<td>QD+11</td>
<td>122</td>
<td>penny guilt.wmv</td>
</tr>
<tr>
<td>QD+12</td>
<td>124</td>
<td>RTpostquit12 - not so good, cough, $ saved</td>
</tr>
<tr>
<td>QD+13</td>
<td>126</td>
<td>RTpostquit13 - cousins 21st hung out w kids</td>
</tr>
<tr>
<td>QD+14</td>
<td>128</td>
<td>RTpostquit11- support from smkg friends</td>
</tr>
<tr>
<td>QD+15</td>
<td>130</td>
<td>oneinfour.3pg - ninja, cancer deaths</td>
</tr>
<tr>
<td>QD+16</td>
<td>132</td>
<td>RTPostquit18 - neice video message</td>
</tr>
<tr>
<td>QD+17</td>
<td>134</td>
<td>RTPostquit17 - benefits, $$</td>
</tr>
<tr>
<td>QD+18</td>
<td>136</td>
<td>RTpostquit20 – dad</td>
</tr>
<tr>
<td>QD+19</td>
<td>138</td>
<td>hiseyes.3pg</td>
</tr>
<tr>
<td>QD+20</td>
<td>140</td>
<td>RTPostquit19 - CI dance enjoying life</td>
</tr>
<tr>
<td>QD+21</td>
<td>142</td>
<td>RTPostquit 23 - buddy slips</td>
</tr>
<tr>
<td>QD+22</td>
<td>144</td>
<td>smoker in tree shorter.mp4</td>
</tr>
<tr>
<td>QD+23</td>
<td>146</td>
<td>roadcrash.3pg - student,deaths</td>
</tr>
<tr>
<td>QD+24</td>
<td>148</td>
<td>farewell and thanks text (ID txt 17)</td>
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<td>File name</td>
<td>Summary</td>
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</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>RTcountdown1</td>
<td>Done with smoking - watched dad &amp; don’t want to be like him. Day 1 - Time to give up</td>
<td></td>
</tr>
<tr>
<td>RTcountdown2</td>
<td>2nd time quitting, know what to expect</td>
<td></td>
</tr>
<tr>
<td>RTcountdown3</td>
<td>Feeling good today - re thinking about what worked last time</td>
<td></td>
</tr>
<tr>
<td>RTcountdown4</td>
<td>Why relapsed - next time I get stressed I wont reach for a cigarette</td>
<td></td>
</tr>
<tr>
<td>RTcountdown5a</td>
<td>Document why giving up. Pregnant. Scary but good reason to give up</td>
<td></td>
</tr>
<tr>
<td>RTcountdown5b</td>
<td>STUB IT: feel a craving &amp; need xtra help? txt us on 5552 4 a craving tip. Txt either CRAVE STRESS, CRAVE BORED, CRAVE MATES, CRAVE DRINKING or just CRAVE</td>
<td></td>
</tr>
<tr>
<td>RTcountdown6</td>
<td>Concerned about mood swings and grumpiness ‘witch’ but looking forward to smelling nicer and having more money</td>
<td></td>
</tr>
<tr>
<td>RTcountdown7</td>
<td>Worried about 1st cigarette in morning - guess have to go for run</td>
<td></td>
</tr>
<tr>
<td>RTcountdown8</td>
<td>Tomorrow D day/quit day. Bit nervous. Feeling good. Throw away cigarettes tonight</td>
<td></td>
</tr>
<tr>
<td>RTquitday1</td>
<td>Quit Day - 11:34am. Made it through morning ‘hanging out’ period. Txt everyone to say its my quit day</td>
<td></td>
</tr>
<tr>
<td>RTquitday2</td>
<td>End of day - not feeling as great. Withdrawal symptoms creeping in but going to movies with Tania.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit1</td>
<td>Today not a good day - feeling effects of ‘hanging out’ really shitty/grumpy</td>
<td></td>
</tr>
<tr>
<td>RTpostquit2</td>
<td>Another hard day - figty, drinking lots of coffee, cant concentrate. Take it one day at a time, it will get better eventually</td>
<td></td>
</tr>
<tr>
<td>RTpostquit3</td>
<td>Having big cravings, getting difficult but optimistic. Tracy tried patches so something to think about</td>
<td></td>
</tr>
<tr>
<td>RTpostquit4</td>
<td>Lunch times were hard. Body/brain knows its smoke time. Didn't go outside. Read magazines, cleaned desk - cleanest in building. Feel good.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit5</td>
<td>Mornings really hard - signed up at Gym and have gym buddy. Good motivator</td>
<td></td>
</tr>
<tr>
<td>RTpostquit6</td>
<td>Made change to morning ritual. Don't have coffee. Get to sleep in</td>
<td></td>
</tr>
<tr>
<td>RTpostquit7</td>
<td>Hit the town last night. Did not fail. Danced. Didn't hang around smokers. Good bar and good music. Gym gives more energy</td>
<td></td>
</tr>
<tr>
<td>RTpostquit8</td>
<td>So pleased with myself. Last night went out for dinner with Tracy. Will get manicure and pedicure with money saved.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit9a</td>
<td>Come to a realisation that used cigarettes as a way to relieve stress. But it didn’t help at all. Go for a walk or listen to music instead. Not missing cig.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit9b</td>
<td>Only took one cig last time. If I have a slip up this time I know that I wont go back to smoking.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit10</td>
<td>Friends and family have been so good. Txting and calling. Dad is even thinking of giving up.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit11</td>
<td>Surprising that smoking friends have been the most supportive. Don’t smoke around me. Been really great.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit12</td>
<td>Not feeling so good today. Developed a cough. But bought new pair of earrings with money saved from not smoking.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit13</td>
<td>Went to cousins 21st. 1st family get together. Smoking aunties not attractive. Hung out with the kids</td>
<td></td>
</tr>
<tr>
<td>RTpostquit14</td>
<td>Had a big fight with boss today. Felt like a cigarette. Rang mum instead, reminded me why.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit15</td>
<td>Starting to feel good. Sense of achievement. Feeling better physically. Hair smells better. Good reasons to carry on.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit17</td>
<td>Starting to notice the benefits. Having more money but still poor. Feeling good and sense of achievement.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit18</td>
<td>Video message of niece. She smells nice now. Play video message when feeling down.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit19</td>
<td>Gone back to Cook Island dance. Feeling good. Not thinking about smoking.</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>RTpostquit20</td>
<td>Thinking about Dad. Start to encourage him to think about quitting. Like to know he will be around to see baby grow up.</td>
<td></td>
</tr>
<tr>
<td>RTpostquit22</td>
<td>Recently met someone who is also quitting - been going through same obstacles. Txt eachother for encouragement</td>
<td></td>
</tr>
<tr>
<td>RTpostquit23</td>
<td>Just got a call from friend. She had a slip up and had a puff. Talked her through it. Helped motivate her - it's a good feeling.</td>
<td></td>
</tr>
<tr>
<td>txt -Consent</td>
<td>STUB IT: Hi &amp; thx 4 yr interest in our STUB IT study. Once u have read the info sheet @ <a href="http://www.stubit.co.nz">www.stubit.co.nz</a> text 'I consent' to 5552 to continue</td>
<td></td>
</tr>
<tr>
<td>txt -Consent reminder</td>
<td>STUB IT: r u still interested in our stop smoking study? If so text 'I consent' to 5552 to continue</td>
<td></td>
</tr>
<tr>
<td>txt -Consented response</td>
<td>STUB IT: Thx 4 joining the study. Now go 2 <a href="http://www.stubit.co.nz">www.stubit.co.nz</a> 2 cmplte yr reg form, thn we can strt sending u our quit smkng progrme. U need yr mob # 2 logon.</td>
<td></td>
</tr>
<tr>
<td>txt -complete forms reminder</td>
<td>STUB IT: Hey there! Don’t stop now - remember 2 go 2 <a href="http://www.stubit.co.nz">www.stubit.co.nz</a> 2 fill in yr details, thn we can strt sndng u our quit smkng progrme!</td>
<td></td>
</tr>
<tr>
<td>txt -Welcome message</td>
<td>STUB IT: Welcome to our pilot study. U will get 2 messages/day 4 next 4 wks. Any probs call 0800 STUBIT.</td>
<td></td>
</tr>
<tr>
<td>txt -Instructions - crave</td>
<td>STUB IT: feel a craving &amp; need xtra help? txt us on 5552 4 a craving tip. Txt either CRAVE STRESS, CRAVE BORED, CRAVE MATES, CRAVE DRINKING or just CRAVE</td>
<td></td>
</tr>
<tr>
<td>txt - other morning ideas</td>
<td>STUB IT: other morning ideas - go 4 walk, cook &amp; eat proper breakfast, sleep in so u have 2 rush &amp; have no time 2 smk</td>
<td></td>
</tr>
<tr>
<td>txt - where to get nrt</td>
<td>STUB IT: if u r finding it tuff &amp; would like 2 try patches or gum 2 relieve withdrawal symptoms - ring quitline 0800 778778</td>
<td></td>
</tr>
<tr>
<td>txt - send us yr best quitting tips</td>
<td>STUB IT: take a video of yrself telling us yr best craving buster. Email to <a href="mailto:info@stubit.co.nz">info@stubit.co.nz</a> &amp; we'll put best ones on the website 4 all 2 c</td>
<td></td>
</tr>
<tr>
<td>txt - send us yr best quitting tips 2</td>
<td>STUB IT: think u can do better? Make yr 30sec vid on yr best quitting tips 4 others, send to <a href="mailto:info@stubit.co.nz">info@stubit.co.nz</a>. If its good we’ll use it</td>
<td></td>
</tr>
<tr>
<td>txt - stress relievers</td>
<td>STUB IT: other stress relievers - exercise, take time out just 4 yrself, relax all yr muscles, download some happy music, yell!</td>
<td></td>
</tr>
<tr>
<td>txt - what to do if slip</td>
<td>STUB IT: its best not 2 have even 1 puff - but don’t panic if u do, just try again. U can resist the temptation 2 go back 2 smkg</td>
<td></td>
</tr>
</tbody>
</table>
**txt - take vid of family**

STUB IT: take a video of someone important to you reminding you why you are quitting. Save it on your phone & replay in times of need.

**txt about adding up $ saved & treat**

STUB IT: Have you tried adding up how much you have saved by not smoking? What could you buy with it to treat yourself?

**txt about slips**

STUB IT: If you slip, resist the temptation to go back to full smoking. Think about how much effort you have put in so far & keep going.

**txt - coming 2 end**

STUB IT: Your programme is coming to an end - hope we have helped. Stick with it & if you need more help try www.quit.org.nz.

**txt - farewell and thanks**

STUB IT: Today is the last day of your programme. Thank you very much for participating. We will be in touch to ask how you liked it.

**txt - How to opt out**

STUB IT: Hey! If you want to stop getting messages from us, you can opt out of the programme by texting STOP to 5552 or email info@stubit.co.nz or call 0800 STUB IT.

**txt - Withdrawn**

STUB IT: You have withdrawn from STUB IT, you will no longer receive messages from us, however we will need to contact you at the end of 4 weeks to see how you found the programme.

**txt about sending in videos**

STUB IT: If you reckon you've got some helpful craving tips, email them to info@stubit.co.nz, we may use them to help others going through the same thing.
Appendix 13: Chapter 4: Pilot study questionnaire

1. Did you like the programme in general? (tick one only)
   - Yes
   - Most of the time
   - Not at all

2. What did you like MOST about the programme? *(box for comment)*

3. What did you like LEAST about the programme? *(box for comment)*

4. We are interested in finding out if you liked or disliked particular aspects of the video clips where you watched someone go through the process of quitting. (tick yes, no, or unsure boxes for each)
   - Did you like…
     - These type of video clips
     - How the person talked in the clips
     - The way the person looked
     - The way the videos were shot
   *(box for comment)*

5. Could you relate to what the person was saying in the video clips? (tick one only)
   - Yes
   - Most of the time
   - Not at all
   *(box for comment)*

6. Did you find the person in the video clips to be believable (prompt: did they seem ‘real’ to you)? (tick one only)
   - Yes
   - Most of the time
   - Not at all
   *(box for comment)*

7. Did you like the other type of video clips (the ones that did NOT have the person quitting in them)?
   - Yes
   - Most of the time
   - Not at all
8. Generally speaking, what did you do with the clips you liked? Did you… (tick one only)
   - delete them after viewing
   - forward them onto mates
   - save them and watch them again later
   - Other (please explain)
   (Box for comment)

9. What did you think of the daily quantity of messages you received? (tick one only)
   - Too many
   - About right
   - Not enough
   (box for additional comment)

10. What times during the day did you NOT like to receive messages? (tick as many that apply)
    - early morning (6am-10am)
    - lunchtime (10am-2pm)
    - afternoon (2pm-6pm)
    - evening (6pm-10pm)
    - late at night (10pm-2am)
    - None of the above
    - Anytime suited
    (box for additional comment)

11. Generally speaking, when did you view the clips? (tick one only)
    - As soon as they arrived
    - A few minutes after they arrived
    - A few hours after they arrived
    - Not at all
    (box for additional comment)

12. Was the language in the video clips understandable? (tick one only)
    - Yes
    - Most of the time
    - No, please explain (box for comment)
13. Was the language **appropriate**? (tick one only)
   - Yes
   - Most of the time
   - No, please explain *(box for comment)*

14. Was the **quality** of the video clips adequate? (tick one only)
   - Yes
   - Most of the time
   - No, please elaborate *(box for comment)*

15. Were there any technical issues that you experienced? (tick as many that apply)
   - No issues
   - the clips often arrived at the same time
   - the size of the files
   - I couldn’t open them
   - quality of picture
   - quality of sound
   - Other, please explain *(box for comment)*

16. Would you like to have MORE, LESS, or THE SAME amount of the following things in the programme? (tick more, less, or the same to each of the following items)
   - Text messages
   - The video clips of the person stopping smoking
   - The other video clips
   - Anti tobacco industry stuff
   - The crave messages
   - The facts and quitting tips
   *(box for additional comments)*

17. Would you have liked to have received the following additional components in the programme: (tick yes, no or maybe for each of the following items)
   - Jokes
   - Music
   - Cartoons/animation
   - Polls/Quizes
   - Games
18. Would you like to have had some more/different people to watch (tick yes, no, unsure)
   (box for comment)

19. Did you stop smoking during the programme? (tick one only)
   - Yes
   - No – Go to Q. 22

20. Do you think the programme helped you to stop smoking? (tick one only)
   - Yes
   - No – Go to Q. 22
   (box for additional comments)

21. What about the programme helped you the most?
   (box for additional comments)

22. What aspects of the programme do you feel are helpful in stopping smoking (even if you didn’t stop smoking this time)? (tick all that apply)
   - Text messages
   - The video clips of the person stopping smoking
   - The other video clips
   - Anti-tobacco industry stuff
   - The crave messages
   - The facts and quitting tips
   - Other
   If other, (box for additional comments)

23. Would you like to receive the pilot study results? (tick one only)
   - Yes
   - No
   If yes, (box for writing email/postal address)
## Appendix 14: Chapter 4: Example of final intervention programme

<table>
<thead>
<tr>
<th>Clip type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Txt</strong></td>
<td>txt that is associated with/comes after particular video (will be diff. for each program)</td>
</tr>
<tr>
<td><strong>txt tip</strong></td>
<td>general quitting advice</td>
</tr>
<tr>
<td><strong>RM txt</strong></td>
<td>txt sent in maintenance period about selected RM - (if more than 1 RM selected during program then txt is about first one)</td>
</tr>
<tr>
<td><strong>RM video</strong></td>
<td>Video diary from role model</td>
</tr>
<tr>
<td><strong>Vid &amp; Animation vid</strong></td>
<td>video from 'other' content</td>
</tr>
<tr>
<td><strong>Instruction vid</strong></td>
<td><strong>How to…'</strong></td>
</tr>
<tr>
<td><strong>Data collection txt</strong></td>
<td>due at quitday 4wks and 12wks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>prog_id</th>
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<td>2</td>
<td>1</td>
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<td>Instruction Video</td>
<td>1001</td>
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<td>BK_countdown_2</td>
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<td>Role Model Video</td>
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<td>BK_quitday_6</td>
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<tr>
<td>#</td>
<td>Day</td>
<td>Time</td>
<td>Activity/Resource</td>
<td>URL</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 21 | 2 days    | 2    | 21
|    | before    | 5    | quit day                                  | 184                  |
|    | quit day  | 2    | **STUB IT**: reminder that yr quit day is 2 days away. Write down wot u h8 about smking & put it where u can see it! |
|    |           |      |                                           |                      |
| 236| 2         | 6    | quit day                                  | 1006                 |
|    | 1         |      | **/role_models/kate/BK_quitday_7.3gp**    |                      |
| 22 | 2         | 6    | quit day                                  | 25                   |
|    | 2         |      | **STUB IT**: Quit day tomorrow! Make a plan 4 th day 2 & keep busy! Distraction is th key. **STUB IT**: It's yr Quit day, check yr plan 4 th day, go hard & KEEP BUSY!! |
| 23 | quit day  | 3    | 1                                          | 48                   |
|    |           | 1    | **/role_models/kate/BK_postquit_8.3gp**    |                      |
| 239| quit day  | 3    | 1                                          | 1009                 |
|    |           | 2    | **/role_models/kate/BK_postquit_9.3gp**    |                      |
|    |           |      | **data collection txt**                    |                      |
|    |           |      | **STUB IT**: how confident r u tht u can quit? Txt answer from 0-100%. 0% = not confident, 50% = semi confident, 100% = completely confident. Txt to 5552 NOW! |
| 241| intensive | 3    | BK_postquit_9                              | 1011                 |
|    |           | 2    | **/role_models/kate/BK_postquit_10.3gp**   |                      |
| 242| Crave     | 3    | BK_postquit_9                              | 1012                 |
|    |           | 2    | **/instructions/intensive/CRAVE_intensive.3gp** |                      |
|    |           |      | **STUB IT**: If u want extr quit suprt, chek out th online quit community @ www.quit.org.nz. 0800 778778 for low cost patches, gum, support & advice. |
|    |           |      | **/instructions/intensive/ChangingRM_intensive** |                      |
| 244| Changing Program | 3 | BK_postquit_10                              | 1015                 |
|    |           | 3    | **/role_models/kate/BK_postquit_12.3gp**   |                      |
| 245|            | 4    | social smoking.3gp                         | 1016                 |
|    |            | 2    | **/crave/drinking/social_smoking**         |                      |
| 246| Quilline   | 3    | social smoking.3gp                         | 1016                 |
|    |           | 3    | **/crave/drinking/social_smoking**         |                      |
|    |           | 1    | **/crave/drinking/social_smoking**         |                      |
| 25 | other morning ideas - go 4 walk, cook & eat proper breakfast, sleep in so u have 2 rush & have no time 2 smk | 28 |
|    |           | 5    | **/role_models/kate/BK_postquit_12.3gp**   |                      |
| 248|           | 3    | BK_postquit_12                              | 1018                 |
|    |           | 5    | **/role_models/kate/BK_postquit_12.3gp**   |                      |
| 26 |             | 3    | BK_postquit_12                              | 1018                 |
|    |             | 6    | **/role_models/kate/BK_postquit_12.3gp**   |                      |
|    |             | 1    | **/role_models/kate/BK_postquit_12.3gp**   |                      |

336
STUB IT: take a video of someone important 2u reminding u why u r quitting. Save it on yr phone & replay in times of need.

STUB IT: remember u can txt us on 5552 for a craving buster. Txt either CRAVE STRESS, CRAVE BORED, CRAVE DRINKING or just CRAVE.

STUB IT: write down a list of activities so that when u get a crave u can refer 2 th list 2 keep busy - will help get u thru it.

STUB IT: think u can do betta? Send us yr 30sec vid by email 2 info@stubit.co.nz. Go to www.stubit.co.nz 4 instructions.
STUB IT: check out the money saved calculator @ www.stubit.co.nz and buy yourself something special.

STUB IT: save yr fav happy song 2 yr fone play it when u feel a craving coming on my fav is ‘walking on sunshine’ - it really helps!

STUB IT: have u tried taking a vid of someone important 2u on yr phone so u can replay when u need support

STUB IT: If u slip, resist the temptation 2 go back to fullon smkg. Think about how much effort u have put in so far & keep going. Txt RELAPSE to 5552
<p>| | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
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<td>282</td>
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<td>STUB IT: Hi Kate here. 6 weeks gone &amp; Im still quit - so stoked that I stuck with it. Feel so much better for it.</td>
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STUB IT: Remember smoking is an addiction - but that nicotine is outa yr body now - u r kicking it!

STUB IT: Hey that’s it fr th team, hope u found th program helpful. plse go to www.stubit.co.nz complte yr final form & go into draw 2 WIN NEW 3G FONE!
Multimedia Mobile Phone Quit Smoking Study

Welcome to the home of STUB IT. Researchers at Auckland Uni have come up with a new way to help young people who want to quit smoking. The STUB IT study is an innovative multimedia package sent straight to people who want to quit, and it’s completely FREE!

If you live in Northland, Auckland, Waikato, Bay of Plenty, Lakes or Taipa, have a Vodafone video capable mobile phone and want to quit, then we WANT YOU!!

Are you 2.5G capable?

Here’s some more information about STUB IT

INTERESTED?
CLICK HERE TO TAKE PART!

The 5thth programme has been developed to provide support and distraction so we will be sending a mixture of video, post and text messages to you via your video capable mobile phone. If you decide to join the study and are eligible you will be randomly assigned (like the toss of a coin).
Appendix 16: Chapter 5: Participant Information Sheet and consent form

A multimedia mobile phone study to help young people stop smoking

You are invited to take part in a study that proposes a new intervention to help young people to stop smoking, including a personalised video-based programme delivered to you via your mobile phone over six months.

Your participation is entirely voluntary (your choice). You do not have to take part in this study. If you choose not to take part in this study you will not be affected in any way.

If you agree to take part in the study, you may withdraw at any time, without having to give a reason. However, if you do decide to withdraw, we will still need to contact you at end of the study to ask you some quick questions.

To assist you in making a decision about participating in the study, we ask that you read this information sheet.

Who is coordinating this study?

The study is co-ordinated by the Clinical Trials Research Unit (University of Auckland).

What is the aim of this study?

Our aim is to determine whether receiving the multimedia programme delivered via mobile phone is effective at increasing smoking cessation rates in young people.

Why have I been selected?

You have been selected to take part in this study because you are a smoker who wants to quit and you own a Vodafone mobile.

You also meet the other strict entry criteria for the study.

Where will the study take place?
The study will take place at the Clinical Trials Research Unit in Auckland and you must live in New Zealand to be eligible to participate.

**How long will the study take?**

Each participant will be involved in the study for the *six month* programme duration.

The study, from its development through to analysis will run from September 2007 to September 2009 (approx 3yrs).

**What is involved if I take part?**

If you decide to take part in this study you will need to give us your permission and this will be in reply to a txt message sent to you by us. You will then be allocated to one of the two groups. This allocation is determined randomly by our computer (like the toss of a coin). One group will receive an intensive form of the smoking cessation programme whilst the other group will receive a simpler form.

At 4 weeks and 6mths after your quit day you will be asked to answer some detailed questions, it is important that you answer these regardless of whether or not you have quit smoking. You will also be asked to answer these questions even if you have withdrawn early from the study.

A Research Assistant may verify your smoking status (i.e. smoker or non-smoker) by checking your nicotine levels. This will be done by a. visiting you to obtain a saliva sample, or b. you coming to a study centre to provide the sample, or c. you sending the sample in a pre-paid envelope to the study centre. You should also be prepared to update study staff with any change of contact details that you may have over the duration of the study.

**Will there be any costs involved?**

There is no cost for receiving the programme or for contacting us, and you will be reimbursed for your time.

**What are the risks and benefits of this study?**

There are no risks in being involved in the study. Being in the programme may help you to quit smoking and everyone involved will be reimbursed for their time at the start and at the end of the programme.

**Compensation**

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by the Accident Compensation Corporation (ACC) legislation. ACC cover is not automatic and each case is assessed by ACC, according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are a wage earner or non-earner.
ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, please contact your nearest ACC office or ask us for more information before you agree to take part.

Confidentiality

The study files and all other information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study. The information will be kept securely at the Clinical Trials Research Unit, University of Auckland and destroyed after 15 years according to national research guidelines. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

Results

The study results will be available on our website for you to download or if you would prefer we can send them out to you. Please note that there may be a delay of some months or even a year or more between conducting the study and providing feedback to you about the results.

Ethical Approval

This study has received ethics approval from the Multi-Regional Ethics Committee.

Your Rights

If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health and Disability Advocate on 0800 555 050

You are encouraged to ask questions at any time during the study. You can contact the study manager on:
Study Investigators: Dr Robyn Whittaker, Dr Anthony Rodgers, Dr Chris Bullen, Dr Hayden McRobbie, Dr Ralph Maddison, Mr Tim Corbett, Dr Dale Bramley, Dr Simon Denny, Mr Ruey-bin Lin, Mrs Penny Salmon.

Please keep this sheet for your information. Thank you for taking the time to read about this study.
CONSENT FORM

- I understand the information sheet for volunteers taking part in this study dated Version 7 June 2008, which has been read and discussed with study researchers, and designed to investigate whether receiving a video-based multimedia programme via mobile phone is useful for people who want to quit smoking.

- I have had the opportunity to discuss this study with a Research Assistant and I am satisfied with the answers I have been given.

- I have had the opportunity to use whanau/family support or a friend to help me ask questions and understand the study.

- I understand that I may be asked to provide a spit (saliva) sample to determine my smoking status by checking my nicotine levels.

- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without having to give a reason. If I do decide to withdraw early, I understand I will still be contacted to answer some simple questions throughout the 6mth study period.

- I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.

- I understand the compensation provisions for this study.

- I have had time to consider whether to take part.

- I know whom to contact if I have any questions about the study.

- I agree to provide responses to the follow-up questions at the beginning of the study, at 4 weeks at 12 weeks and at 6 months after my quit date. I understand that there will be no personal details that identify me (such as my name, date of birth, address) on any forms.

- I agree to update study staff with my contact details should they change during the programme.

- I understand that any data collected as part of this study will be stored securely for 15 years at the Clinical Trials Research Unit, University of Auckland in accordance with the Privacy Act, 1994. After this time the information will be safely destroyed.

- I understand that any information collected, as part of this study will not be used for any other purpose, without my permission and ethical approval, nor given to any other third party outside of the research team.

- I understand that there may be a significant delay between data collection and publication of the results.

**Consent to take part**

- If you agree to these statements and would like to take part in the study, txt the exact words ‘I consent’ to 5552 now.

- If you do not wish to take part, txt the exact words ‘I do not consent’ to 5552.

If you need more information to help you decide do not hesitate to contact the study staff on 0800STUBIT (0800788248)

*This study has received approval from the Multi-Regional Ethics Committee*
Appendix 17: Chapter 4: Role model profiles

**Josh**
Josh is a laid back 21yr old student. He is a casual smoker who has been smoking since 3rd form. The big thing for Josh is not smoking when he is out drinking with the boys. He has had enough of wasting money on cigarettes and plans to spend the money he has saved on a new longboard.

**Penny**
Penny is a 20yr old student who smokes half a pack a day. She is highly motivated and determined to quit this time. The cigarette she most enjoys is the after dinner one, so that’s her biggest challenge.

**Aroha**
Aroha is a 27yr Māori woman who works full time and is determined to quit for her unborn child. She smokes ½ a pack a day and her morning cigarette is going to be the hardest one to stop. She worries about weight gain but has had enough of smoking.

**Rawiri**
Rawiri is a 25yr old Māori male who can ‘smack back’ about a pack a day. He identifies strongly with his Māori roots and believes that support from his whanau and keeping busy with activities on the marae will help him to quit this time. His mum is his inspiration to quit.

**Matt**
Matt is a 22yr old student who smokes about 6 a day. He loves a good night out with the boys and reckons that the association with beer and cigs will be the toughest to separate. Sport, in particular rugby, is important to Matt and he may lose his place on the team unless he sharpens up his fitness ….time to quit.

**Kate**
Kate is a 20yr old café worker who has just met the man of her dreams, he is a non smoker and so now is the perfect time to quit. She started smoking when she was 14 and smokes ½ pack a day.
## Appendix 18: Chapter 4: Final control programme

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STUB IT: if u want xtra quit suport check out the online quit community @ www.quit.org.nz. 0800778778 4 low cost patches, gum, support & advice.
Appendix 19: Chapter 5: Form D

FORM D: 4 week follow-up

Hey thanks for coming back to answer these few questions. As this is a research study we need to get your feedback along the way to see if it is working. Please complete this short form and then submit at the end.

Thanks again, we value your time and commitment to the study and to quitting smoking!

1.01 Have you smoked tobacco at all since your Quit Day? (Select one only)
   - No, not a single puff – Go to Question 1.09
   - Yes between 1 and 5 cigarettes
   - Yes more than 5 cigarettes

1.02 Have you smoked tobacco in the last 7 days? (Select one only)
   - No, not a single puff – Go to Question 1.09
   - Yes between 1 and 5 cigarettes
   - Yes more than 5 cigarettes

1.03 Have you gone back to daily smoking? (Select one only)
   - Yes
   - No (if No go to Q 1.09)

Submit point (in case they don’t complete the entire form, these are the most important questions)

1.04 How confident are you that you could quit again in the future? (Select one only)
   - □ 0% - not at all confident
   - □ 10%
   - □ 20%
   - □ 30%
   - □ 40%
   - □ 50% - somewhat confident
   - □ 60%
   - □ 70%
   - □ 80%
   - □ 90%
   - □ 100% - completely confident

1.05 When did you go back to daily smoking? (Approximately if you can’t remember)
   - Popup calendar or dd/mm/yyyy (Allow only dates from registration to current)
   - Or select,
No idea
Never quit

How many cigarettes are you now smoking on average each day?
1.06 Ready-made (or manufactured or tailored) cigarettes Per day (2 boxes)
        And/Or
1.07 Roll-your-own cigarettes (or loose tobacco) Per day (2 boxes)
        And
1.08 How much loose tobacco are you using on average? For example, a 30gram pack every 5 days ........gram pack every .......days (2 boxes)

Go to Question 1.10

1.09 How confident are you that you will be able to stay quit at this attempt?
        □ 0% - not at all confident
        □ 10%
        □ 20%
        □ 30%
        □ 40%
        □ 50% - somewhat confident
        □ 60%
        □ 70%
        □ 80%
        □ 90%
        □ 100% - completely confident

Apart from this programme, have you had any other help to stop smoking in the last 4 weeks? (Please answer all questions)

1.10 Nicotine gum Yes No
1.11 Nicotine patches Yes No
1.12 Nicobrevin Yes No
1.13 Zyban Yes No
1.14 Nortriptyline (or Norpress) Yes No
1.15 Quitline Yes No
1.16 Stop smoking counsellor Yes No
1.17 Internet stop smoking site Yes No
        1.18 If yes, Specify website name or address
1.19 Other Yes No
        1.20 If yes, please specify

1.21 How much of the time have you felt the urge to smoke in the past week? (Select one only)
Not at all (skip to 1.23)
A little of the time
Some of the time
A lot of the time
Almost all of the time
All of the time

1.22 How strong have the urges been? (Select one only)
   Slight
   Moderate
   Strong
   Very strong
   Extremely strong

1.23 During the study, were you involved in a car crash? (Select one only)
   Yes
   No (if N, go to 1.28)

   If Yes: 1.24 Were you the driver? (if No go to Q 1.28)
           Yes         No

   1.25 Did the crash happen while you were using your mobile phone?  
           Yes         No

   1.26 Did the crash happen while you were smoking?  
           Yes         No

   1.27 Did the crash happen within 5 minutes of you receiving a message on 
your phone? Yes         No

1.28 Are there any changes to your contact details? Yes  No

[Populate with current contact details from Form B, allow to be edited and updated in Form B]

Home.................................................................
Work.................................................................
Mobile...............................................................

Thanks for completing this form, we appreciate your time and we hope that being involved helps you to quit smoking. Please stay with us; you will continue to receive messages from us but they will come less frequently now (1 every 4 days), we will be in touch again soon.

STUB IT crew
Appendix 20: Chapter 5: Form E

FORM E: 6 month follow-up

Reg num: (4 boxes)   Initials: (3 boxes)

Participant ID: (mobile no, start with 6421 then up to 14 boxes)

DOB: (10 boxes e.g. 01/10/1980)

RA screen
The purpose of this form is to collect final follow-up data at six months post Target Quit Date.
This form can be completed by participants via a link sent to their phone that will take them
directly to the web-based form. If they do not complete the form, the Research Assistant will
call them and complete over the phone.

Hey thanks for coming back to answer these few FINAL questions. As this is a research
study we need to get your feedback to see if it has worked for you. Please complete this
form and then submit at the end.
Thanks again, we value your time and commitment to the study and to quitting smoking!

1.01 Have you smoked tobacco at all since your Quit Day? (Select one only)
   No, not a single puff – Go to Question 1.09
   Yes between 1 and 5 cigarettes
   Yes more than 5 cigarettes

1.02 Have you smoked tobacco in the last 7 days? (Select one only)
   No, not a single puff – Go to Question 1.09
   Yes between 1 and 5 cigarettes
   Yes more than 5 cigarettes

1.03 Have you gone back to daily smoking? (Select one only)
   Yes
   No (if No go to Q 1.09)

Submit point (in case they don’t complete the entire form, these are the most
important questions)

1.04 How confident are you that you could quit again in the future? (Select one only)
   □ 0% - not at all confident
   □ 10%
   □ 20%
   □ 30%
☐ 40%
☐ 50% - somewhat confident
☐ 60%
☐ 70%
☐ 80%
☐ 90%
☐ 100% - completely confident

1.05 When did you go back to daily smoking? (Approximately if you can’t remember)
Popup calendar or dd/mm/yyyy (allow only dates from registration to current)
Or select,
No idea
Never quit

How many cigarettes are you now smoking on average each day?
1.06 Ready-made (or manufactured or tailored) cigarettes Per day (2 boxes)
And/Or
1.07 Roll-your-own cigarettes (or loose tobacco) Per day (2 boxes)
And
1.08 How much loose tobacco are you using on average? For example, a 30 gram pack every 5 days ..........gram pack every ..........days (2 boxes)

Go to Question 1.10

1.09 How confident are you that you will be able to stay quit?
☐ 0% - not at all confident
☐ 10%
☐ 20%
☐ 30%
☐ 40%
☐ 50% - somewhat confident
☐ 60%
☐ 70%
☐ 80%
☐ 90%
☐ 100% - completely confident

1.10 How many quit attempts did you make during the study period? (Select one only)

None

Just the one
More than one

1.11 If more, specify number of attempts (2 boxes)

Apart from this programme, have you had any other help to stop smoking in the last 4 weeks? (Please answer all questions)

1.12 Nicotine gum Yes No
1.13 Nicotine patches Yes No
1.14 Nicobrevin Yes No
1.15 Zyban Yes No
1.16 Nortriptyline (or Norpress) Yes No
1.17 Quitline Yes No
1.18 Stop smoking counsellor Yes No
1.19 Internet stop smoking site Yes No
1.20 If yes, Specify website name or address

1.21 Other Yes No
1.22 If other, please specify

1.23 How much of the time have you felt the urge to smoke in the past week? (Select one only)
   Not at all
   A little of the time
   Some of the time
   A lot of the time
   Almost all of the time
   All of the time

1.24 How strong have the urges been? (Select one only)
   Slight
   Moderate
   Strong
   Very strong
   Extremely strong

1.25 During the study, were you involved in a car crash? (Select one only)
   Yes
   No (if N, go to Q 2)

   If Yes: 1.26 Were you the driver? (if No go to Q 2)
           Yes No
   1.27 Did the crash happen while you were using your mobile phone?
           Yes No
   1.28 Did the crash happen while you were smoking?
           Yes No
   1.29 Did the crash happen within 5 minutes of you receiving a message on your phone?
If in the control group, go to Q 2.28

### 2. Intervention Group only:
*We are interested to know if any particular aspects of our programme worked well for you.*

Can you rate the following parts of the programme according to whether you liked them or disliked them?

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<td>What did you dislike most about the programme? (if anything)</td>
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<td>Do you have any suggestions for us on how to do it better in the future?</td>
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Which of the following parts of the programme do you think were **important in helping you to stop smoking**, even if you lapsed later?

(Please answer all questions)

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<td>2.21</td>
<td>Feeling like I belonged/like there were others going through the same thing as me</td>
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</tr>
<tr>
<td>2.22</td>
<td>Being supported to feel like I could do it</td>
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</table>
2.23 Yes No Getting messages at the right times
2.24 Yes No Messages/games/whatever distracting me from the cravings
2.25 Yes No It was fun
2.26 Yes No It made me get support from my friends/family
2.27 Yes No The free stuff

2.28 Are there any changes to your contact details? Yes No

[Populate with current contact details from Form B, allow to be edited and updated in Form B]

Postal address.................................................................
Home address..............................................................
Mobile.................................................................

Thanks very much for your help.

Submit form

*Thanks for taking part in the STUB IT program, we appreciate your time and we hope that being involved helped you to quit smoking; it certainly helped us to work out if a program similar to this will help other young people quit.*

*STUB IT team*

*If participant qualifies as a quitter (ticks any of the first 2 boxes of question 1) then this screen pops up…*

*Congratulations on stopping smoking! We will be sending you a Saliva Test Pack in the mail (if you have changed you address please email us at info@stubit.co.nz). You need to complete the test according to the instructions, and send the test strip back to us in the free post envelope provided. It is really important for our research that you return the completed strip to us. Everyone who returns their strip will go into a draw to win a new 3G phone!*
Appendix 21: Chapter 5: Standard HONC questions

1. Have you ever tried to quit, but couldn't?
2. Do you smoke now because it is really hard to quit?
3. Have you ever felt like you were addicted to tobacco?
4. Do you ever have strong cravings to smoke?
5. Have you ever felt like you really needed a cigarette?
6. Is it hard to keep from smoking in places where you are not supposed to?
    When you tried to stop smoking ... (or, when you haven't used tobacco for a while ...)
7. Did you find it hard to concentrate because you couldn't smoke?
8. Did you feel more irritable because you couldn't smoke?
9. Did you feel a strong need or urge to smoke?
10. Did you feel nervous, restless or anxious because you couldn't smoke?
    Note. Each item is answered yes or no.
CONSORT Statement 2001 Checklist
Items to include when reporting a randomized trial

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<th>Item</th>
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Appendix 22: Chapter 5: CONSORT checklist
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<td>Randomization -- Implementation</td>
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<tr>
<td>Blinding (masking)</td>
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| 1 | **How participants were allocated to interventions** (e.g., "random allocation", "randomized", or "randomly assigned"). |
| 2 | **Scientific background and explanation of rationale.** |
| 3 | **Eligibility criteria for participants** and the **settings and locations where the data were collected.** |
| 4 | **Precise details of the interventions intended for each group and how and when they were actually administered.** |
| 5 | **Specific objectives and hypotheses.** |
| 6 | **Clearly defined primary and secondary outcome measures** and, when applicable, any **methods used to enhance the quality of measurements** (e.g., multiple observations, training of assessors). |
| 7 | **How sample size was determined** and, when applicable, **explanation of any interim analyses and stopping rules.** |
| 8 | **Method used to generate the random allocation sequence, including details of any restrictions** (e.g., blocking, stratification) |
| 9 | **Method used to implement the random allocation sequence** (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned. |
| 10 | **Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.** |
| 11 | **Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.** If done, **how the success of blinding was evaluated.** |
| 12 | **Statistical methods used to compare groups for primary outcome(s):** **Methods for additional analyses**, such as subgroup analyses and adjusted analyses. |
### RESULTS

<table>
<thead>
<tr>
<th>13</th>
<th><strong>Participant flow</strong></th>
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<tbody>
<tr>
<td></td>
<td>Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.</td>
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<tr>
<th>14</th>
<th><strong>Recruitment</strong></th>
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<tbody>
<tr>
<td></td>
<td>Dates defining the periods of recruitment and follow-up.</td>
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<tr>
<th>15</th>
<th><strong>Baseline data</strong></th>
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<tbody>
<tr>
<td></td>
<td>Baseline demographic and clinical characteristics of each group.</td>
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<tr>
<th>16</th>
<th><strong>Numbers analyzed</strong></th>
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<tbody>
<tr>
<td></td>
<td>Number of participants (denominator) in each group included in each analysis and whether the analysis was by &quot;intention-to-treat&quot;. State the results in absolute numbers when feasible (e.g., 10/20, not 50%).</td>
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<tr>
<th>17</th>
<th><strong>Outcomes and estimation</strong></th>
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<tbody>
<tr>
<td></td>
<td>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).</td>
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<tr>
<th>18</th>
<th><strong>Ancillary analyses</strong></th>
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<tr>
<td></td>
<td>Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.</td>
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<tr>
<th>19</th>
<th><strong>Adverse events</strong></th>
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<tbody>
<tr>
<td></td>
<td>All important adverse events or side effects in each intervention group.</td>
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<tr>
<th>20</th>
<th><strong>DISCUSSION Interpretation</strong></th>
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<tr>
<td></td>
<td>Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.</td>
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<tr>
<th>21</th>
<th><strong>Generalizability</strong></th>
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<tbody>
<tr>
<td></td>
<td>Generalizability (external validity) of the trial findings.</td>
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<th>22</th>
<th><strong>Overall evidence</strong></th>
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<tr>
<td></td>
<td>General interpretation of the results in the context of current evidence.</td>
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Appendix 23: Chapter 6: Qualitative substudy participant information sheet and consent form

Participant Information Sheet

You have been invited to participate in a sub-study of the STUB IT trial as you have recently received the full STUB IT smoking cessation programme on your mobile phone.

Your participation in this sub-study is entirely voluntary (your choice) and you can withdraw at any time. You can withdraw the information you provide us up to two weeks after your interview. Your choice to participate or not will not affect your relationship with the STUB IT trial in any way.

Participation in this sub-study will involve a researcher arranging a time that is suitable for you to undertake a phone interview. This interview with the researcher will take approximately 20 minutes. They will be asking you for your opinions on aspects of the STUB IT programme and on how it may be used in the future. The phone interview will be audio-taped and later transcribed for analysis.

The findings of this sub-study will appear in reports on the STUB IT research project. We would like to be able to use direct quotes if you give your consent. However no information that can identify you will be reported or published.

The information you provide is confidential and the tapes and transcriptions will be kept securely and in a non-identifiable manner at the University of Auckland. This information will be kept for approximately 15 years according to usual research protocols.

If you have any questions you can contact the researchers directly on the numbers below. If you have any concerns about rights of participants in this study you may wish to contact Health Advocates Trust on 623-5799.

This study has been approved (as a sub-study of the STUB IT trial) by the Multi-Region Ethics Committee. Ref: NTX/06/10/130

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Sub-Study Researcher
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STUB IT Sub-Study
Consent Form

- I have read the Participant Information Sheet and have had a chance to ask questions about this substudy
- I agree to participate in this substudy and I understand that this involves a phone interview
- I understand that this interview will be audio-taped and that the tapes and transcriptions will be stored securely on University premises for 15 years, and after this time will be destroyed
- I understand that no identifiable information will be reported or published
- I agree to direct quotes from my interview being published
- I understand that taking part in this substudy is entirely voluntary (my choice) and that I am free to withdraw at any time or to withdraw information I have provided up to two weeks after the interview
- I understand that any information collected as part of this substudy will not be used for any other purposes without my permission and ethical approval, nor given to any third party outside of the research team

Name:

Signed:

Dated:
Appendix 24: Chapter 6: Qualitative sub-study questionnaire

• Introduce myself
• Explain purpose:
  – To gain feedback on what you thought about the Stub it programme. What you
    liked/disliked and what parts were helpful in your quit attempt.
• I do not have the information regarding whether you quit smoking or not, less interested in this.
  More interested in your feedback on the programme. This will give us direction on what areas
  could be improved.
• Interview will take approx 20 minutes.
• As per information sheet, this phone call is being recorded but all identifying information will
  not be used in the reporting of this. Does that sound OK to you?

Appeal of the programme
1. What initially attracted you to the stub it programme?
2. What do you think about the idea of using a mobile phone to deliver a programme to help
   people quit smoking?
3. How did you find using this programme compared to other things you may have tried in the
   past?

Motivation to quit
4. When did you really decide you wanted to quit smoking?
   Prompts: Was it before you signed up? Or sometime during the programme?
5. Did you feel confident that you could have a successful quit attempt? Did this change
   throughout the course of the programme?

Role modelling as observational learning
Part of the programme involved getting video diary messages from a role model, someone else
who was going through the process of quitting smoking.
6. Why did you select the person you did?
   Prompts: What was most important in that decision? Did you choose someone who you
   saw as being similar to you, or different? Is there someone else you would have
   preferred to hear from?
7. How did seeing someone else go through the process of quitting make you feel about your
   own attempt?
   Prompts: More confident? Less confident?
8. Did watching others go through similar things make you feel more supported? How/why not?
9. Did you use any of the tips/techniques that your role model discussed in their video diary?
   a. Which ones? Why?

Self-efficacy
10. If you didn’t quit, do you feel like you still learnt stuff for next time? Did it increase
    confidence in your ability to quit next time?

11. Any other feedback or suggestions you would like to give? Improvements for future
    programmes? Delivered over a computer?

If time… then ask about engagement with the programme:
   a. study website
   b. crave messages
c. relapse

d. What would have prompted you to engage with the programme more?