Optimising the development of effective mobile health behaviour change interventions

Text messages to support smoking cessation in Thailand

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The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

Background: Tobacco smoking is recognised as a leading threat to global population health. Rigorous evaluations of mobile health (mHealth) behaviour change interventions for smoking cessation were reported to be mixed due to the diverse and complex nature of these interventions. There is a lack of evidence in guiding intervention designs to maximise effects of mHealth interventions. The Multiphase Optimisation Strategy (MOST) is an approach which aims to optimise and evaluate multicomponent interventions consisting of screening, refining, and confirming phases. It can be applied to develop and test complex interventions.

Objectives: 1) to systematically identify effective components of mHealth behaviour change interventions (e.g. behaviour change techniques (BCTs), modes of delivery, functionality) associated with improvements in smoking cessation; 2) to design mHealth behaviour change interventions that contain effective components to support smoking cessation among Thai smokers; and 3) to simultaneously test whether effective components in mHealth behaviour change interventions improve smoking cessation rates among Thai smokers.

Methods: For the first objective, a systematic review, a meta-analysis, and a meta-regression of randomised controlled trials (RCT) of mHealth interventions for tobacco cessation were conducted to identify the effect sizes of mHealth interventions and to quantify the association of the characteristics of mHealth interventions with effect size. For the second objective, mobile text messages were designed to provide support for smokers aimed at three theory-based behaviour change components, namely: 'Capability', 'Opportunity', and 'Motivation'. The development involved three steps: 1) selecting BCTs and constructing text messages; 2) testing for the inter-coder reliability of the BCT-enhanced text messages; and 3) validating the acceptability of BCT-enhanced text messages among stakeholders in Thailand using a structured face-to-face focus group discussion. For the third objective, an RCT employing a 2×2×2 full factorial design was conducted to simultaneously assess the effectiveness of the BCT-enhanced text messages for smoking cessation individually, and in combination, among Thai smokers. Effect sizes are presented

using odds ratios (OR) and 95% confidence intervals (CI). Kappa's statistic (k) was used to quantify the level of agreement between the two BCT coders.

Results: For the first objective, there were 24 mHealth studies identified from the systematic review with the majority being SMS-based interventions. The effect size (OR) of mHealth intervention for smoking cessation was 1.41 (95% CI: 1.19 to 1.67) at 6-months follow-up. From the meta-regression analysis of 23 studies, interventions reported BCTs in the following BCTTv1 domains: *'Feedback and monitoring'* (OR 1.39, 95% CI: 1.08 to 1.78), *'Comparison of behaviour'* (OR 1.36, 95% CI: 1.12 to 1.65), *'Comparison of outcomes'* (OR 1.37, 95% CI: 1.13 to 1.66), and *'Antecedents'* (OR 1.29, 95% CI: 1.09 to 1.54), *Covert learning'* (OR 1.83, 95% CI: 1.21 to 2.75) were associated with an increased odds of smoking cessation. Interventions reported BCTs mapped onto all three theory-based behaviour change components (OR 1.30, 95% CI: 1.05 to 1.59), use theory to inform an intervention (OR 1.51, 95% CI: 1.14 to 1.99), use theory to develop an intervention (OR 1.42, 95% CI: 1.15 to 1.74), and tailoring interventions to participant's needs (OR 1.56, 95% CI: 1.26 to 1.94) were also associated with an increased odds of smoking cessation. These results suggest further research to make efficient, causal conclusions about components as well as about packages of components.

For the second objective, text messages were designed based on 39 evidence-based BCTs mapped onto three behaviour change components. Inter-coder reliability for BCT coding suggested that there was a substantial level of agreement (k = 0.78) between the two BCT coders and none of the discrepancies fell into different behaviour change components. However, only 32 BCTs were found to be acceptable among the Thai expert panel involved with tobacco control and was included in the final set of text messages.

For the third objective, a total of 1,571 smokers were randomised to receive one of the eight combinations of BCT-enhanced text messages (Placebo, C, O, M, CO, CM, OM, and COM) twice a day for 30 days. 1,260 participants (80%) received all 60 text messages as intended and 94% of the participants reported that they had opened and read the text messages. The overall 7-day self-reported smoking abstinence rate was 40% (n = 521) at 1-month follow-up. Providing BCT-enhanced text messages aimed at supporting smokers' capability to quit (OR 1.20, 95% CI: 0.77 to 1.86), smokers' opportunity to quit (OR 1.05, 95% CI: 0.67 to 1.64), or smokers' motivation to quit (OR 1.13, 95% CI: 0.73 to 1.77) did not significantly improve the 7-day smoking abstinence rate at 1-month follow-up. The

additional components of BCT-enhanced text messages (two or more) showed a trend of decreasing the odds of quitting, which suggested an antagonistic interaction effect.

Conclusion: This study optimised and evaluated multicomponent mHealth behaviour change interventions in a resource-limited country with emerging mHealth technology. Though a meta-regression suggested a promising result of combinations of BCT-contained mHealth interventions, the interventions failed to provide a significant improvement in cessation rates in a trial setting. Moreover, the addition of two or more behaviour change components decreased the effect size suggesting the importance of experimental studies for decision making. Understanding the effects of these fine-grained behaviour change components rather than a whole set of interventions as a 'black box' will advance knowledge in this field of research using a factorial design.

List of Abbreviations

AUDIT	Alcohol Use Disorders Identification Test
BCT	Behaviour change techniques
BCTTv1	Behaviour change techniques taxonomy version 1
BCW	Behaviour change wheel
CC	Complete case analysis
CONSORT	Consolidated standards of reporting trials
DALY	Disability-adjusted life year
FCTC	Framework Convention on Tobacco Control
FTND	Fagerström test for nicotine dependence
GBP	Great Britain Pound
HITAP	Health Intervention and Technology Assessment Program
ISRCTN	International standard randomised controlled trial number
ITT	Intention-to-treat
IVR	Interactive voice response
LMICs	Low- and middle-income counties
mHealth	Mobile health
MI	Multiple imputations
MMS	Multimedia messaging service
MOST	Multiphase optimisation strategy
MRC	Medical Research Council
RCT	Randomised controlled trial
SMART	Sequential Multiple Assignment Randomised Trial
SMS	Short messaging services
THB	Thai baht
TNQ	Thailand National Quitline
TTM	Transtheoretical model
WHO	World Health Organization

Definition of terminology used in this thesis

Tobacco products: products containing nicotine—addictive psychoactive ingredients—which are intended to be smoked, sucked, chewed or snuffed. Tobacco products include manufactured cigarettes, roll-your-own cigarettes, and other products such as cigars, pipes and e-cigarettes.

Smokers: People who have consumed any tobacco product during the past 7 days at the time of research, either daily or occasionally.

Current smoker: Daily and occasional (non-daily) tobacco smokers.

Smoking cessation: Smokers who did not consume any tobacco products at the time of data collection and 7 days prior to the day of measurement.

Quitline: Telephone-based counselling call centres for smoking cessation.

Behaviour change techniques: the smallest elements of behaviour change interventions that can bring about change on their own in favourable circumstances.

Behaviour change components: the components in the COM-B behaviour change system: 'Capability', 'Opportunity', and 'Motivation'.

Intervention components: the intervention components in this Thesis refer to three behaviour change components: 'Capability', 'Opportunity', and 'Motivation'.

mHealth intervention: Mobile health intervention is a form of digital health intervention that uses information and communication technologies for health.

Text messages: A telecommunication between mobile phone users via the Short Messages Service (SMS) protocol which allows for the interchange of short written messages.

BCT-enhanced text messages: Text messages that were designed to contain behaviour change techniques for smoking cessation.

Placebo text messages: Text messages that did not contain behaviour change techniques for smoking cessation.

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Thesis structure

This thesis comprises eight chapters (see **Figure 0.1**). **Chapter 1** provides relevant background information, including the smoking epidemic and its negative consequences, existing evidence on the mHealth interventions for tobacco cessation, and contextual information about the tobacco situation and tobacco control measures in Thailand. **Chapter 2** presents the aims, objectives, research questions, and the methodological approach. **Chapter 3** presents the methods and results of the systematic review and meta-analysis study that systematically identify active components of mHealth behaviour change interventions associated with improvements in smoking cessation. **Chapter 4** provides details about the development of BCT-enhanced text messages. **Chapter 5** presents the methods of the factorial randomised controlled trial (RCT) to test different combinations of BCT-enhanced text messages. **Chapter 6** presents the challenges and the methods to overcome trial recruitment challenges. **Chapter 7** presents results of the factorial RCT. Finally, C**hapter 8** discusses the key findings and provides concluding remarks and future implications for mHealth policy.

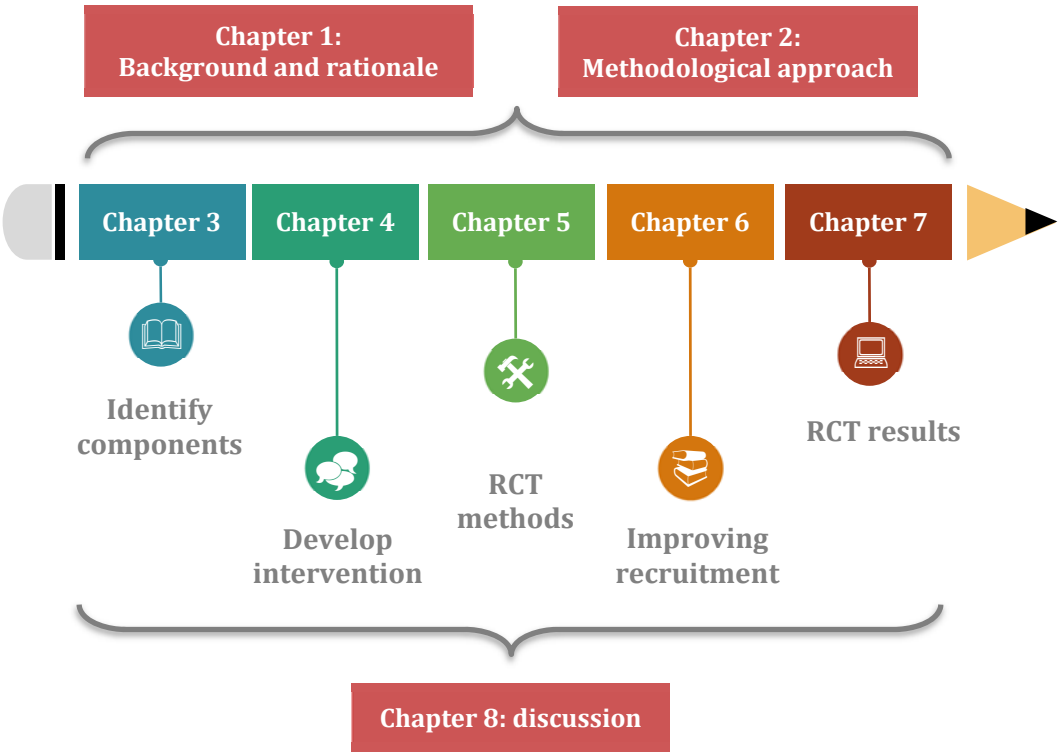


Figure 0.1 Structure of the thesis

Chapter 1: Background and rationale

1.1 Smoking and its negative consequences

Tobacco smoking is recognised as one of the leading threats to population health. It is estimated that there are one billion adult smokers in the world (1). Tobacco use is an avoidable behavioural risk factor of many diseases such as cardiovascular diseases, respiratory diseases, and several cancers and neoplasms. The Global Burden of Disease Study in 2010 indicated that smoking is the leading contributor towards population disability-adjusted life year (DALY) (2). Annually, 6.4 million out of 63 million deaths globally were attributable to tobacco use in 2015, with this number increasing to 8.3 million out of 73 million deaths per year by 2030 (3). Although the trend for smoking is decreasing in high-income countries, its prevalence is increasing in low- and middle-income countries (LMICs) (3).

Smoking also contributes to society's economic loss through health care spending, productivity loss from premature death, and absenteeism and presenteeism from disability related to tobacco use. Moreover, within settings where health care is publicly available, spending on smoking-related diseases has been increasing. For example, in Canada, smoking-related health expenditure was estimated to be $21,288 (£11,850)[1] million for all smokers in 2012; it was also found that every 1% reduction in smoking prevalence annually would reduce the burden by $26.4 (£14.7)[1] billion over a 20-year period (4).

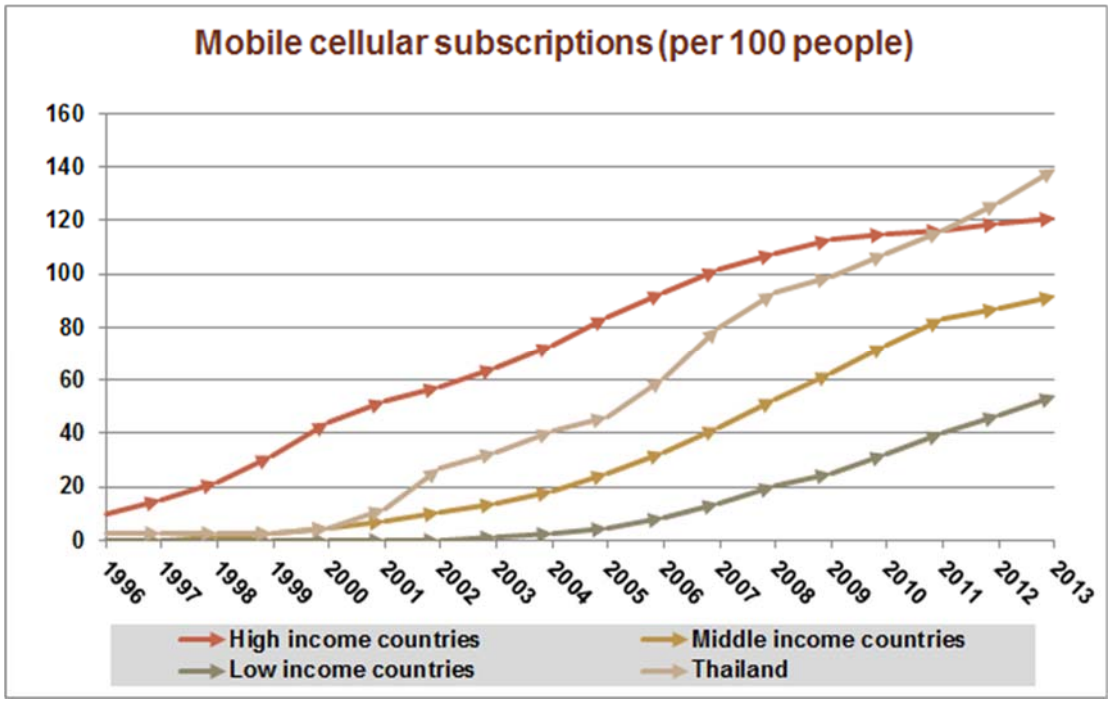
1.2 Mobile health behaviour change intervention

1.2.1 Mobile health (mHealth)

The World Health Organization Global Observatory for eHealth defines mobile health (mHealth) as the use of mobile wireless technology such as mobile phones, patient monitoring devices, and personal digital assistants (PDAs) and wireless devices to support

[1] Costs are converted into GBP using purchasing power parity (PPP) from http://eppi.ioe.ac.uk/costconversion/default.aspx

medical and public health practices (5). mHealth is a subsection of eHealth—the use of information and communication technologies for health. The growing global penetration of mobile devices allows for their use in health care. The use of mobile devices, specifically mobile phones, has dramatically increased since the year 2000, with a global subscription rate of 91.3 per 100 population in 2013 (6); this trend is the same for both high-income countries and LMICs (see **Figure 1.1**).



Source: World Bank Open Data [Data accessed: 21 May 2015] (6)

Figure 1.1 Mobile cellular subscriptions in high-, middle-, and low-income countries, and Thailand

1.2.2 Complexity of mHealth interventions

mHealth interventions are believed to be a promising tool to aid health care systems. However, the design, development, and evaluation of mHealth interventions are challenging because of interactions between technology, health service design, context, and people (7). Complex interventions contain several interacting components and have several dimensions of complexity (8); this complexity also increases the challenges in defining intervention components. Recent studies have shown variability in the effectiveness of mHealth behaviour change, disease management, and internet-based interventions (9-11). Several interactions of components within these complex interventions may affect the outcome such as mode of delivery (9), the duration and intensity of intervention (12, 13),

and tailored functionality (12, 14). Therefore, the details of these complex interventions are vital to their evaluation.

1.2.3 Scoping literature review: what do we know?

To understand the complexity of mHealth behaviour change interventions, a scoping literature review was conducted to identify mHealth intervention studies aimed at increasing the rate of smoking cessation. A pre-specified keyword search (**Appendix A**) was used to search Ovid MEDLINE(R) until the second week of September 2015. The inclusion criteria were systematic review or meta-analysis studies that included mHealth interventions for smoking cessation as a standalone study or as a combination of health behaviour.

Of 21 systematic reviews identified from the search, nine studies matched the inclusion criteria and were included. An additional five systematic reviews were identified through reference lists. Systematic reviews of mHealth behaviour change interventions were either smoking cessation (15-19) or all health behaviours (including smoking cessation) (11-13, 20-25). The results were presented as three themes: behaviour change theories, behaviour change techniques, and mHealth functionality.

1.2.3.1 Behaviour change theories

The UK Medical Research Council (MRC) encourages the use of theory to design and develop complex interventions. Their framework has been applied in many research settings to improve the quality of the development, evaluation, and implementation of complex interventions and has led to more meaningful research results (26). One of the key issues in this framework is whether the appropriate theories were employed during the development of the complex intervention(s). The explicit application of theories may lead to better interventions which may produce improved outcomes (9).

From the scoping review, a meta-analysis of 19 RCTs of text messaging-based interventions for health promotion reported that the use of theory was not associated with the intervention effect size; however, the definition of theory used was simply yes or no and some reported using theory when actually they only used it minimally (12). These results differed from the study conducted by Webb *et al.* (2010) where extensive use of theory was associated with an increase in effect size of internet-based behaviour change

interventions (9). Moreover, mHealth literature in LMICs often lack theoretical framework applied for intervention designs and outcomes measurement (27); this limits the translation of interventions into policy and practice and highlights a gap of knowledge in the development of theory-based mHealth interventions in LMICs.

1.2.3.2 Behaviour change techniques

A common language to define and recognise behaviour change techniques (BCTs) improves cumulative knowledge of complex behaviour change interventions (28). There is a need for a standard and agreed upon terminology for behaviour change interventions to reduce diversity in different terms used (29); a taxonomy—a scheme of classification in a systematic manner—of BCTs is crucial to identify the active ingredients reliably and systematically. The latest hierarchically structured taxonomy of behaviour change techniques—BCTTv1—was developed to serve as a generic specification of BCTs (30). From the scoping review, there was only one systematic review of mHealth interventions which descriptively reported the number of BCTs used (11); the other review studies focused on mHealth functionality rather than BCT content. Thus, there is currently a gap in the literature on the understanding of the effects of BCTs for mHealth behaviour change interventions in smoking cessation using this latest taxonomy.

1.2.3.3 mHealth functionality

Three systematic reviews focused on the functionality or features (message frequency, directionality, and tailoring) of mHealth interventions; one review focused on smoking cessation interventions (15) and the others included other health behaviours (12, 13). Messaging frequencies in smoking cessation interventions were found to be mixed in results, with no association with smoking cessation rates (15) or increased smoking cessation rates (12, 13). No association was found with the directionality of text messages. Mobile text messages were tailored to participant characteristics, needs or stages of change. Only one study found that text messages that were targeted and tailored to participants correlated with a better effect size on health behaviour change interventions (12).

1.3 Research context: Thailand

1.3.1 Tobacco consumption

From the Thai national census data, the prevalence of tobacco smoking[1] was 19.1% in the Thai population aged 15 years and above in 2017 (37.7% in males and 1.7% in females) (31). On average, Thai people start to smoke on a regular basis at the age of 19 years and smoke 11 cigarettes per day, with the majority (67% of smokers) smoking 1-10 cigarettes per day (31).

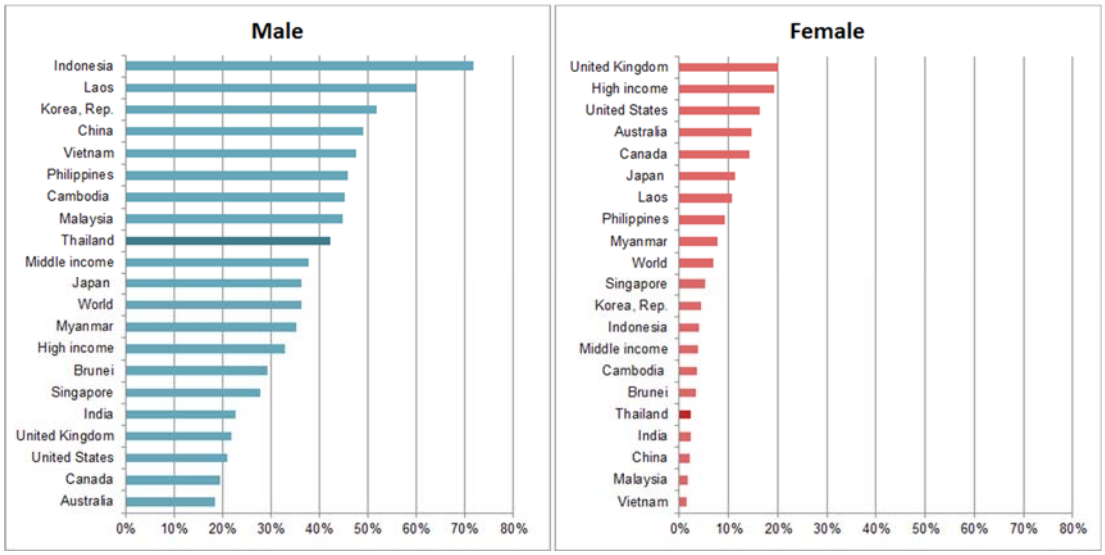
While the prevalence of smoking among males in Thailand is lower than in other Asian countries such as Indonesia (71.8%) and China (49%), it is higher than in high-income counties such as the United Kingdom (21.8%) and Australia (18.4%) (32). However, the prevalence of smoking among females Thailand and many other Asian countries is lower compared to Western countries (see **Figure 1.2**) (32).

1.3.2 Health and economic impact on the Thai society

In Thailand, tobacco use was recognised as the number one risk factor attributed to death in males and the sixth in females (see **Figure 1.3**); it is estimated that 17.7% of deaths in males and 4.1% of deaths in females are attributable to tobacco, resulting in a loss of 755,000 DALYs to the Thai society (33). It is also estimated that a total of 9,857 (£393)[2] million Thai baht (THB) was spent on smoking-attributable out-of-pocket medical costs per year in 2006 (34). For every smoker, society experiences losses of around 85,000 (£3,313)[2] and 158,000 (£6,159)[2] THB for female and male smokers, respectively (35). Therefore, any public health interventions that assist smokers to stop smoking would gain Thai society enormous benefits.

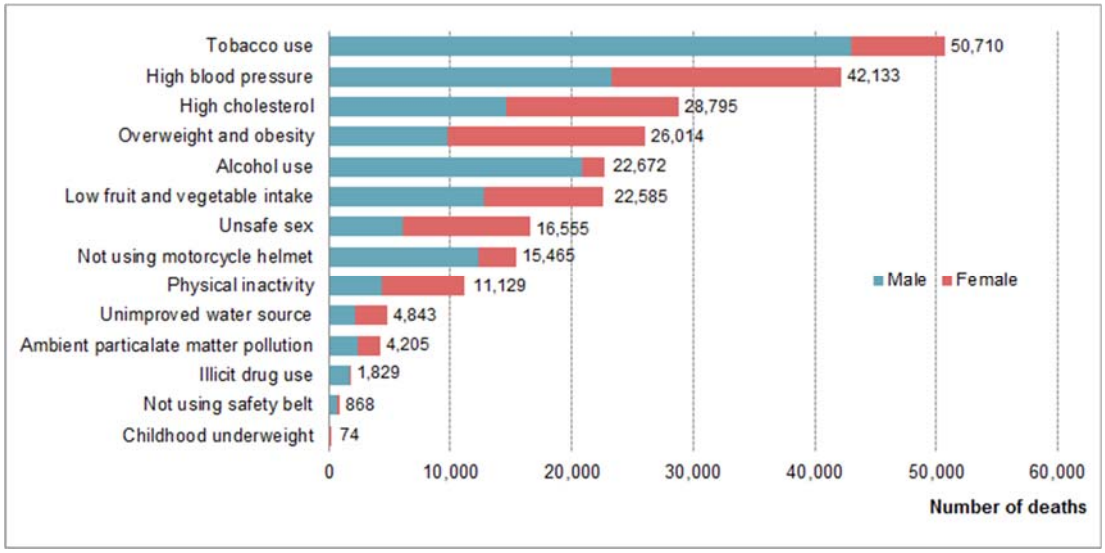
[1] Daily and occasional (non- daily) tobacco—including cigarettes, cigars, pipes or any other smoked tobacco products—smokers

[2] Costs are converted into GBP using the purchasing power parity (PPP) from http://eppi.ioe.ac.uk/costconversion/default.aspx



Source: World Development Indicators [Data accessed: 18 September 2015] (32)

Figure 1.2 Prevalence of smoking as a percentage among males and females aged 15 years and above



Source: International Health Policy Program (33)

Figure 1.3 Number of deaths attributable to various risk factors in the Thai population

1.3.3 Tobacco control measures

Several tobacco control measures have been implemented to reduce tobacco use and exposure to second-hand smoke in Thailand, including the establishment of tobacco

control policies[1] and health promotion policies[2], regulations, and an international health treaty—the WHO Framework Convention on Tobacco Control (FCTC). An overview of systematic reviews of international studies of tobacco control policies suggested that there is consistent evidence to support the benefits of smoke-free policies and raising taxes on tobacco, whereas interventions such as financial assistance or incentives for smoking cessation have shown conflicting evidence (36).

To characterise the current situation and understand the gap of knowledge, policies and interventions related to tobacco control in Thailand were reviewed and summarised by Pritaporn Kingkaew (PK). The Behaviour Change Wheel (BCW)—a framework to characterise behaviour change interventions into nine intervention functions[3] and seven policy categories[4] (37)—was used to classify the Thai tobacco control measures more systematically by linking the sources of behaviour with intervention functions and policy categories. The BCW had previously been used to characterise the UK tobacco control strategies; it provided an inter-rating agreement of 88% on the mapping of the UK tobacco control measures (37).

The Thai tobacco control measures were classified into four groups: 1) reduce the demand of smoking, 2) reduce the supply of tobacco, 3) increase supportive measures to stop smoking, and 4) improve protection from tobacco smoke (see **Table 1.1**). Most tobacco control measures focused at the policy-level which mapped into 'legislation' (50% of all measures), 'regulation' (13% of all measures), and 'fiscal measures' (6% of all measures) policy categories. A mixed range of intervention functions was found among the Thai tobacco control measures; however, evaluation of individual-level interventions for tobacco cessation in Thailand was not found. Importantly, there is currently no formal evaluation or publication of public mHealth initiatives in Thailand. Moreover, there is a lack of knowledge for applications, policy framework, and technical expertise in addition to the unknown cost-effectiveness, all of which serve as barriers towards implementing mHealth initiatives for public health interventions (38).

[1] The Tobacco Products Control Act, B.E. 2535 (1992), the Non-smokers' Health Protection Act, B.E. 2535 (1992), and the Tobacco Act, B.E. 2509 (1966, amended 2009)
[2] The Health Promotion Fund Act, B.E. 2544 (2001)
[3] Education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring, and restriction
[4] Environmental/social planning, communication/marketing, legislation, service provision, regulation, fiscal measures, and guidelines

Table 1.1 Tobacco control measures in Thailand, classified by intervention functions and policy categories

Tobacco control measure	Policy category	Intervention function	Source
Reduce the demand of smoking			
1. Increasing tobacco prices and taxes - Excise taxes, tariffs, value added tax, and local maintenance tax (87% of retail prices as of 2014)	Fiscal measures	Coercion	Tobacco Products Control Act, B.E 2535 (1992) and Ministerial Regulations of the Ministry of Finance
2. Prohibition of sales, giveaways, complimentary goods, trading with tobacco products, and/or exchange with other services or merchandise and no sample hand-outs	Legislation	Restriction	Sections 6 and 7 of the Tobacco Products Control Act, B.E 2535 (1992)
3. Cigarette manufacturers or importers must print labels bearing images, warning statements, and contact channels for smoking cessation on the cigarette package, covering at least 85% of the total packaging space	Legislation	Education	Ministry of Public Health Notices (volume 130, 2013) under the Tobacco Products Control Act, B.E 2535 (1992)
4. Cigarettes manufacturers or importers must declare the list of ingredients: toxin and carcinogen labels	Legislation	Education	Ministry of Public Health Notices (volume 16, 2011) under the Tobacco Products Control Act, B.E 2535 (1992)
5. Tobacco advertising promotions and sponsorships are banned (television and radio, print media, and at sales points)	Legislation and Environment/social planning	Environmental restructuring	Section 8 of the Tobacco Products Control Act, B.E 2535 (1992)
6. Mass media public campaigns targeted at general public and specific communities	Communication/ marketing	Persuasion	Section 5.4 of the Health Promotion Fund Act, B.E. 2544 (2001)

Tobacco control measure	Policy category	Intervention function	Source
7. Raise awareness of hazardous behaviours	Communication/ marketing	Education	Section 5.3 of the Health Promotion Fund Act, B.E. 2544 (2001)
8. Community mobilisation (ad hoc community-based projects)	Service provision	Education, persuasion and training	ThaiHealth establishment (39)
Reduce the supply of tobacco			
9. Illicit trade in tobacco products	Regulation	Coercion	Tobacco Act, B.E. 2509 (1966)
10. Sales to and by minors under 18 years of age	Legislation	Restriction	Section 4 of Tobacco Products Control Act, B.E 2535 (1992)
11. Prohibit tobacco sales from vending machines	Legislation	Restriction and Environmental restructuring	Section 5 of Tobacco Products Control Act, B.E 2535 (1992)
Increase supportive measures to stop smoking			
12. Reduction of tobacco dependence and cessation - National telephone-based counselling call centre - Smoking cessation services in hospitals and community-based pharmacies	Service provision	Education, persuasion and training	Tobacco situation in Thailand (40-42)
13. Clinical practice guidelines for smoking cessation	Guidelines	Education and training	(43)
14. Mass media awareness campaigns - e.g. "Smoking Kid" campaign (https://www.youtube.com/channel/UCTYfWVDgWzFqAsYswpna0SQ)	Communication/ marketing	Persuasion	Smoking Kid campaign (44)

Tobacco control measure	Policy category	Intervention function	Source
Improve protection from tobacco smoke			
15. Establishment of non-smoking areas - e.g. health care and educational facilities, parks and sports fields, workplaces, shops and shopping centres, common areas of residences, gas stations, marketplaces, religious buildings, public transportation stops and stations	Legislation and Regulation	Restriction and Environmental restructuring	Ministry of Public Health Notices (volume 19, 2010) under the Non-smokers' Health Protection Act, B.E. 2535 (1992)
16. Health promotion financing system - 2% surcharge levied on alcohol and tobacco excise tax for the Thai Health Promotion Foundation (ThaiHealth). The mission of ThaiHealth is "to inspire, motivate, coordinate and empower individuals and organisations in all sectors for the enhancement of health promotive capability as well as healthy society and environment"	Legislation and Environmental/ social planning	Enablement	Section 11 of the Health Promotion Fund Act, B.E. 2544 (2001)

Intervention functions: education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring, and restriction

Policy categories: environmental/social planning, communication/marketing, legislation, service provision, regulation, fiscal measures, and guidelines

1.3.4 Smoking cessation services

Under Article 14 of the WHO FCTC, smoking cessation services should be easily accessible through advice from health care providers or a national telephone quitline. Behavioural therapies are associated with higher quit rates; such interventions include proactive telephone counselling via quitlines (45) and brief advice from physicians (46). Smoking cessation services are publicly available in Thailand (see **Table 1.2**). From the Thai national census, only 16% of smokers in Thailand have attempted to quit smoking of which 59% have tried to quit more than once (31). Around 97% of Thai smokers who tried to quit used an unassisted method (so called "cold turkey") to stop smoking (47). As health care for problems related to smoking is publicly available through the Universal Health Coverage Scheme, helping smokers quit by the age of 30 would result in lifetime cost savings of around 71,000 (£2,768) THB per person in males and 40,000 (£1,559) THB in females, with subsequent decreases in cost-savings as age increases (35).

Table 1.2 Characteristics of smoking cessation services in Thailand

Characteristic	Thailand National Quitline	Smoking cessation clinics	Community pharmacies
Type of service	- Telephone counselling by trained counsellors (20-30 minutes per complete session) - U-Quit: internet registration for call back services	- Face-to-face counselling by trained nurses or psychologists - Arrange a follow-up at the clinic on an agreed date or referral to the Thailand National Quitline	Face-to-face counselling by trained pharmacists
Availability	Monday to Friday: 7.30 - 20.00 Saturday to Sunday: 9.00 – 17.00 Closed: Public holidays	Monday to Friday: 8.30-16.30 (91.4% of public health facilities have these services (48))	Varies on pharmacy opening times (487 pharmacies)
Costs of service	Free of charge[1]	Free of charge	Free of charge
Monitoring	Monitoring for 6 times: within 7- and 15-day, and 1-, 3-, 6-,	Monitoring for 6 times: within 7- and 15-day, and 1-, 3-, 6-,	Varies

[1] The services are free of charge for both landline and mobile since 2011 and 2013, respectively

Characteristic	Thailand National Quitline	Smoking cessation clinics	Community pharmacies
	and 12-month after a set quit date	and 12-month after a set quit date (practices vary)	
Pharmaceutical therapy	No medication offered	Nortriptyline (free of charge)	Medicines (out-of-pocket)
Service utilisation	Data record: 92,045 smokers (and 24,817 relatives of smokers) between 2009 and 2012 (40)	Estimated 150 persons per year per clinic	Estimated 10 persons per year per pharmacy
Population coverage	Younger, educated, students, cigarette smokers compared to the national survey (40)	No available data	No available data
Cessation rates	12-month cessation rate: 19.5% (95%CI 14.5 to 26.2) for callers with complete counselling (40)	3-month cessation rate: 29.4% (49) 6-month cessation rate: 28.4% (49) 46.6% in chronic disease patients (50)	No available data
Cost-effectiveness study	**Cost savings:** $1,341 per quitter (40)	No available data (Thai context)	**Cost savings:** 17,504 THB for men and 21,500 THB for women (42)
Note on technology-assisted interventions	Planned implementation: 21-day motivation text messages for smokers who set a quit date	Only 1% use text messages as a medium to follow-up[1]	No available data

Source: Updated information from a policy brief for the development of health promotion and disease prevention policies for adults aged 25-59 years in Thailand published by Health Intervention and Technology Assessment Program.

[1] Current clinical guideline in Thailand does not contain SMS follow-up for smoking cessation. Therefore, the use of SMS depends on each smoking cessation clinic.

1.3.5 Assessing for research context

Possible research context, i.e. the delivery of short messaging service (SMS) interventions that were feasible for this PhD was assessed using seven criteria: acceptability; practicability; effectiveness; cost-effectiveness; affordability; side-effects (safety); and equity, otherwise known as the APEASE criteria (51). Since there is no standardised provision of smoking cessation services by community pharmacies (41), possible research context between the Thai National Quitline (TNQ) and smoking cessation services in hospitals was assessed using the APEASE criteria. A comparison of these criteria between the TNQ and smoking cessation clinics in Thailand is shown in **Table 1.3**. From the acceptability, affordability, and practicability viewpoints, the TNQ was chosen over the smoking cessation clinics as it was likely to be feasible for research management within the PhD timeframe, given that the TNQ is a national organisation.

Table 1.3 The APEASE criteria for designing and evaluating text messages services to support smoking cessation services in Thailand

Criteria	Thailand National Quitline	Smoking cessation clinics
Acceptability: Likely to be acceptable to key stakeholders	It is likely to be acceptable by the **public** and **professionals** if SMS is found to be effective with no additional costs. It is likely to be acceptable by **Thailand National Quitline** (TNQ) as SMS is planned for future implementation.	It is likely to be acceptable by the **public** and **professionals** if SMS is found to be effective with no additional costs. It is uncertain that SMS would be acceptable by **smoking cessation clinics** as there is no current finance system.
Practicability: Likely to be implemented at scale	Services can be delivered as designed without additional effort as there is only one service provider in Thailand.	Routine clinical practice may not be achievable because there are many levels of service providers in Thailand.
Effectiveness	The effect size in the Thai population is unknown; however, adding text messages to existing provision may improve cessation rates.	The effect size in the Thai population is unknown; however, adding text messages to existing provision may improve cessation rates.

Criteria	Thailand National Quitline	Smoking cessation clinics
Cost-effectiveness	It is likely to be very cost-effective if the intervention is shown to be effective among the Thai smokers.	The cost of implementation in the real setting is likely to be high; therefore, it is uncertain whether the intervention will be cost-effective.
Affordability: Implemented at the desired scale	The TNQ has developed an infrastructure to support an automated SMS service.	The cost of SMS provision is unknown.
Side-effects/Safety	It is unlikely to cause any unwanted side-effects or unintended consequences	It is unlikely to cause any unwanted side-effects or unintended consequences
Equity	It is likely to decrease health disparities as SMS provides smoking cessations supports from a distance with greater coverage whereas mobile app may worsen by excluding disadvantages.	It is likely to decrease health disparities as SMS provides smoking cessations supports from a distance with greater coverage whereas mobile app may worsen by excluding disadvantages.

1.3.6 Thailand National Quitline

The Thailand National Quitline (TNQ) was established in September 2008 to provide a countrywide-accessible telephone service for tobacco cessation. The service currently runs from 7.30 – 20.00 on Mondays to Fridays and from 9.00 – 17.00 on Saturdays and Sundays. There are no services available on public holidays, except for automated voice messages. The service has been free-of-charge through a toll-free number (1600) for landline phone users since 2011 and for mobile phone users since 2013. The TNQ applies the 5A's framework (**Ask** for tobacco use status, **Advise** to quit smoking, **Assess** the willingness to quit, **Assist** for quit attempt, and **Arrange** for follow-up) (52) and a transtheoretical model or the stage of change model in their service provision (41).

The TNQ provides counselling to all smokers who are interested in quitting smoking. Counselling services in the TNQ are provided by call-takers and counsellors. Call-takers are the persons responsible for short communications with callers and serve as the initial screener to identify whether the callers are smokers and would like to receive counselling

from the TNQ. Since the calls may not come from smokers, when the caller is identified as a smoker, he or she will be referred to a TNQ counsellor to assess smoking behaviour and offer support via follow-up services when smokers set their quit date within a month. This time point is used as it correlates with intention to stop smoking (53). Then, the TNQ counsellor will provide either a brief intervention (which includes mentioning the harms of smoking and offering advice to quit smoking) if the smokers have limited time to talk on the phone, or a full quit smoking counselling session that usually lasts for 20-30 minutes. After providing the counselling, if the smoker sets a quit date within a month, he or she will be offered follow-up calls at 7-day, 15-day, 1-month, 3-month, 6-month, and 12-month intervals after the quit date. If smokers refuse to set a quit date or to receive follow-up services, they will no longer receive any service from the TNQ. A referral service between the TNQ and smoking cessation clinics is also available free of charge for smokers who would like further support. **Figure 1.4** shows the telephone service provided by the TNQ.

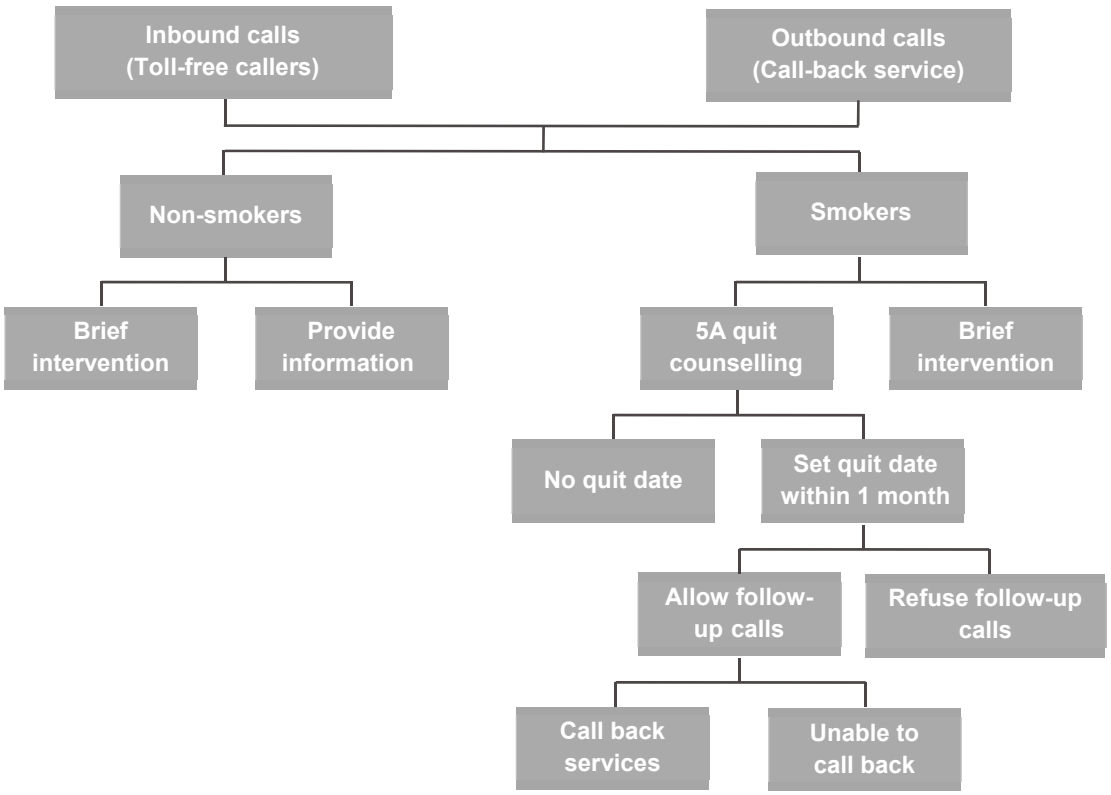
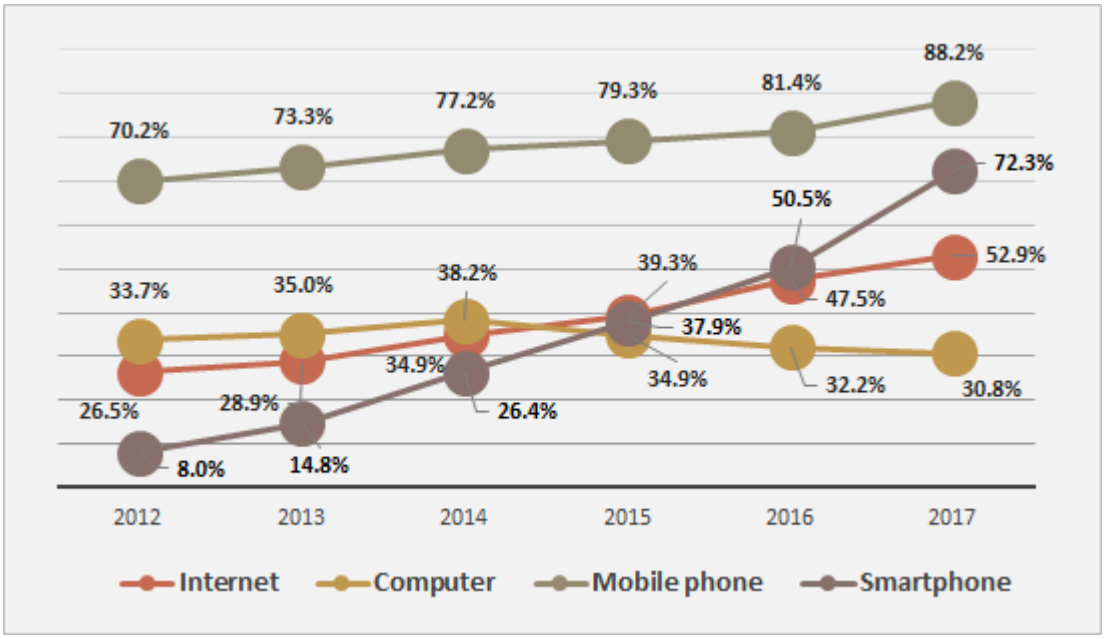


Figure 1.4 Thailand National Quitline service flow

1.3.7 Mobile phone usage

Mobile phones have become popular and are now considered an important part of everyday life. From the Thai national census (54, 55), the ownership of mobile phones

increased from 70% in 2012 to 88% in 2017 (see **Figure 1.5**); 55.6 million Thais aged more than six years own a mobile phone. The coverage of smartphones and feature phones[1] in Thailand was estimated to be 72% and 30%, respectively (55). Besides the basic functionality of calling others, 72% of mobile phone users used SMS while 48% accessed the internet (55). The increasing trend in digital technology has raised a demand for the development of a national policy. Hence, the Ministry of Digital Economy and Society of Thailand was established in 2016 and aims to put in place a 20-year National Digital Economy Masterplan, including 1) the development of digital infrastructure; 2) acceleration of the digital economy; 3) promoting a digital society; and 4) developing e-Government law (56). This national policy environment for digital technology should provide the foundation necessary to allow for the quicker proliferation and adoption of mHealth in Thailand.



Source: The 2016 and 2017 Household Survey on the Use of Information and Communication Technology (54, 55)

Figure 1.5 Percentage of Thai population aged six years and over who used the internet, computer, mobile phone and smartphone between 2012 and 2017

[1] A type of mobile phone which allows the basic functionality of a mobile phone (including voice calls, text messages, multimedia, and internet capability) and has pre-installed apps from the manufacturer but unable to install additional third-party apps. Feature phones are inexpensive compared to smartphones.

Chapter 2: Methodological approach for this thesis

2.1 Chapter overview

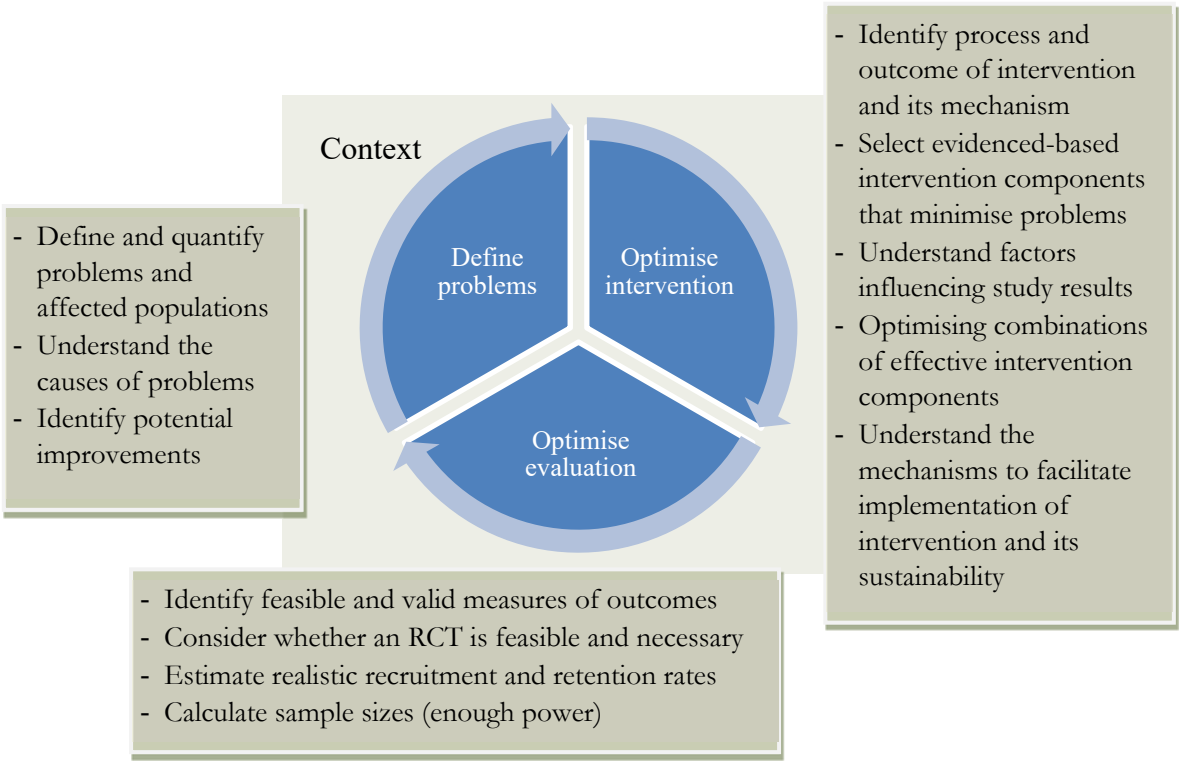
This chapter explains the philosophical orientation and theoretical basis underpinning, the aims, objectives, and research questions. The research plan is briefly summarised. For research studies that involved human subjects, research ethics and governance are detailed.

2.2 Philosophical orientation and theoretical basis

The philosophical orientation (paradigm) of viewing knowledge involves the beliefs of what reality is (ontology) and how knowledge can be generated (epistemology). The philosophical orientation directs attention and provides a framework for interpreting observations (57). In this thesis, the epistemology underpinning is post-positivism, where the reality of knowledge exists, but it can only be known imperfectly with a degree of uncertainty. Such phenomena can be measured using the deductive approach, or theory-driven approach, and it is possible to explain association and causation through a range of quantitative study designs. Bonell and colleagues propose a 'realist randomised controlled trials' approach that synergised between RCTs and realist approaches for evaluating complex public health interventions (58). The approach not only embraces the notion of causality derived from an RCT but also focuses on the understanding of mechanisms with consideration of the cultural, social and political context that can impact knowledge generation. Realist RCTs place emphasis on understanding the effects of intervention components separately as well as in combination, and the mechanism of changes.

Theory is positioned as a crucial starting point for intervention development and evaluation and is emphasised by the UK Medical Research Council (MRC) framework (59, 60) (see **Figure 2.1**). The results of theory-based interventions to change behaviour in the literature were mixed. For example, Webb's meta-regression of internet-based behaviour change interventions suggested that extensive use of theory to develop intervention was associated

with a greater effect size compared to not applying any theory (9); however, it contradicted in Prestwich's meta-regression of diet behaviour change studies, which coded use of theory in more detail (61). However, the meta-regression is a type of observational study reported as an association rather than as a causal relationship. There are over 93 behaviour change theories available in the literature (62). The majority of behaviour change theories were developed in high-income countries where the applicability of theory in a different context such as LMICs requires further exploration; more research is needed to integrate contexts into these theories.



Source: adapted from Campbell et al. (2007) Medical Research Council framework (8)

Figure 2.1 Medical Research Council framework to design the evaluation for theory-based behaviour change complex interventions for health promotion

There was a gap of knowledge in the design and formal evaluation of individual based-interventions from the mapping exercise of the Thai policies and interventions related to tobacco control (**Chapter 1, Section 1.3.3**). Therefore, the focus of this thesis is on individual-level behaviour change theory. Criteria for theories relevant to the area of behaviour change include 1) clarity of constructs, 2) clarity of relationship between constructs, 3) measurability, 4) testability, 5) being explanatory, 6) describing causality, 7) achieving parsimony, 8) generalizability, 9) evidence-based (62).

The theoretical framework underpinning smoking cessation behaviour for this thesis is depicted in **Figure 2.2**. Individual behaviour is explained by the COM-B system which suggests that the interaction of capability (C), opportunity (O), and motivation (M) leads to behaviour change (B); likewise, behaviour can alter the capability, opportunity, and motivation of individuals (37). **Capability** is defined as "the individual's psychological and physical capacity to engage in the activity concerned" such as knowledge and skills to perform a behaviour. **Motivation** is defined as "all those brain processes that energise and direct behaviour, not just goals and conscious decision-making". **Opportunity** is defined as "all the factors that lie outside the individual that make the behaviour possible or prompt it". This theoretical framework was chosen because of its clarity of constructs and the relationship between constructs, ability to achieve parsimony, and generalisability to any types of health behaviour change. However, there is still a gap of knowledge regarding whether this theoretical framework is measurable, testable, explanatory, or can describe causality.

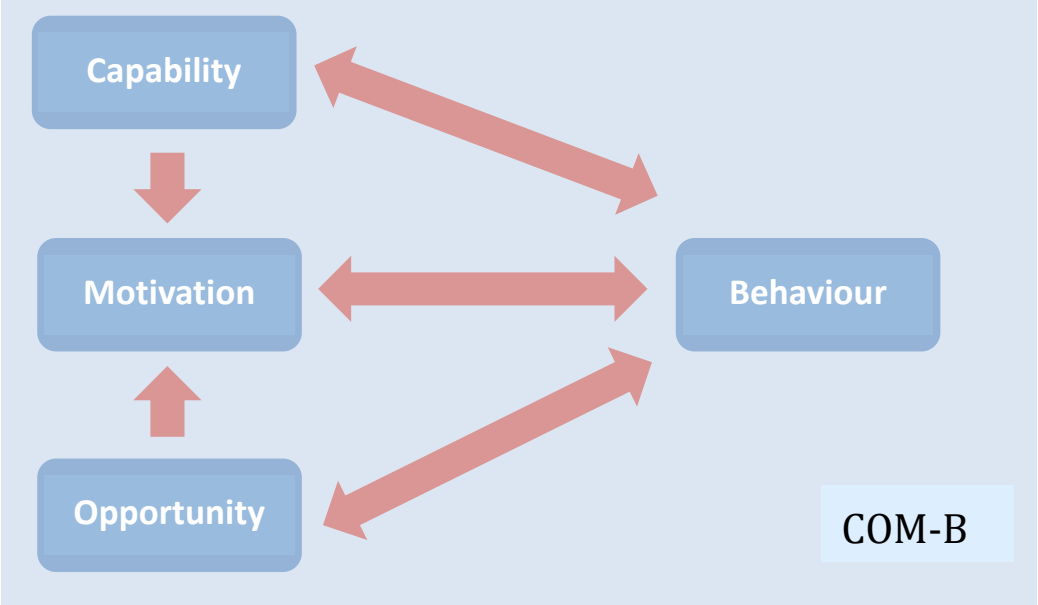


Figure 2.2 COM-B system (37)

2.3 Thesis aims

This research aims to improve smoking cessation rates among Thai smokers by understanding the effective components of mHealth behaviour change interventions associated with improvements in smoking cessation. It is also expected that the findings from this PhD thesis should be beneficial to researchers planning for and developing

complex mHealth interventions and to the Thailand National Quitline (TNQ) to enhance their existing routine practices.

2.4 Thesis objectives

The primary objectives of this thesis are:

1. To systematically identify effective components of mHealth behaviour change interventions (e.g. behaviour change techniques, modes of delivery, functionality) associated with improvements in smoking cessation;
2. To design mHealth behaviour change interventions that contain effective components to support smoking cessation among Thai smokers; and
3. To simultaneously test whether effective components in mHealth behaviour change interventions improve smoking cessation rates among Thai smokers.

2.5 Research questions

The research questions for the first objective are:

1) What is the effectiveness of mHealth behaviour change interventions for smoking cessation?

2) Which active components of mHealth behaviour change interventions are associated with improvements in smoking cessation rates?

The research question for the second objective is:

1) What are acceptable text messages aimed at different behavioural components for smoking cessation in Thailand?

The research questions for the third objective is:

1) What behavioural components in mobile text messages can improve behaviour to support smoking cessation at 1-month follow-up in Thai smokers?

2.6 Research plan

This research was divided into three studies (**Figure 2.3**). Study 1 was a systematic review, meta-analysis, and meta-regression to identify and synthesise the effective components of mHealth interventions associated with improvements in smoking cessation. The results from Study 1 informed the design of the mHealth intervention (Study 2) by combining the active components into an intervention and testing its impact (Study 3) on Thai participants.

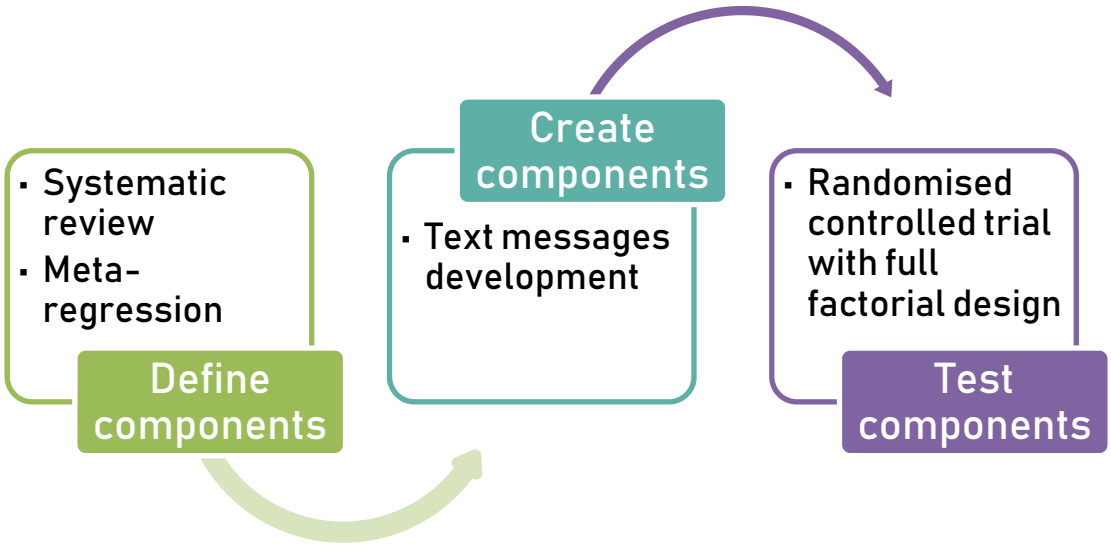


Figure 2.3 Flow diagram of this research

2.7 Research ethics approval

There was no human participant involvement in the systematic review, meta-analysis, and meta-regression study (Study 1); therefore, ethical approval was not required. However, Study 2 and Study 3 involved human participants so an ethical review was obtained prior to undertaking the research.

The ethical review was conducted by 1) the Institute for the Development of Human Research Protections, Thailand, and 2) the School of Medicine Research Ethics Committee, University of Leeds (MREC16-001). Ethical approvals for this thesis were

granted on 27 September 2016 and 31 October 2016, respectively. Three amendments were made to Study 3 (see **Appendix B** for ethical approval letters and amendments).

2.8 Research governance

2.8.1 Confidentiality

Participant's mobile phone numbers were used as the link between the baseline questionnaire and the 1-month follow-up questionnaire. A trial identification number was assigned to participants once data from the baseline questionnaire and 1-month follow-up were merged. When the data was checked, validated, and cleaned, the mobile number was kept in a separate file and identification numbers were used instead. Other confidential information such as personal information and email addresses were not linked to the questionnaire data and were kept in a separate file or location.

The report of outcomes was presented in an aggregated form; therefore, it is very unlikely that confidentiality was breached. However, measures to prevent accidental breaches of confidentiality were taken as follows:

- All information collected from this study were stored on a password-protected server at the University of Leeds with remote access through a password protected "Desktop Anywhere" software.
- For data that were transferred between research teams, transferral occurred via a secure file transfer system and kept on a password-protected secure server. Any files that contained identifiable data were marked as confidential.
- Any hard copies of confidential information were kept in a locked cabinet at the Health Intervention and Technology Assessment Program (HITAP) during the data collection period in Thailand. Once transferred to the United Kingdom, the information was kept in a locked cabinet at the Leeds Institute of Health Sciences.
- In the case where a breach of confidentiality may have occurred, guidance from the University of Leeds ethical committee was to be sought.

2.8.2 Data protection

Online questionnaires were created using a secured Bristol Online Survey account (subscribed by the University of Leeds), available from https://www.onlinesurveys.ac.uk/. All survey data and backups were stored on servers located at the University of Bristol, United Kingdom. Therefore, this complies with the Data Protection Act.

2.8.3 Data sharing

Checked, validated, and cleaned data were backed up and stored electronically with no link to any personal information of the participants. The clause: "I understand that other genuine researchers may use my answers in publications, reports, web pages, and other research outputs only if they agree to preserve the confidentiality of the information as requested in this form" in the participant consent form allows for the use of aggregate data by other research teams.

2.9 Research funding

Study 2 and Study 3 were funded by the Health Promotion Economic Evaluation Collaborative Center in Thailand (Budget from ThaiHealth Promotion Foundation), Grant number 58-00-0385. The application for funding was submitted in November 2015 and research funding was awarded for 1,595,000 Baht (£37,000) from 15 August 2016 to 10 April 2018 (**Appendix C**). HITAP managed this grant. The funders had no role in study design, data collection and analysis, nor in the decision to publish the results.

Chapter 3: Identifying effective components for mobile health behaviour change interventions for smoking cessation: a systematic review and meta-analysis

3.1 Chapter overview

A lack of evidence on effective components of mHealth behaviour change interventions for smoking cessation (the scoping review in **Chapter 1**) limit the future design of the intervention. A systematic review was conducted as an extensive review of current literature to systematically identify mHealth behaviour change interventions for smoking cessation. A meta-analysis was performed to assess the smoking cessation rate of mHealth behaviour change interventions identified from the systematic review. Lastly, a meta-regression was used to understand what characteristics of mHealth behaviour change interventions at the study level associated with improvements in smoking cessation. The methods and results of the systematic review, meta-analysis, and meta-regression are presented and discussed in this chapter.

3.2 Aim and objectives

3.2.1 Aim

To understand the effective components in mHealth behaviour change interventions for smoking cessation

3.2.2 Objectives

- To identify existing mHealth behaviour change interventions for smoking cessation
- To assess the effects of mHealth behaviour change interventions for smoking cessation

- To identify factors associated with the effectiveness of mHealth behaviour change interventions for smoking cessation

3.3 Rationale for the systematic review, meta-analysis, and meta-regression

A systematic review is a type of literature review that involves steps to exhaustively summarise literature for a specific question with the aim for a totality of current knowledge. It involves steps to specify the research questions, identify relevant literature, extract relevant information, assess the quality of evidence, and synthesise evidence. A systematic review is preferred over traditional or narrative reviews because it requires an extensive review of current literature and avoids the subjectivity of included studies. Moreover, it provides a structured procedure prior to the review and minimises bias in order to provide reproducible conclusions.

A meta-analysis is a type of statistical analysis that combines the results of two or more studies. The advantages of pooling results from more than one study are to increase the power to detect an effect from an intervention and to improve the precision of estimates due to an increase in samples from multiple studies (63). However, the complexity of mHealth behaviour change intervention pose challenges to the conventional meta-analysis methods. Heterogeneity—the variation in study outcomes—in meta-analysis of complex public health intervention are expected; therefore, the more important question is to address how these variations occur.

Meta-regression is an extension of the meta-analysis to investigate how the treatment effects vary with the characteristics of included studies (64). The unit of analysis can be at an individual-level using individual participant data or at a study-level using aggregate data. However, such individual data is required from other research groups which demand more resources and time. A meta-regression using aggregate data requires a sufficient number of synthesised studies to be able to conduct this analysis (similar to a regression analysis). It can be used to identify potential moderators of treatment effects and applied for tailoring variables for adaptive interventions (65). However, meta-regression should be viewed as an observational study reported as an association rather than causation (66). Building on the knowledge of others, a meta-regression can explain how the effect size of smoking

cessation varies across various components of mHealth behaviour change interventions (behaviour change techniques, technology functionality, and theory-based design).

3.4 Methods

3.4.1 Protocol registration and reporting guidelines

The protocol of this systematic review was registered on the PROSPERO International prospective register of systematic reviews (PROSPERO CRD42016026918) to provide transparency in the review process. The Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 (67) and its supporting paper (68), and the Cochrane Handbook for Systematic Reviews of Interventions (63) were used as guides to developing the protocol for the systematic review and meta-analysis study. The study protocol was also published in the Systematic Reviews journal (69). For reporting the results of the systematic review and meta-analysis study, the PRISMA checklist (70) and its supporting paper (71) were used as a guide (see details in **Appendix D**).

3.4.2 Eligibility criteria

The PICOS acronym—'**P**articipants', '**I**nterventions', '**C**omparators', '**O**utcomes', and '**S**tudy designs' (72)—was used as a tool to identify relevant literature for this systematic review. PICOS is an extension of PICO with an addition of the 'Study design' element. The PICO is applied and recommended as a framework for a quantitative systematic review (73). It provides a clear set of an outline to develop keywords for a comprehensive search and selection of studies for analysis. The eligibility criteria for the inclusion and exclusion of studies for this systematic review were:

Participants:

Participants were smokers of any age regardless of their intention to quit smoking. Participants were recruited from any country or setting (e.g. public health programme or primary health care).

Interventions:

Any interventions aimed at smoking cessation that were delivered through or in combination with mobile phones via short messaging services (SMS), multimedia

messaging services (MMS), phone calls, interactive voice responses (IVR), emails, web browsers, social media, and mobile apps were included. The rationale to include different types of mHealth interventions was to allow for all types of communication through mobile phones and their characteristics. The use of mobile phones only for research design facilitation or for data collection purposes were excluded. Interventions aimed at preventing new smokers were also excluded from this study. Web-based interventions that were not delivered through mobile phones were excluded from this study as it requires participants to own a personal computer.

Comparators:

All types of comparators such as no interventions, usual care, and alternative mHealth interventions were included. The rationale to include alternative mHealth interventions was to understand the characteristics and different types of controls used in mHealth intervention studies.

Outcomes:

The primary outcomes were smoking abstinence, biochemically-verified or self-reported, at any follow-up period (e.g. 1-, 3-, 6-months or 12-months). Secondary outcomes included biochemically-verified smoking abstinence at any follow-up period and self-reported uptake of smoking cessation services at any follow-up period defined as the number of smoking cessation services attendance (service utilisation) and status of setting a quit date.

Study designs:

Any design of randomised controlled trials (RCTs) was included in the review. Quasi-experimental studies such as controlled clinical trials (CCTs), controlled before-after (CBA) studies were excluded from the review to avoid the risk of selection bias from non-random assignment of treatment groups. Observational studies that did not have a control group such as cross-sectional studies, case series, and case reports were also excluded because these types of studies provide descriptive information or associations only, and do not provide evidence for any causal relationships between interventions and outcomes.

3.4.3 Search strategy

A literature search was conducted using electronic databases to identify relevant studies systematically and reproducibly. Though MEDLINE and EMBASE are the most commonly used databases for literature searching (74), additional databases were added for an inclusive literature search. A consultation on the electronic databases and search terms for the review topic were conducted with Judy Wright—an information specialist at the Leeds Institute of Health Sciences—before the actual search.

Pritaporn Kingkaew (PK) performed the search by searching Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, EMBASE, PsycINFO, Web of Science, and CINAHL (EBSCOhost). Text words and subject heading terms (if available) for mobile phone, text messaging, mobile application, interactive voice response, email, internet, web browser, social media, smoking cessation, tobacco use, smoking, tobacco use disorder, smoking behaviour, and randomised controlled trial were used. **Appendix E** shows the electronic search strategies for all databases. To minimise publication bias, a review of the grey literature was conducted through a search from Open Grey and WorldCat. Reference lists of included studies were screened for relevant studies.

3.4.4 Study selection

There is no standard process recommended in guidelines for study selection; common practice used for the selection process involved three steps: 1) remove duplicated references, 2) screen for relevant titles and abstracts, and 3) assess for eligible studies (71). All search records from the electronic databases were managed using a reference management software, EndNote version X7 (Thomson Reuters (Scientific) LLC, New York). All duplicates of the same publication from different databases were screened and removed by the 'find duplicate' function in EndNote X7.

Titles and abstracts of studies were screened by one reviewer (PK) using a study eligibility form (**Appendix F**). Though two independent investigators for the study selection process were recommended in practice to reduce the possibility of selection bias (75), it was not feasible for this PhD. To avoid potential error of judgement, a random sample containing 20% of all abstracts was independently screened by two reviewers, PK and Liz Glidewell (LG). Reliability and agreement rate was tested prior to full review. The review authors

resolved the disagreements over the inclusion of the 20% abstract samples through discussion (76). Cohen's kappa was used to report the degree of agreement (77).

The full text of included studies was then retrieved and assessed for eligibility by one reviewer (PK) using a study eligibility form which was designed by PK for this study (**Appendix F**). Again, a random sample containing 20% of the full texts was independently checked by two reviewers (PK and LG). Disagreements between the review authors over the inclusion of the 20% full text samples were resolved by discussion.

3.4.5 Data collection and data extraction

Detailed descriptions of mHealth behaviour change interventions allow for the future design and replication of interventions. A CONSORT checklist has been developed especially for reporting web-based interventions and mHealth interventions (78). It expanded the descriptions of mHealth interventions to include mode of delivery, features, functionalities, components of intervention and comparators, and the theoretical background for intervention development.

In this field of research, it is recommended that more than one reviewer should extract data to minimise errors and reduce biases (63). As mentioned above, an additional reviewer was not feasible for this PhD. As such, one review author (PK) independently extracted the data using the data extraction form (**Appendix G**). A random sample containing 20% of data extraction was independently checked by two reviewers (PK and LG) to ensure the quality of extracted data. The discussion for discrepancy was used as an input for the rest of the data collection process.

The extracted data are summarised in **Table 3.1**. Full text of eligible studies was explored for information related to the development of the interventions. If it was stated elsewhere, such as in the study protocol or descriptive and qualitative study, additional references were included for data extraction purposes only. Separate notation of sources of information was identified. Coding for theory used and BCTs was conducted for both intervention groups and comparator groups (control, usual care, and alternative interventions). Details for data extraction are provided in the section below.

Table 3.1 Extracted information from eligible studies

Item heading	Extracted information
Publication details	First author name, year of publication
Study setting	Country and source of participants, e.g. primary / secondary care, pharmacy, advertisement
Duration of intervention and follow-up	Reported information on the duration of the intervention and follow-up for each outcome (in weeks/months)
Year of study	Study period
Participant demographics	Participant mean age, percentage of current smokers, average number of cigarettes per day
Sample size	Sample sizes included in the analysis
Perceived barriers	Identified barriers of behaviour change prior to intervention design
Theory used to design intervention	Theory Coding Scheme (79), prioritised to 5 domains: 1) theory used to inform interventions; 2) theory used to classify participants; 3) theory used to tailor interventions according to participants; 4) theory used to measure outcome changes; and 5) theory used in discussion of study
Behaviour change techniques	Coding scheme for behaviour change technique using BCTTv1 (30)
Mapping behaviour change techniques	Theoretical Domains Framework (80) and BCTS
Mobile functionality	SMS, MMS, e-mail, phone call, internet, apps, interactive voice responses (IVR)
Tailored design	No tailoring function (fixed intervention)/ Personalised to user characteristics / Tailored to participant needs
Communication pathway	One-way/ two-way/ interactive communication
Description of technology engagement	Detailed description of any form of measurement for engagement in technology, e.g. automated monitoring of users' interactions with the system, etc.
Description of control and intervention groups	Detailed description of control and intervention groups
Outcomes measured	Self-reported smoking abstinence (number) Verified smoking abstinence (number) Uptake of smoking cessation services, e.g. service utilisation, status of quit date set, etc.
References of additional information	Additional information elsewhere that is related to the intervention design

3.4.5.1 *The use of theory for intervention development*

The explicit application of theories is associated with improved outcomes in internet-based behaviour change interventions (9). To improve the quality of the development, evaluation, and implementation of complex mHealth interventions, the way theories have been used is a key issue for future development. The Theory Coding Scheme offers a description of how theory can be applied in the behaviour change intervention study and a 19-item Theory Coding Scheme was developed to specify the use of theory (79). **Figure 3.1** highlights the main mechanism of theory used and comprises five pathways: 1) theory used to inform interventions; 2) theory used to classify participants; 3) theory used to tailor interventions according to participants; 4) theory-relevant constructs measured as mediators or outcomes; and 5) results used to refine theory or constructs. Theory used was coded as a binary variable, yes or no, for each pathway. A subgroup of the use of theory for intervention development included pathways 1 to 3.

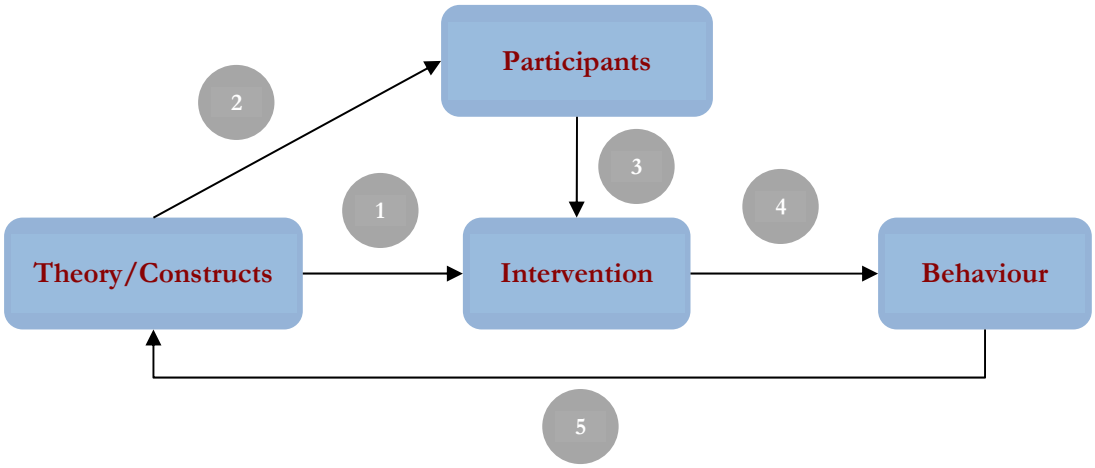


Figure 3.1 Mechanism of theory used in behaviour change intervention studies

3.4.5.2 *Behaviour change techniques*

Behaviour change techniques (BCTs) are the smallest elements of behaviour change interventions (30). With different labels or terms used for behaviour change techniques, the synthesis of evidence and replication of behaviour change interventions is limited. A taxonomy specific for identifying BCTs for smoking cessation intervention is available (81). However, the Behaviour Change Technique Taxonomy version 1 (BCTTv1)—a generic BCT taxonomy—was used to allow for cross-comparison across different types of behaviours and disciplines (30). The BCTTv1 comprises 93 clearly-defined BCTs that are

grouped into 16 domains, with the definition of each BCT and the examples publicly available at *http://www.bct-taxonomy.com/*.

Standardising the coding of BCTs requires experience (82). Prior to the coding, the principal investigator (PK) was self-trained using the BCTTv1 training online (available at *http://www.bct-taxonomy.com/*). For consistency of data extraction, a coding manual for BCT data extraction was developed. The BCTs were classified by PK and referred to the BCTTv1 smartphone application and the coding manual for reference. Two trained coders (PK and LG) independently identified the BCTs from 20% of all included studies. Discrepancies regarding the BCT coding were resolved through discussion. From the discussion, the coding manual was revised accordingly to accommodate an agreed coding system. For example, any support from the smoking cessation counselling were to be coded as *BCT Social support (practical)* and *BCT Social support (emotional)* to ensure the consistency of data coding. Presence of BCTs was coded as a binary variable, yes or no, for each BCT and behaviour change domain.

3.4.5.3 Coding behaviour change techniques into COM-B behaviour change components

Referring to Michie's COM-B system, individual behaviour can be explained by the capability (C), opportunity (O), and motivation (M) of individuals that leads to behaviour change (B) (37). To guide the future intervention development, individual BCT of behaviour change interventions can be grouped into the COM-B system as potential effect modifiers. However, the BCTs within the 16 domains of BCTTv1 were shown to overlap across behaviour change components, including domains *Goal and planning*, *Feedback and Monitoring*, *Natural consequences*, *Associations*, *Regulation*, *Antecedents*, and *Identity*.

To avoid multicollinearity between the 16 domains of BCTTv1 when conducting a meta-regression, the 93 BCTs were coded into COM-B components of behaviour: 'Capability', 'Opportunity', and 'Motivation'. Presence of COM-B components was coded as a binary variable, yes or no. There were no explicit mapping methods available. The Theoretical Domains Framework (TDF) (80) was used as an initial guide to categorising BCTs into theoretical constructs from previous work conducted by Cane *et al.* 2012, 2015 (83). PK mapped 93 BCTs into 'Capability', 'Opportunity', and 'Motivation' behaviour change components of the COM-B system (see Table **3.2**).

Table 3.2 Mapping behaviour change techniques to the COM-B system

COM-B		TDF	Behaviour change techniques (BCTs)
Capability	Psychological	Knowledge	All BCTs in the **Shaping knowledge** domain
			BCT 2.2 Feedback on behaviour BCT 2.6 Biofeedback BCT 2.7 Feedback on outcome(s) of behaviour
			BCT 5.1 Information about health consequences
		Skills	All BCTs in the **Repetition and substitution** domain
			BCT 1.2 Problem solving
			BCT 12.4 Distraction
		Memory, attention and decision processes	BCT 11.3 Conserving mental resources
		Behavioural regulation	BCT 2.1 Monitoring of behaviour by others without feedback BCT 2.3 Self-monitoring of behaviour BCT 2.4 Self-monitoring of outcome(s) of behaviour BCT 2.5 Monitoring of outcome(s) of behaviour without feedback
	Physical	Skills	BCT 12.6 Body changes (association of physical activity rather than TDF Skills)
Opportunity	Social	Social influences	All BCTs in the **Social support** domain
			All BCTs in the **Comparison of behaviour** domain
			BCT 12.2 Restructuring the social environment
			All BCTs in the **Identity** domain, except BCT 13.5 Identity associated with changed behaviour
	Physical	Environmental context and resources	BCT 11.1 Pharmacological support
			All BCTs in the **Associations** domain, except BCT 7.8 Associative learning
			All BCTs in the **Antecedents** domain, except BCT 12.4 Distraction
Motivation	Reflective	Social/professional role & identity	BCT 13.5 Identity associated with changed behaviour
		Beliefs about capabilities	All BCTs in the **Self-belief** domain
		Optimism	BCT 15.1 Verbal persuasion about capability
		Beliefs about consequences	All BCTs in the **Comparison of outcomes** domain
			All BCTs in the **Covert learning** domain
			BCT 5.2 Salience of consequences BCT 5.3 Information about social and environmental consequences BCT 5.5 Anticipated regret
		Intentions	BCT 1.8 Behavioural contract BCT 1.9 Commitment
		Goals	BCT 1.1 Goal setting (behaviour) BCT 1.3 Goal setting (outcome)

COM-B		TDF	Behaviour change techniques (BCTs)
			BCT 1.4 Action planning BCT 1.5 Review behaviour goal(s) BCT 1.6 Discrepancy between current behaviour and goal BCT 1.7 Review outcome goal(s)
	Automatic	Social/professional role & identity	BCT 13.5 Identity associated with changed behaviour
		Optimism	BCT 15.1 Verbal persuasion about capability
		Reinforcement	All BCTs in the **Rewards and threat** domain
			All BCTs in the **Scheduled consequences** domain
			BCT 7.8 Associative learning
			BCT 11.4 Paradoxical instructions
		Emotions	BCT 5.4 Monitoring of emotional consequences BCT 5.6 Information about emotional consequences
			BCT 11.2 Reduce negative emotions

Note: TDF: Theoretical domain framework; **BCTs:** Behaviour change techniques

3.4.5.4 The design of mHealth interventions

Mobile functionality in this study is defined as the use of a mobile phone to deliver intervention content (or the mode of delivery). Examples of the mode of delivery for mHealth interventions include SMS, MMS, e-mail, phone call, IVR or the use of mobile phones to access web-based information or mobile apps.

Communication pathways include one-way, two-way, and interactive communications. One-way communication entails a single direction of information exchange from sender to receiver, while two-way communication involves feedback from the receiver to the sender as well. Interactive communication refers to a conversation or IVR type of communication where responses are instant.

A tailored design aims to create an intervention targeting a specific patient or individual (individualised), similar to market segmentation—grouping customers—in the business field. The main goal is to enhance the relevance of information provided to a particular individual. The mechanism on how tailored design can offer relevant information to recipients should be primarily focused to advance knowledge in this field (84). Head *et al.* (2013) found that targeted and tailored messages correlated with a better effect size (12). Personalisation is defined as a form of design specifically for the individual receiving intervention, 'just for you' type of individualisation and not necessary to meet individual needs. Personalisation uses person-specific characteristics such as name, age, gender, and

birth date to increase attention, relevance or motivation to process messages (84). Tailoring to participant needs provides a higher level of information that meets the needs of the individual. Examples of tailoring to participant needs include tailoring to a participant's stage to quit smoking or a need for support for smoking cravings.

3.4.5.5 Outcomes measured

The primary outcome was self-reported or validated smoking abstinence at any follow-up, which is a dichotomous outcome variable. The secondary outcomes included other smoking abstinence measured and uptake of smoking cessation services, e.g. service utilisation and status of a set quit date.

3.4.5.6 Risk of bias

A bias is a systematic error that can either lead to the underestimation or overestimation of the true intervention effect. The sources of bias in an RCT include selection bias, performance bias, detection bias, attrition bias, reporting bias, and other types of biases; all of which can be assessed using the Cochrane Risk of Bias Tool (63). To avoid potential error of judgement, a random sample containing 20% of the full texts was independently assessed by two reviewers, PK and Rebecca Walwyn (RW). Disagreements between the review authors over the risk of bias were resolved through discussion. Discussion for discrepancy was used as an input for the rest of the quality assessment process. For example, any studies with an assumption to treat missing outcome data as smokers (a common approach to dealing with the issue in smoking cessation studies) were coded as 'unclear risk of bias'. A description of the risk of bias was summarised across included studies. The results of the meta-analysis were to present an estimated effect based on all available studies.

3.4.6 Synthesis of results

3.4.6.1 Meta-analysis

When there is a sufficient number of studies (more than 10 studies) reporting similar outcomes (85), a meta-analysis can be used to estimate the pooled treatment effect. To determine the effect size, the odds ratio (OR) was used for the primary outcome, self-reporting or verified smoking abstinence (e.g., smoking status: yes/no). The standardised mean difference, using Hedges' g statistic (86), was used for continuous outcome

measurements comparing between the treatment and control groups (e.g., increase in the number of attendances at a smoking cessation service). All statistical analyses were undertaken using Stata/IC software (Release 14; StataCorp, 2015) (87).

From the scoping review (**Chapter 1**), it was expected that the nature of the studies included in this systematic review differed (intervention and patient population), and heterogeneity between studies was expected. Consistent with this assumption, the random-effects model was used to estimate a pooled treatment effect because it recognises within study variance and between-study variance. A meta-analysis (the ***metan*** command) was conducted using the random-effects model (Inverse-variance methods and DerSimonian and Laird methods of moment estimator), with 95% confidence intervals and significance level set at 5% (88). Heterogeneity between studies was assessed using the I^2 statistic. When I^2 exceeds 50% (moderate heterogeneity), heterogeneity will be addressed through a meta-regression (89, 90).

To explore any publication bias, a funnel plot of the log odds ratio against the standard error of the log odds was displayed for each outcome. Egger's test was used to test for asymmetry for continuous outcomes (91) while the Peters (92) and Harbord (93) test was used for binary data. The Peters and Harbord test is proposed to avoid the mathematical association between the log odds ratio and its standard error (false-positive test results) that may occur from Egger's test (63). The fixed- and random-effects estimates of the intervention effect were compared for any small-study effects. When there is evidence of small-study effects on the pooled effect, sensitivity analysis based on selection models proposed by Terrin *et al.* (2003) (94) will be used to estimate a pooled effect adjusted for selection bias (95). This method is recommended over the trim-and-fill method as it provides better performance in a simulation study.

3.4.6.2 Meta-regression

A meta-regression analysis was conducted to identify which components of mHealth behaviour change interventions are associated with improvements in smoking cessation rates and uptake of smoking cessation services when there is at least 10 studies (85). All statistical analyses were undertaken using Stata/IC software (Release 14; StataCorp, 2015) (87). Pre-specified covariates are recommended in order to avoid false positive conclusions. Covariates that were fitted in univariate analysis include the duration of intervention, the use of theory to design the intervention, BCTs, mobile functionality, tailored design, and

communication pathway. The rationale for these covariates are provided in the data extraction section (**Section 3.4.5**).

Two approaches for the meta-regression analysis were employed. The first approach assumes all control interventions across studies are the same (the ***metareg*** command). This first approach regresses only covariates (characteristics) from intervention arms using a random-effects meta-regression. The second approach considers the characteristics of controls in addition to the first approach. A multilevel logistic regression for repeated measures, allowing for different follow-up times, was fit to estimate the effect of interventions towards binary outcomes, including the primary outcome—self-reporting smoking abstinence (the ***meqrlogit*** command).

3.5 Results

3.5.1 Description of included studies

A total of 1,593 studies were identified until the second week of October 2015. After removing duplicates, 730 studies were screened based on titles and abstracts. The agreement rate for the title and abstract screening stage was 86%. Discussions between PK and LG resolved any discrepancies. Of these studies, the full texts of 110 studies were screened for detailed assessments, with twenty-four meeting the inclusion criteria. However, as one study did not report smoking cessation outcomes (96), only 23 studies were included in the meta-analysis and meta-regression results. **Figure 3.2** shows the details of the PRISMA flow diagram.

A descriptive summary of the study characteristics is summarised in **Table 3.3**, with the notation of sources of information in additional references. **Table 3.4** reports the design of mHealth interventions, theory used, and the domain of BCTs. Most of the trials were parallel RCTs (83%), two studies were cluster RCTs (8%), and two studies were factorial RCTs (8%). Most of the trials were conducted in Western countries with a high-income setting (92%), and two trials were conducted in China. Most studies targeted the general public (67%). Five studies (21%) conducted in health facility settings, and three were conducted in school settings (12%).

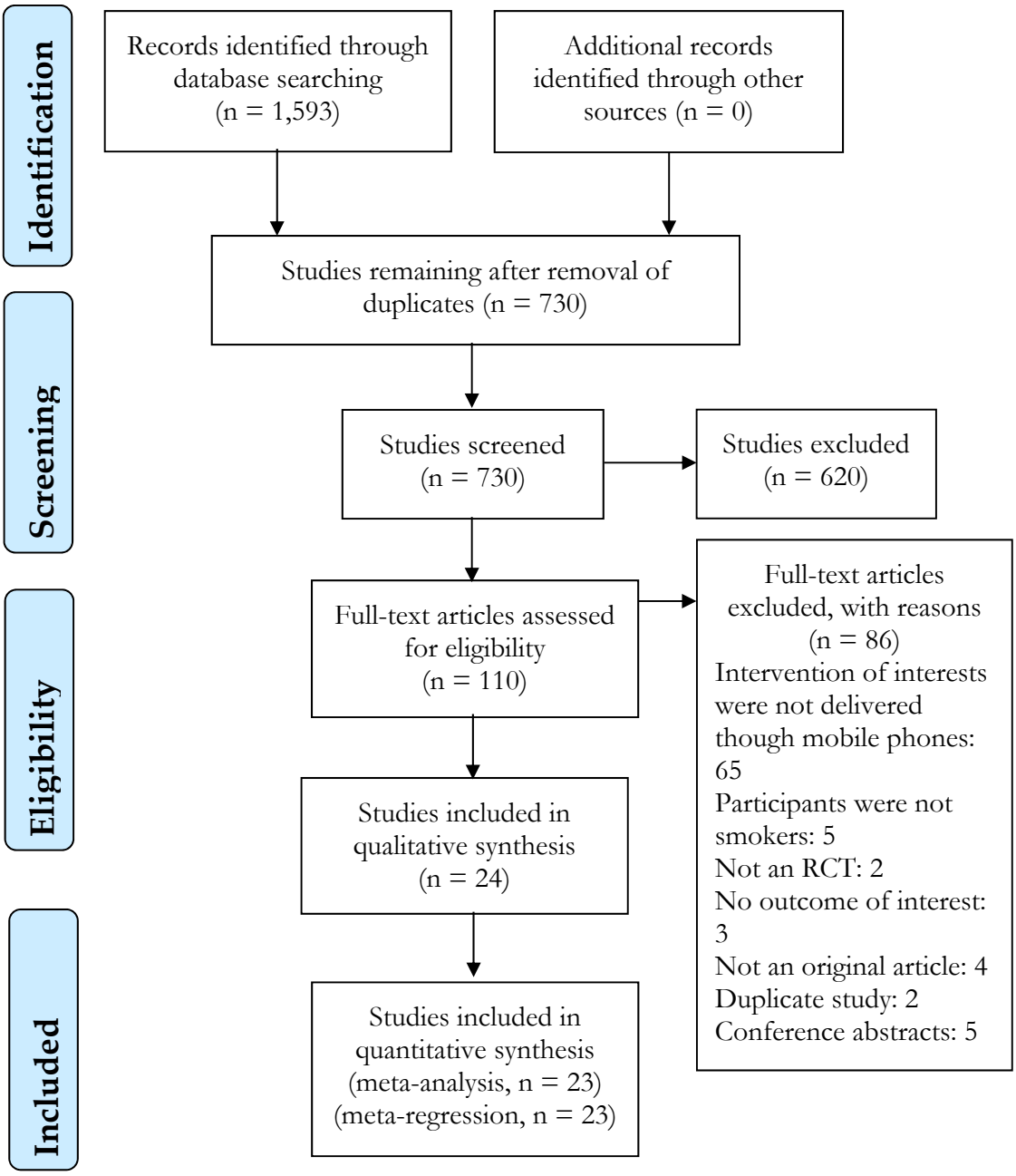


Figure 3.2 PRISMA 2009 Flow Diagram

Table 3.3 Characteristics of included studies in the systematic review

Study	Study design	Country, year	Settings	Characteristics of participants				Interventions		Control	Add. Ref
				Participants	%Male	Age	Cig./ day	Type	Frequency & Duration		
Abroms, 2014 (97)	Parallel group RCT	USA, 2011-2012	General public (internet)	Current smokers (≥5 cig/day) with a QD within 30 days	34%	35.7	17.3	Text2Quit: automated, tailored, bidirectional SMS with text request function (DATE, CRAVE, STATS, SMOKE)	- Varied (5/d to 3/w, and 1/w) - 26 weeks	Web link to smokefree.gov	(98)
Bock, 2013 (99)	Parallel group RCT	USA, 2011	General public (phone, text, internet)	Current daily smoker who interested to quit within 30 days (vary QD)	43%	30.7	16.3	TXT-2-Quit: automated, tailored, bidirectional SMS with text request function (CRAVE, SLIP)	- Varied - 8 weeks	Daily non-smoking related text	
Borland, 2013 (100)	Factorial RCT	Australia, 2008 - 2009	General public (Quitline, website, internet survey)	87.4% smokers, including recent quitter within 2 weeks and vary QD	40%	42.1	16.9	onQ: automated, tailored, bidirectional SMS	- Varied (3-8/d, 2-6/d, and 1-4/d) - At least 30 days	Minimal intervention control	
Brendryen, 2008a (101)	Parallel group RCT	Norway, 2005	General public (internet)	Smokers (≥10 cig/day) who willing to make a quit attempt on a specific date	50%	35.9[I], 36.4[C]	18.3[I], 18.1[C]	Happy Ending: automated digital multimedia (email, webpage, SMS, and IVR)	- Varied - 54 weeks	Booklet contained general information about smoking cessation and channels to receive help from quitline and online sources	(102)

Study	Study design	Country, year	Settings	Characteristics of participants				Interventions		Control	Add. Ref
				Participants	%Male	Age	Cig./ day	Type	Frequency & Duration		
Brendryen, 2008b (103)	Parallel group RCT	Norway, 2006	General public (internet)	Smokers (≥5 cig/day) who willing to make a quit attempt on a specific date	50%	39.5[I], 39.7[C]	16.6[I], 17.6[C]	Happy Ending: automated digital multimedia (email, webpage, SMS, and IVR)	- Varied - 54 weeks	Booklet contained general information about smoking cessation and channels to receive help from quitline and online sources	(102)
Bricker, 2014 (104)	Parallel group RCT	USA, 2013	General public (internet)	Current smokers (≥5 cig/day) with a QD within 30 days	48%	41.5[I], 41.6[C]	N/A	SmartQuit: smartphone app on iPhone only	- Varies (user depend) - 2 months	Smart phone app	
Buller, 2014 (105)	Parallel group RCT	USA, 2010	General public (internet)	Young adult, curren smokers who interested to quit	49%	24.9	17	REQ-Mobile: smartphone app	- Varies (user depend) - 12 weeks	Text messages	(100)
Chan, 2015 (106)	Parallel group RCT	Hong Kong, China, 2009	General public	Current smokers (≥1 cig/day)	82%	40-59 (49%)	1-10 (42%); 11-20 (43%)	Fixed text messages	- 8 SMS - At least 7 days after quit date	Self-help booklet and the contact information of the smoking cessation services	
Fraser, 2014 (107)	Factorial RCT	USA, N/A	General public (website)	Current smokers (≥5 cig/day) with a QD within 30 days	32%	39.3	19.3	Email messaging (via mobile phones or computers)	- Varied (2/d, 1/d, and 1/3 d) - 3 months	Participants did not received email message	

Study	Study design	Country, year	Settings	Characteristics of participants				Interventions		Control	Add. Ref
				Participants	%Male	Age	Cig./ day	Type	Frequency & Duration		
Free, 2011 (108)	Parallel group RCT	UK, 2007 - 2009	General public (text, online)	Smokers willing to make a quit attempt in the next month	55%	37	N/A	Txt2stop: automated, tailored, bidirectional SMS with text request (CRAVE, LAPSE)	- Varied (5/d, 3/w) - 31 weeks	Fortnightly, simple, short, generic text messages (not related to smoking cessation)	(109-111)
Free, 2009 (109)	Parallel group RCT	UK, N/A	General public (text)	Current smokers (≥1 cig/day) and interested in quitting	63%	36	20	Txt2stop: automated, tailored, bidirectional SMS with text request (CRAVE, LAPSE)	- Varied (1/d, 5/d, 3/w) - 26 weeks	Fortnightly, simple, short, generic text messages (not related to smoking cessation)	(110, 111)
Gritz, 2013 (112)	Parallel group RCT	USA, 2007 - 2009	HIV clinic	People living with HIV/ AIDS (PLWHA) smokers (≥5 cig/day and CO ≥7 ppm) with a QD within 7 days	70%	44.8	19.2	Proactive phone counselling intervention and on demand support	- 9 times - 3 months	Usual care: participants were provided with written smoking cessation material and instructions on how to obtain NRT	(113)
Haug, 2009 (114)	Parallel group RCT	Germany, 2007	University	Daily smokers with various motivation to quit	43%	25	11.2-12.4[I], 11.7[C]	SMS-COACH: weekly SMS assessment, SMS feedback (1 or 3 SMS), and SMS craving helpline	- Varied - 14 weeks	No intervention	

Study	Study design	Country, year	Settings	Characteristics of participants				Interventions		Control	Add. Ref
				Participants	%Male	Age	Cig./ day	Type	Frequency & Duration		
Haug, 2013 (115)	Cluster RCT	Switzer-land, 2011	Vocational school	Daily (76%) or occasional (24%) smokers (≥4 cig within a month, (≥1 cig within a week)	48%	18.2	10.6	SMS-COACH: weekly SMS assessment, SMS feedback (1 or 3 SMS), and SMS craving helpline	- Varied - 3 months	No intervention	(116)
Naughton, 2014 (117)	Parallel group RCT	UK, 2009 - 2011	Primary care (NHS)	Current smokers (1 cig/day) with a QD within 14 days	47%	41.8	18.3	iQuit: automated, tailored, bidirectional SMS with text request (HELP, SLIP, STOP)	- 0 – 2 per day - 90 days	Usual care: Advice by smoking cessation adviser	suppl
Naughton, 2012 (118)	Parallel group RCT	UK, 2008 - 2009	Primary care (NHS)	Current pregnant smokers (≤7 cig/ week) with mix quit plan (8% not plan to quit)	0%	26.8	8.9	MiQuit: automated, tailored, bidirectional SMS with text request (HELP, SLIP, STOP)	- 0 – 2 per day - 11 weeks	A non-tailored self-help leaflet and assessment texts (no intervention text)	suppl
Reid, 2007 (119)	Parallel group RCT	Canada, 2004 - 2005	Tertiary care (Cardiac facility)	Smokers (≥5 cig/day) hospitalised for coronary heart disease	68%	54	≥16 cig/day (43%)	IVR system and telephone counselling	- 3 times (day 3, 14, and 30 after discharge) - 8 weeks	No intervention	
Rodgers, 2005 (110)	Parallel group RCT	New Zealand, N/A	General public	Current smokers (≥1 cig/day) and interested in quitting within the next month	42%	25	15	Automated, tailored, bidirectional SMS Text request (CRAVE, POLLS, QUIZZES)	- Varied (5/d, 3/w) - 26 weeks	One message every two weeks to thank participants	(111)

Study	Study design	Country, year	Settings	Characteristics of participants				Interventions		Control	Add. Ref
				Participants	%Male	Age	Cig./ day	Type	Frequency & Duration		
Shi, 2013 (120)	Cluster RCT	China, N/A	Vocational school	Adolescent, current smokers (≥1 cig/week and smoke for at least 12 weeks)	96%	17	7.2[I], 5.5[C]	Tailored, bidirectional SMS	- Varied range from 104 to 217 - 12 weeks	Printed self-help pamphlet	
Skov-Ettrup, 2014 (121)	Parallel group RCT	Denmark, 2007 - 2009	General public (online)	Young daily smokers with a QD between 14 Feb 2007 and 1 Aug 2009	41%	19	15.4[I], 15.6[C]	Automated, tailored, SMS	- Varied (1/w, 1/d, 2/d, 4-5/w) - 12 weeks	Untailored message with personalized name	
Vidrine, 2006 (122)	Parallel group RCT	USA, 2004	HIV clinic	PLWHA smokers (≥5 cig/day and CO ≥7 ppm) with a QD within 7 days	78%	42.8	19.5[I], 20.6[C]	Proactive phone counselling intervention and on demand support	- 9 times - 2 months	MD advice, set quit date within 7 days, 10-week supply NRT, personalised quit-smoking plan, general self-help pamphlet, tip sheet	
Whittaker, 2011 (123)	Parallel group RCT	New Zealand, 2007 - 2009	General public (online)	Young daily smokers wanted to quit	53%	27	N/A	STUB IT: automated SMS and video	- Varied (1/d, 2/d, 1/2 d, 1/4 d - 6 months	Set quit date and received general health video	
Ybarra, 2012 (124)	Parallel group RCT	Turkey, 2010 - 2011	General public (in person and phone)	Daily smokers who seriously thinking about quitting in the next 15 days	61%	36.1[I], 35.6[C]	18.7[I], 20.4[C]	SMS Turkey: semi-automated tailored SMS	- Varied (5/d, 1/d) - 6 weeks	A 7-page brochure about smoking cessation	(125)

Study	Study design	Country, year	Settings	Characteristics of participants				Interventions		Control	Add. Ref
				Participants	%Male	Age	Cig./ day	Type	Frequency & Duration		
Ybarra, 2013 (126)	Parallel group RCT	USA, 2011	General public (online)	Young smokers (≥24 cig/week) who seriously thinking of quit smoking in 30 days	56%	21.6	12.4[I], 11.9[C]	Stop My Smoking USA: automated, tailored, bidirectional SMS with text request (CRAVE)	- Varied (1-9/d) - 6 weeks	Messages aimed to improve sleep and exercise	(127)

Note: QD: a quit date; I: intervention group; C: Control group; d: day; w: week; Cig: cigarettes; Add Ref: additional references; IVR: interactive voice response; suppl: Supplemental materials; RCT: randomise controlled trial; SMS: short messaging services; CO: Carbon Monoxide; MD: medical doctors; NRT: nicotine replacement therapy

Analysis: did not account for clustering effect in cluster RCT; select only the relevant interventions from the factorial RCT

Table 3.4 Summary of characteristics of intervention and control groups for studies included in the systematic review

Moderators	N (% of 24 studies)	
	Intervention	Control
The use of theory (number of studies, (%))		
No theory used	6 (25%)	22 (92%)
Theory used to inform interventions	7 (29%)	0 (0%)
Theory used to classify participants	3 (13%)	0 (0%)
Theory used to tailor interventions according to participants	8 (33%)	1 (4%)
Theory used to measure outcome changes	5 (21%)	1 (4%)
Theory used in discussion of study	1 (4%)	1 (4%)
The use of theory in the intervention development	18 (75%)	1 (4%)
Mobile functionality (number of studies, (%))		
No intervention/leaflet/information	-	16 (67%)
SMS only	7 (29%)	7 (29%)
SMS plus supporting website/email/interactive voice response (IVR)	12 (50%)	1 (4%)
Mobile calls/IVR and mobile calls	3 (13%)	-
Smartphone apps plus email and text messages	2 (8%)	-
Communication pathway (number of studies, (%))		
One-way	4 (17%)	15 (63%)
Two-way	17 (71%)	1 (4%)
Interactive communication	3 (13%)	1 (4%)
Tailored design (number of studies, (%))		
No tailoring function	5 (21%)	22 (92%)
Personalisation based on participant characteristics	1 (4%)	1 (4%)
Tailored to participant needs	18 (75%)	1 (4%)
Reported domains of behaviour change techniques (number of studies, (%))		
Goals and planning	23 (96%)	6 (25%)
Feedback and monitoring	12 (50%)	1 (4%)
Social support	20 (83%)	2 (8%)
Shaping knowledge	18 (75%)	9 (38%)
Natural consequences	15 (63%)	4 (17%)
Comparison of behaviour	14 (58%)	1 (4%)
Associations	6 (25%)	0 (0%)
Repetition and substitution	9 (38%)	3 (13%)
Comparison of outcomes	14 (58%)	2 (8%)
Reward and threat	11 (46%)	1 (4%)
Regulation	17 (71%)	7 (29%)
Antecedents	12 (50%)	1 (4%)
Identity	12 (50%)	1 (4%)
Scheduled consequences	3 (13%)	0 (0%)
Self-belief	18 (75%)	2 (8%)
Covert learning	2 (8%)	0 (0%)
Reported components of behaviour change techniques (number of studies, (%))		
Capability	24 (100%)	11 (46%)
Opportunity	22 (92%)	7 (29%)
Motivation	23 (96%)	6 (25%)
All components	21 (88%)	5 (21%)

3.5.2 The design of mHealth interventions

The type of intervention, frequency, and duration are reported in **Table 3.3**. The majority of mHealth interventions were mobile text messages (79%). Of these, bidirectional text messages were studied in the majority of the studies. This two-way communication allowed participants to obtain text messages by request. For example, participants sent a text request 'CRAVE' or 'HELP' to receive further support for reducing their cravings. Four studies provided one-way text messages for their participants (106, 107, 121, 124). There were two studies on smartphone applications (8%): Bricker *et al.* (2014) compared two types of smartphone apps with different content (the SmartQuit app which contained Acceptance and Commitment Therapy versus QuitGuide) (104) while Buller *et al.* (2014) assessed the REQ-Mobile mobile app with text messages intervention (OnQ) (105). Mobile phone-based counselling was assessed in three studies (112, 119, 122), with one study providing IVR prior to the counselling (119).

The majority of mHealth interventions in this review were tailored to participant stage of smoking cessation or psychological conditions (99, 100, 114, 115, 117, 118, 124, 126). Whittaker *et al.* (2011) provided text messages that were personalised to participants based on a self-selected quit date and timing of the messages (128).

Technology engagement was measured by the utilisation of the intervention through computer record in automated bidirectional SMS trials such as the percentage of participants sending at least one text to the system (97), using a text respond function (126), or sending a 'STOP' text to the system (117, 118). For mobile apps studies, how often the mobile app were opened (104), and web-recorded intervention usage (105) were measured as a technology engagement indicator. In studies with telephone counselling, rates of contacts were measured as the indicator (112, 119, 122).

3.5.3 The use of theory for intervention development

Three-quarters of mHealth interventions for smoking cessation were based on theory (18 from 24 studies). Multiple theories were applied in most studies; only two studies used one theory (97, 128). The Social Cognitive Theory (61%), the Transtheoretical Model and the stage of change model (44%) are the most frequently used theory in smoking cessation interventions. For the use of theory in the intervention design, seven studies (29%) used

theories to inform their intervention development (97, 101, 103-106, 128). Three studies classified their participant according to theory (108-110), and eight studies used theories to tailor their interventions according to participants (99, 100, 114, 115, 117, 118, 121, 129). Five studies measured relevant theory-based constructs/predictors as cognitive determinants (short-term efficacy) of intervention effectiveness (114, 115, 118, 121, 129). Theory-relevant constructs included the stage of change (114, 115, 129), smoking cessation self-efficacy (114, 118, 121), belief about smoking/decisional balance (114, 118, 121), and motivation (118). Interventions were found to have a significant positive effect on theory-relevant constructs in two studies (118, 129). Skov-Ettrup *et al.* (2014) (121) discussed the results in relation to theory (Elaboration Likelihood Model, or ELM); however, that study did not explicitly measure the theoretical construct of ELM. Instead, it measured 'self-efficacy' and 'belief about smoking' which serves as a theory construct in social cognitive theory.

3.5.4 Behaviour change techniques and behaviour change components

Given that there was limited information about the intervention description in published literature, 50 unique BCTs were extracted from 24 studies. The number of BCTs ranged from 3 to 31 per individual study, depending on the level of detail reported in the original papers and related articles. **Table 3.5** reported the number of BCTs in each study classified by 16 domains of BCTTv1. The most frequently used were from domain *'goals and planning'* which were coded from 23 studies (96%) and the least were from domain *'covert learning'* which were coded from two studies (8%). **Table 3.6** shows the number of studies that contain BCTs in the intervention and control groups, mapped into the behaviour change components. Almost all study interventions (96%) reported BCT *'problem solving'*.

Table 3.5 Number of behaviour change techniques coded from the intervention and control groups from the included studies

Study	16 domains of behaviour change techniques (BCTTv1)																	
	Goals and planning	Feedback and monitoring	Social support	Shaping knowledge	Natural consequences	Comparison of behaviour	Associations	Repetition and substitution	Comparison of outcomes	Reward and threat	Regulation	Antecedents	Identity	Schedule consequences	Self-belief	Covert learning	Number of BCTs in intervention	Number of BCTs in control
Abroms, 2014	3	3	3	1	1	2			1			2			1		17	0
Bock, 2013	3	1	1	1					1		1				1		9	0
Borland, 2013	3			1	1	1		1	1	2	2	3	1		1		17	0
Brendryen, 2008a	2	1	3	1/1	2	2		1	1	1	2/1	1	1		2	1	21	2
Brendryen, 2008b	2	1	3	1/1	2/1	2		1	1	1	2	1	1		2	1	21	2
Bricker, 2014	2/2	1	2/1		0/1	1	1	0/1		1	1/1		1		0/1		10	7
Buller, 2014	2/3			1/1	1/1	1/1		0/1	1/1	0/2	1/2	0/3	0/1		0/1		7	17
Chan, 2015	1		2	1/1	2		1				2						9	1
Fraser, 2014	1			1											1		3	0
Free, 2011	5		3	1	2	2	1	3	1	2	3	4	1	1	2		31	0
Free, 2009	5	1	3	1	2	1		3	1	2	3	4	1	1	2		30	0
Gritz, 2013	1		3	1/1							1/1		1		1		8	2
Haug, 2009		2	2									2					6	0
Haug, 2013	2	2	1	1	3	1				1		1			1		13	0
Naughton, 2014	4/1	2/1	2	1/1	1	1		1	1	1	1/1	3	1		1		20	4
Naughton, 2012	1	1	1	1/1	4	1			1	1	1	3	1		1		17	1
Reid, 2007	2		1								1				1		5	0
Rodgers, 2005	5		1	1	3	1		3	1	2	3	4	1	1	1		27	0
Shi, 2013	4	1	1	1	2		1										10	0
Skov-Ettrup,2014	1/1				0/3			1	1								3	4
Vidrine, 2006	3/2		3	1/1							1/1				1		9	4
Whittaker, 2011	2		2			2	1								1		8	0
Ybarra, 2012	3/3		1/1	1/2	2			1/1	1/1	1	1/1	2	1		1		15	9
Ybarra, 2013	3	1	1		1	2	1		1		1		1		1		13	0

Note: Numbers represented the number of behaviour change techniques in the intervention group. For studies which included a control group, the two numbers in the table represent the number of behaviour change techniques in the intervention group (top-left) and control group (bottom-right).

Table 3.6 Mapped behavioural change techniques in the intervention and control groups

Behaviour change technique descriptions	Intervention	Control
Capability (15 BCTS)		
BCT 1.2 Problem solving	23	4
BCT 4.1 Instruction on how to perform the behaviour	16	8
BCT 5.1 Information about health consequences	10	4
BCT 12.4 Distraction	10	1
BCT 8.2 Behaviour substitution	7	1
BCT 8.1 Behavioural practice/rehearsal	5	2
BCT 2.2 Feedback on behaviour	6	0
BCT 2.3 Self-monitoring of behaviour	4	0
BCT 4.2 Information about Antecedents	2	2
BCT 2.7 Feedback on outcome(s) of behaviour	3	0
BCT 8.7 Graded tasks	3	0
BCT 11.3 Conserving mental resources	3	0
BCT 2.4 Self-monitoring of outcome(s) of behaviour	2	0
BCT 2.5 Monitoring of outcome(s) of behaviour without feedback	1	1
BCT 2.6 Biofeedback	1	0
Opportunity (14 BCTs)		
BCT 11.1 Pharmacological support	15	7
BCT 3.1 Social support (unspecified)	18	2
BCT 6.2 Social comparison	11	1
BCT 3.3 Social support (emotional)	11	0
BCT 3.2 Social support (practical)	10	0
BCT 12.2 Restructuring the social environment	8	1
BCT 6.3 Information about others' approval	7	0
BCT 12.1 Restructuring the physical environment	6	1
BCT 12.3 Avoidance/reducing exposure to cues for the behaviour	6	0
BCT 7.1 Prompts/cues	4	0
BCT 13.2 Framing/reframing	4	0
BCT 6.1 Demonstration of the behaviour	2	0
BCT 7.3 Reduce prompts/cues	1	0
BCT 7.5 Remove aversive stimulus	1	0
Motivation (21 BCTs)		
BCT 15.1 Verbal persuasion about capability	16	2
BCT 9.2 Pros and cons	14	2
BCT 1.1 Goal setting (behaviour)	11	3
BCT 5.7 Information about consequences (not specific)	12	0
BCT 1.4 Action planning	8	2
BCT 1.5 Review behaviour goal(s)	9	1
BCT 11.2 Reduce negative emotions	9	1
BCT 1.9 Commitment	8	1
BCT 10.9 Self-reward	8	1
BCT 13.5 Identity associated with changed behaviour	8	1
BCT 5.3 Information about social and environmental consequences	4	1

Behaviour change technique descriptions	Intervention	Control
BCT 10.3 Non-specific reward	5	0
BCT 15.3 Focus on past success	4	0
BCT 10.4 Social reward	2	1
BCT 14.10 Remove punishment	3	0
BCT 5.4 Monitoring of emotional consequences	2	0
BCT 5.6 Information about emotional consequences	1	1
BCT 15.4 Self-talk	2	0
BCT 16.1 Imaginary punishment	2	0
BCT 1.6 Discrepancy between current behaviour and goal	1	0
BCT 1.8 Behavioural contract	0	1

3.5.5 Risk of bias assessment

Randomisation was stated in all included studies. The methods of random sequence generation were explicitly reported in 18 studies (75%) and the majority of the studies used a computer random number generator. Sufficient details of allocation concealment were provided in 20 studies (83%). Allocation concealment was broken for the last eight participants and was manually assigned to rectify the imbalance between groups in Ybarra (2013) (126), subject to a high risk of ***selection bias***.

Blinding of participants and personnel were achieved in most studies with a digital platform to allocate treatment groups. Seven studies (29%) reported that it was not possible to blind the participants or participants were aware of which treatment groups they were in and four studies (17%) did not blind the personnel, subject to a high risk of ***performance bias***. Blinding of outcome assessment was sufficient in most trials (75%) and was done through online self-assessed questionnaires or blinding of research staff who conduct follow-up data collection, subject to a low risk of ***detection bias***.

The majority of included studies conducted an intention-to-treat analysis and assumed all missing outcome data were continued smokers and therefore it was unclear how this may have affected the results. Five studies (21%) had appropriate methods for missing data using multiple imputation methods and commented on smoking outcomes. Naughton *et al.* (2012) (118) excluded participants with miscarriage or stillbirth from the analysis and Bricker *et al.* (2014) (104) used complete case analysis, subject to high risk of ***attrition bias***.

There were nine studies (38%) which published trial protocols, providing a low risk of ***reporting bias***. The other studies did not indicate any trial registration, so there is insufficient information to justify this type of bias.

Social approval bias is another type of bias, possible among trials that report a subjective measurement of outcomes (reported status of smoking). There were 11 studies (46%) reporting biological confirmation for smoking status which is considered to entail a low risk for social approval bias. **Figure 3.3** shows the proportion of the risk of bias assessment by type of bias. **Figure 3.4** illustrates judgements about each risk of bias item for each included study.

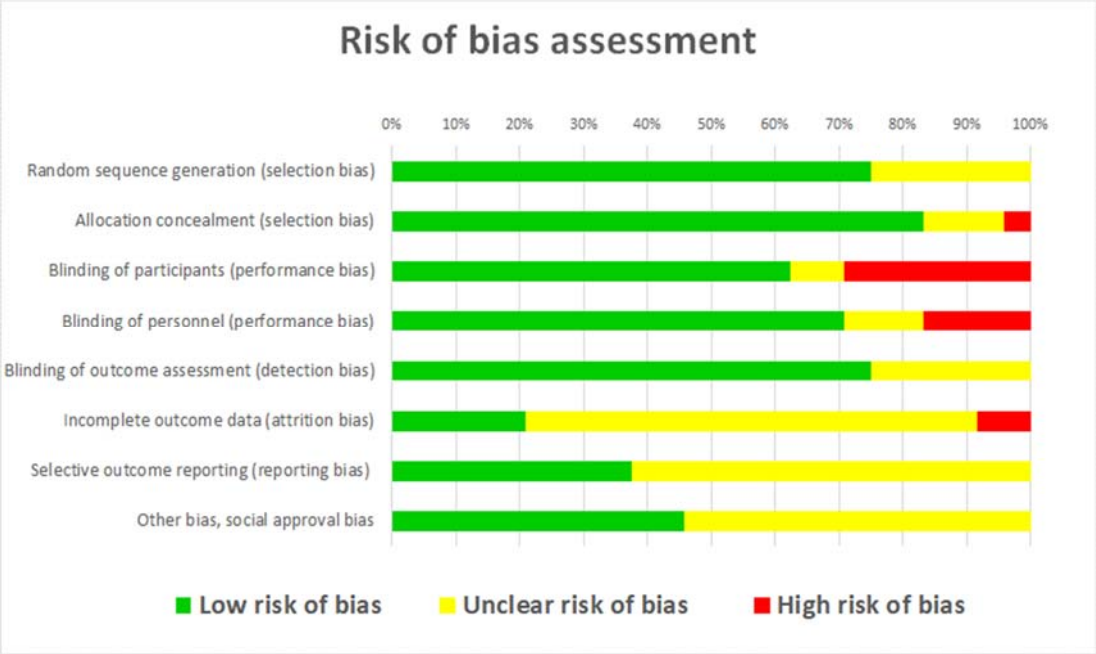


Figure 3.3 Risk of bias summary in percentage: author's judgements about each risk of bias item for each included study

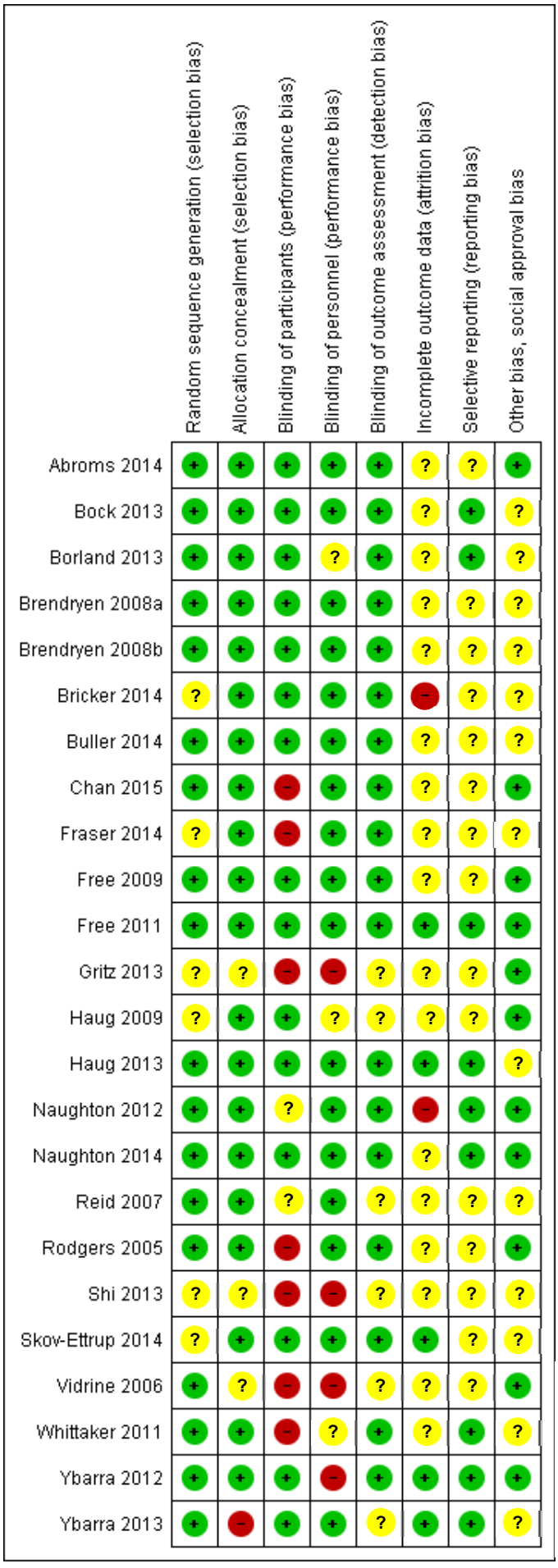
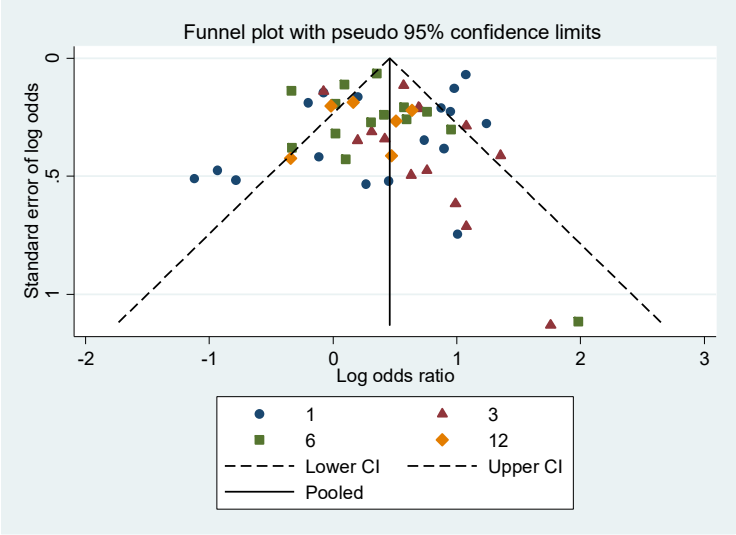


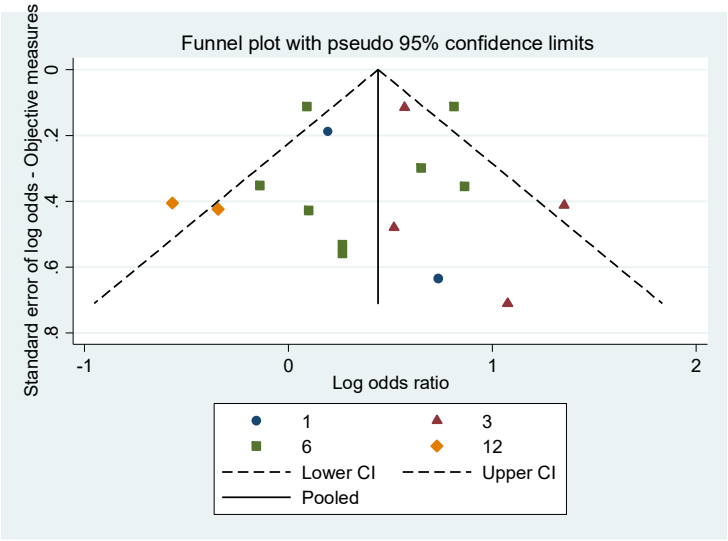
Figure 3.4 Risk of bias summary: author's judgements about each risk of bias item for each included study.

3.5.6 Funnel plot and test for asymmetry

A plot of the estimate of effect size (log odds ratio) in each study was plotted against an estimate of its precision (standard error of log odds). No evidence of asymmetry was found suggesting no evidence for publication bias. **Figure 3.5** illustrates a funnel plot when considered subjective outcomes and objective outcomes of smoking cessation by follow-up period.



(a) subjective measurement



(b) objective measurement

Figure 3.5 A funnel plot for meta-analysis of studies of mHealth interventions on the smoking cessation outcomes

3.5.7 Effect of mHealth intervention for smoking cessation

Of 24 studies, 23 studies reported smoking cessation outcomes and were included in the meta-analysis. **Table 3.7** reports the pooled smoking cessation rate, both self-reported and bio-verified outcomes at the 1-, 3-, 6- and 12-month follow-up. The pooled odds ratio of mHealth intervention was 1.41 (95% CI: 1.19 to 1.67) for self-reported smoking cessation and 1.49 (95% CI: 1.05 to 2.10) for verified smoking cessation at the 6-month follow-up. **Figure 3.6** to **Figure 3.9** show forest plots comparing mHealth interventions versus any control for self-reported smoking cessation outcomes at different follow-up periods. **Figure 3.10Figure 3.6** to **Figure 3.12** show forest plots comparing mHealth interventions versus any control for bio-verified smoking cessation outcomes at different follow-up periods. The heterogeneity of the results across included studies was low among the studies that had longer durations of follow-up. The heterogeneity was high in pooled results from self-reported outcomes at the 1-month follow-up (I^2 = 87.1%, p-value < 0.001), suggesting inconsistency of the results and providing a rationale for further meta-regression analysis in the next section.

Table 3.7 Effect size of mHealth interventions for smoking cessation by outcomes and follow-up

Outcome and follow-up period	**Number of studies**	**Effect size (odds ratio, 95% CI)**	I^2
Self-reported smoking cessation			
1-month	12	1.69 (1.20 to 2.38)	87.1%
3-month	14	1.81 (1.42 to 2.31)	58.6%
6-month	13	1.41 (1.19 to 1.67)	50.3%
12-month	6	1.30 (0.99 to 1.69)	39.3%
Verified smoking cessation			
3-month	4	2.05 (1.44 to 2.92)	21.0%
6-month	8	1.49 (1.05 to 2.10)	73.3%
12-month	2	0.63 (0.35 to 1.12)	0.0%

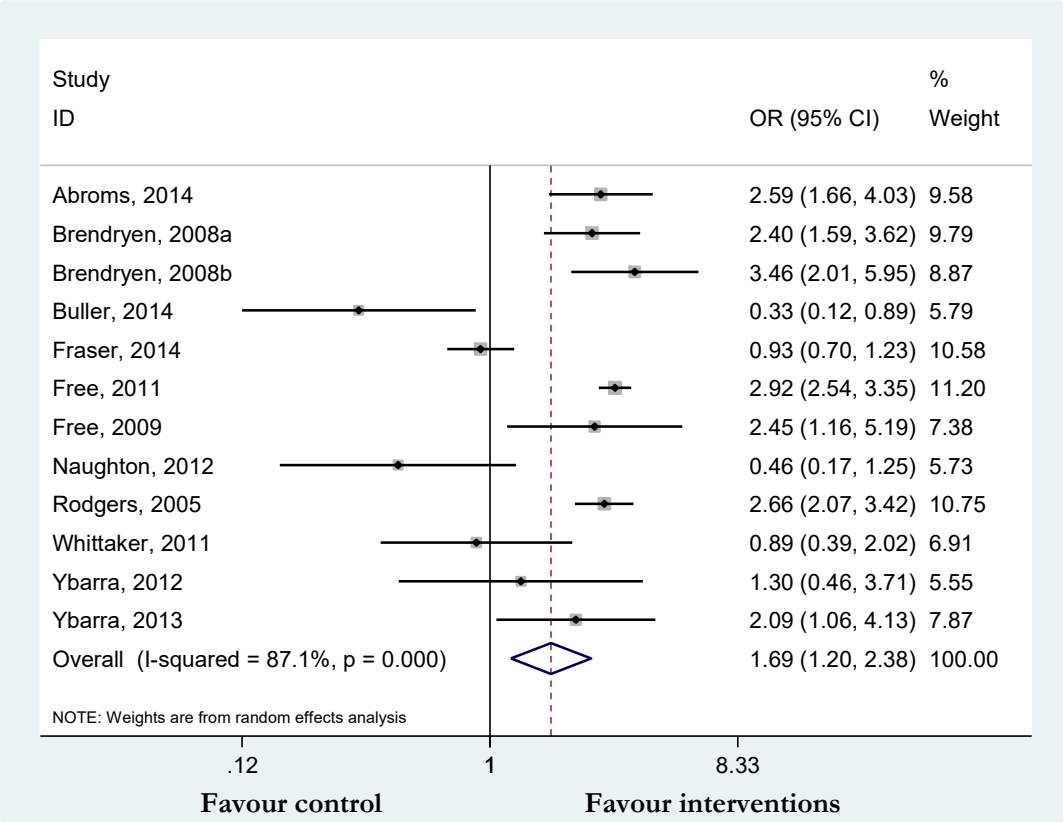


Figure 3.6 Forest plot comparing mHealth intervention versus any control, outcome: self-reported point prevalence abstinence at 1-month follow-up

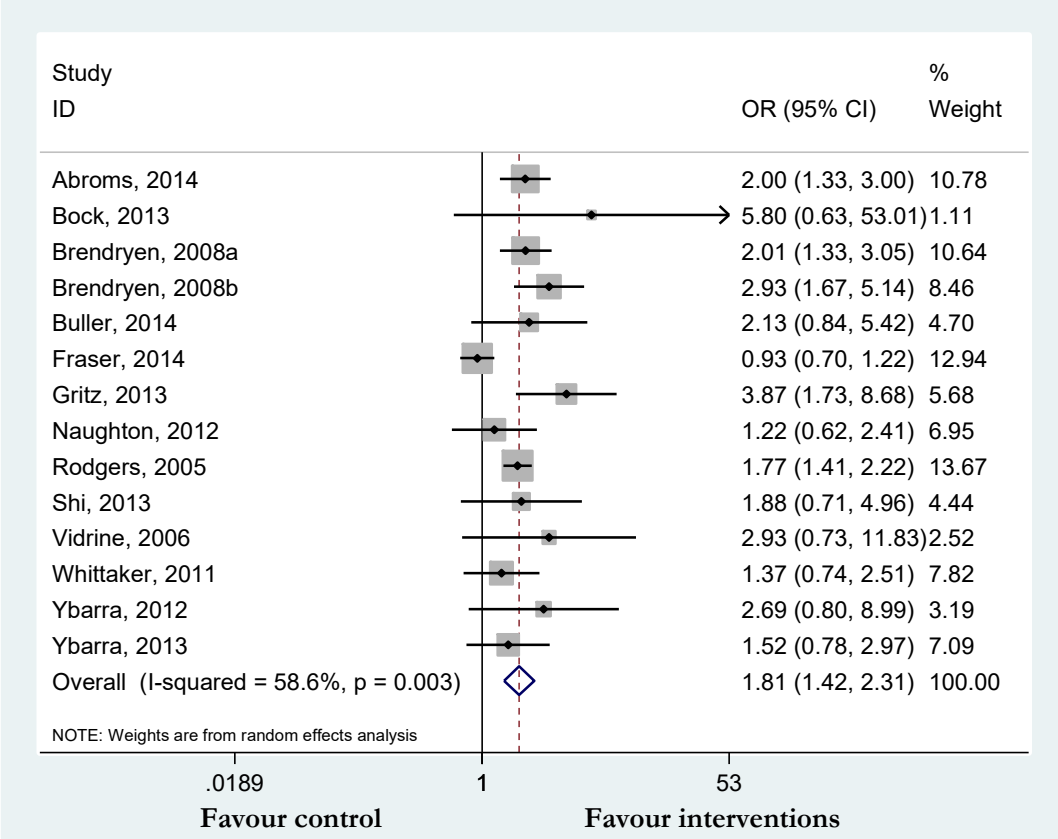


Figure 3.7 Forest plot comparing mHealth intervention versus any control, outcome: self-reported point prevalence abstinence at 3-month follow-up

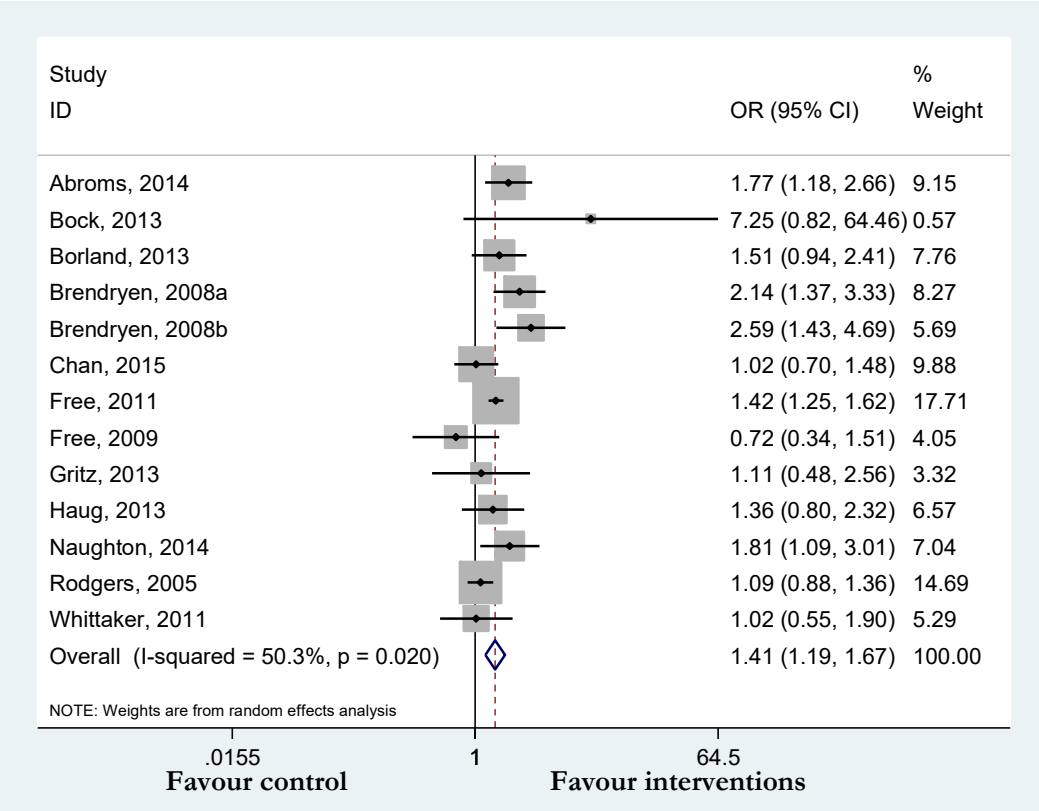


Figure 3.8 Forest plot comparing mHealth intervention versus any control, outcome: self-reported point prevalence abstinence at 6-month follow-up

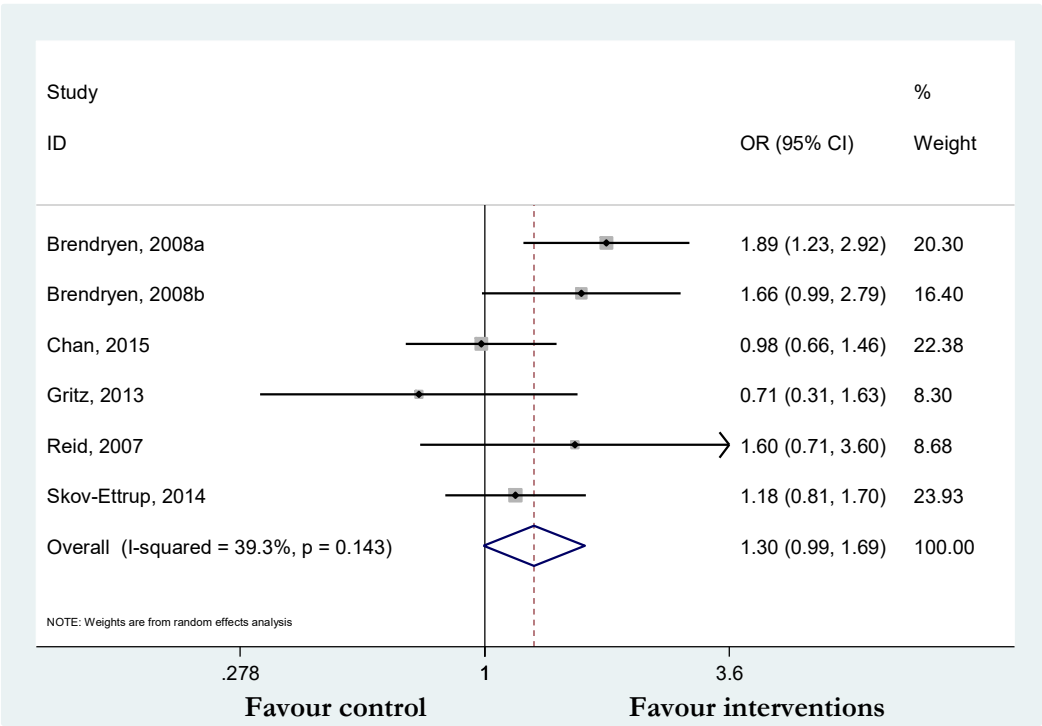


Figure 3.9 Forest plot comparing mHealth intervention versus any control, outcome: self-reported point prevalence abstinence at 12-month follow-up

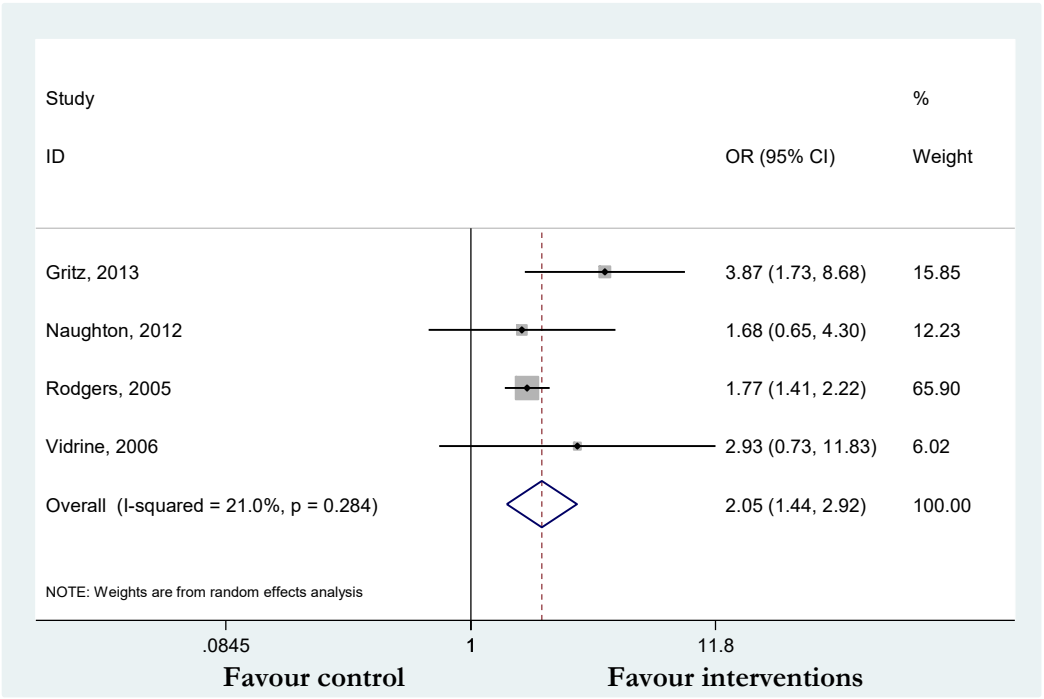


Figure 3.10 Forest plot comparing mHealth intervention versus any control, outcome: verified point prevalence abstinence at 3-month follow-up

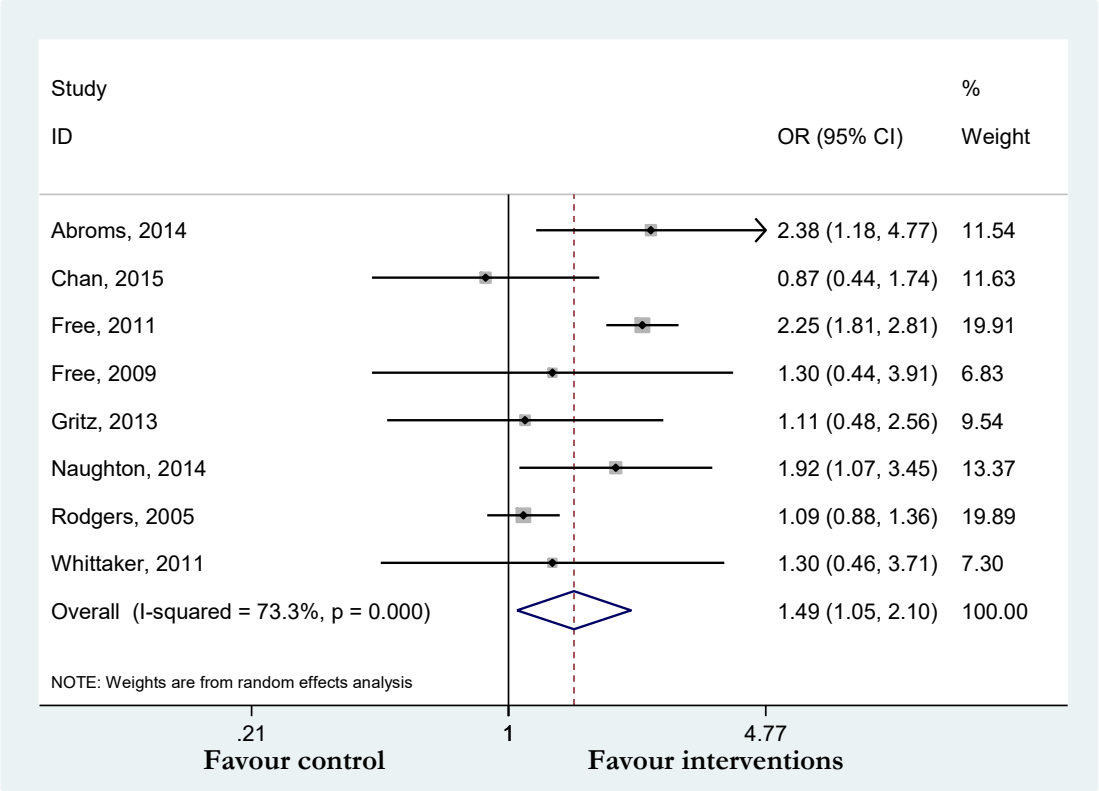


Figure 3.11 Forest plot comparing mHealth intervention versus any control, outcome: verified point prevalence abstinence at 6-month follow-up

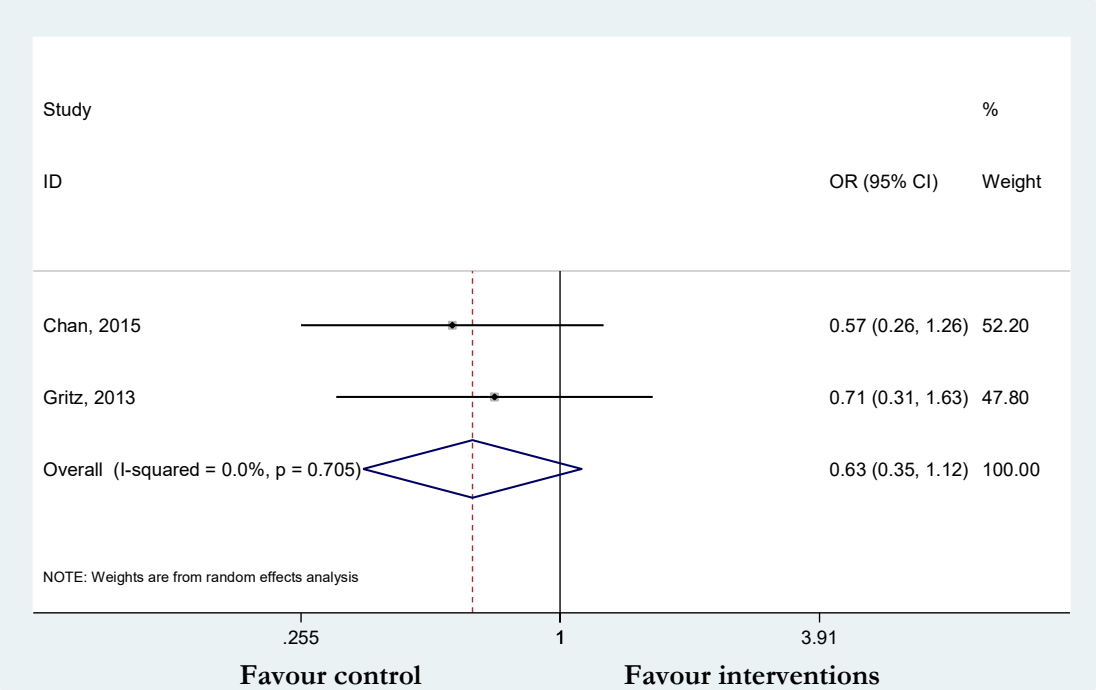


Figure 3.12 Forest plot comparing mHealth intervention versus any control, outcome: verified point prevalence abstinence at 12-month follow-up

3.5.8 Factors that moderate treatment effects

3.5.8.1 Ignoring the characteristics of control groups

This section reports the result from a typical meta-regression when there is no consideration of the characteristics of control groups. Of 24 studies identified from the systematic review, 23 reported any smoking cessation outcomes and were included in the meta-regression. From the random-effects logistic regression models, predictors that were associated with improved smoking cessation rates were intervention reported BCTs in the *'feedback and monitoring'* and *'covert learning'* domains, and interventions contained BCTs in the 'Opportunity' and 'COM' groups (**Table 3.8**).

Table 3.8 Univariate random-effects logistic regression of the association between pre-defined moderators and smoking cessation

Study characteristic	Univariate analysis				
	OR	**95% CI**	**I^2**	**Adj. R^2**	**P-value**
Time	0.961	0.891 to 1.036	54.95%	1.24%	0.283
Intervention duration (weeks)	1.008	0.997 to 1.020	47.76%	21.97%	0.134
Identified barriers	1.107	0.743 to 1.649	56.92%	-11.76%	0.602
The use of theory (versus no)					
Inform interventions	1.259	0.880 to 1.802	54.21%	12.02%	0.196
Classify participants	0.792	0.510 to 1.228	57.66%	-12.87%	0.282

Study characteristic	Univariate analysis				
	OR	**95% CI**	**I^2**	**Adj. R^2**	**P-value**
Tailor interventions according to participants	1.096	0.744 to 1.613	57.11%	-5.79%	0.628
Measure outcome changes	0.939	0.590 to 1.494	57.63%	-9.02%	0.780
Discuss the theory	0.841	0.412 to 1.716	57.38%	-10.34%	0.619
Any intervention development	1.230	0.815 to 1.857	46.37%	16.48%	0.308
Reported domains of behaviour change techniques (versus no)					
Goals and planning	dropped because of collinearity				
Feedback and monitoring	1.404	1.035 to 1.905	47.85%	42.78%	**0.031**
Social support	1.397	0.998 to 1.954	42.15%	34.84%	0.051
Shaping knowledge	1.082	0.694 to 1.687	57.58%	-8.45%	0.715
Natural consequences	1.345	0.950 to 1.905	43.60%	31.89%	0.091
Comparison of behaviour	1.183	0.810 to 1.726	47.96%	14.55%	0.367
Associations	1.022	0.665 to 1.570	54.91%	-9.45%	0.918
Repetition and substitution	1.144	0.814 to 1.608	52.76%	2.08%	0.421
Comparison of outcomes	1.282	0.892 to 1.844	46.01%	20.43%	0.170
Reward and threat	1.186	0.849 to 1.657	51.06%	9.60%	0.300
Regulation	1.211	0.848 to 1.731	51.23%	6.85%	0.277
Antecedents	1.271	0.923 to 1.750	45.87%	27.07%	0.134
Identity	1.180	0.844 to 1.650	51.12%	9.82%	0.315
Scheduled consequences	0.792	0.510 to 1.228	57.66%	-12.87%	0.282
Self-belief	1.067	0.688 to 1.657	57.23%	-7.10%	0.761
Covert learning	1.805	1.077 to 3.026	46.98%	35.69%	**0.027**
Reported components of behaviour change techniques (versus no)					
Capability	dropped because of collinearity				
Opportunity	1.644	1.102 to 2.453	35.32%	46.66%	**0.017**
Motivation	dropped because of collinearity				
All components	1.383	1.040 to 1.838	37.85%	49.05%	**0.028**

Note: this analysis was not applicable with categorical data, e.g. mode of delivery, tailor design, and communication pathway. OR: odds ratio; CI: confidence interval; Adj. R^2: Adjusted R^2.

3.5.8.2 Considering the characteristics of control groups

This section reports the result from the meta-regression where the characteristics of control groups are taken into account in the analysis. From the multilevel logistic regression model (level 1: study and level 2: intervention/control), predictors that were associated with an increase in smoking cessation rate were mHealth intervention, longer intervention duration, theory used to inform interventions, any theory used in the intervention development, interventions that were tailored to participants needs, and the intervention

reported BCTs in the following BCTTv1 domains: *'Feedback and monitoring'*, *'Comparison of behaviour', 'Comparison of outcomes', 'Antecedents', 'Covert learning'* and reported BCTs in the 'COM' group (see **Table 3.9**).

Table 3.9 Univariate multilevel logistic regression model assessing the association between pre-defined moderators and smoking cessation

Study characteristics	Odds ratio	95% CI		P-value
		Lower	Upper	
Being an mHealth intervention	1.346	**<0.001**	1.174	1.542
Duration of intervention (weeks)	1.010	**0.012**	1.002	1.018
Identified barriers (versus none)	1.067	0.683	0.781	1.457
Theory used (versus none)				
Inform interventions	1.505	**0.004**	1.137	1.992
Classify participants	0.847	0.313	0.613	1.170
Tailor interventions according to participants	1.060	0.680	0.803	1.400
Measure outcome changes	1.031	0.895	0.651	1.635
Discuss the theory	1	(omitted)		
Any intervention development	1.416	**0.001**	1.151	1.742
Reported domains of BCTs (versus none)				
Goals and planning	0.811	0.237	0.573	1.148
Feedback and monitoring	1.387	**0.011**	1.079	1.781
Social support	1.306	0.051	0.999	1.707
Shaping knowledge	0.813	0.103	0.634	1.043
Natural consequences	1.092	0.390	0.893	1.336
Comparison of behaviour	1.358	**0.002**	1.121	1.645
Associations	0.952	0.748	0.706	1.284
Repetition and substitution	1.066	0.591	0.844	1.347
Comparison of outcomes	1.368	**0.001**	1.128	1.660
Reward and threat	1.156	0.226	0.914	1.463
Regulation	0.949	0.689	0.736	1.225
Antecedents	1.294	**0.004**	1.086	1.541
Identity	1.155	0.232	0.912	1.462
Scheduled consequences	0.847	0.313	0.613	1.170
Self-belief	1.009	0.946	0.771	1.321
Covert learning	1.829	**0.004**	1.214	2.754
Reported components of behaviour change (versus no)				
Capability	0.797	0.085	0.616	1.031
Opportunity	1.033	0.821	0.778	1.372
Motivation	0.811	0.237	0.573	1.148
All components	1.296	**0.014**	1.054	1.593
Mode of delivery				
SMS only	0.907	0.456	0.701	1.172

Study characteristics	Odds ratio	95% CI		P-value
		Lower	Upper	
SMS plus supporting website/email/IVR, including apps	1.333	0.055	0.994	1.787
Mobile calls/ IVR and mobile calls	1.289	0.388	0.724	2.297
Tailor design				
Personalise to user characteristics	1.190	0.300	0.857	1.653
Tailored to participant needs	1.562	**<0.001**	1.260	1.936
Communication pathway				
One-way	0.784	0.054	0.611	1.005
Two-way	1.040	0.850	0.696	1.554
Interactive communication	1.099	0.778	0.571	2.116

BCT: behaviour change technique, CI: confidence interval, IVR: interactive voice response

3.6 Discussion

3.6.1 Main findings

There were 24 mHealth studies identified from the systematic review; the majority of mHealth studies were SMS-based interventions and the comparators varied from no interventions, usual care to alternative mHealth interventions. From the meta-analysis of 23 studies reporting smoking cessation as an outcome, mHealth interventions improved smoking cessation by 1.41 to 2.05 times, depending on the follow-up time. This study builds on the findings from previous reviews, suggesting that mHealth interventions for smoking cessation are beneficial (11-13, 15-17). However, the pooled results indicated the diverse nature of the interventions and controls of the included studies. Therefore, the heterogeneity of these results was explored through meta-regression analysis.

The meta-regression analyses applied two approaches, the traditional logistic regression approach which ignored the different characteristics of control groups and the novel approach which employed multilevel modelling which adjusted for the control characteristics. Both analyses suggested that interventions reported BCTs in the *'Feedback and monitoring'* and *'Covert learning'* domains, and reported BCTs mapped onto all behaviour change components (COM) were associated with increased smoking cessation rates. Interventions reported BCTs in the following BCTTv1 domains: *'Comparison of behaviour', 'Comparison of outcomes',* and *'Antecedents'*, the use of theory to inform or develop an intervention, and tailoring interventions to participants needs were associated with an increased effect size only when adjusting for the effect of different controls These results

differ from Head's meta-regression study which suggested that the use of theory was not associated with the intervention effect size (12). However, this study classified the use of theory in greater detail compared to Head's study which classified the use of theory as a simple yes or no variable; therefore, the simple coding of theory used might not be able to capture the level of theory applied in intervention design.

The results also suggested that interventions that reported BCTs mapped onto 'Capability' 'Opportunity', and 'Motivation' were associated with an improved cessation rate by 1.3 to 1.4 times compared to no BCTs. A previous meta-analysis of smoking cessation interventions for people with chronic obstructive pulmonary disease showed that action planning, self-monitoring, social support, and advice on weight control were associated with a higher effect size (130). However, Bartlett's study (130) based their coding on the early version of BCT taxonomy specific to smoking cessation (131). Therefore, generalisability of the BCTs that was classified in the previous study limits the ability to compare across studies.

In terms of the design of mHealth interventions, tailored interventions were associated with an improved cessation rate; the majority being tailored to participant's stage of smoking cessation or psychological conditions. The result from this study is similar to Head *et al.* (12) suggesting a benefit of tailored mHealth interventions. Two-way communication allowing for participants to obtain text messages by request was not associated with an increase in smoking cessation, a result similar to two previous studies (12, 13). Bidirectional text messaging requires action and motivation on the participant's end which involves a higher level of effort and those who were not motivated might not engage in, or even receive, the SMS as a consequence.

3.6.2 Strengths and limitations of the study

This is the first review to classify the behaviour change techniques using BCTTv1 in mHealth interventions for smoking cessation. Interventions that reported BCTs mapped into behaviour change components 'Capability' 'Opportunity', and 'Motivation' may provide a better outcome. However, the presence of a BCT does not reflect the quality of operationalisation or the dose delivered (132). The frequency of the intervention from the included studies was found to vary from a fixed schedule, increasing/decreasing schedule, to a user dependent frequency. Therefore, it is not possible to assess the association of dosage with the intervention. Also, it is not necessarily the case that the psychological

components of particular interventions or devices carry the same benefits (133). The effectiveness of such interventions requires rigorous evaluation to determine its benefits.

This study highlighted that the conventional meta-regression could not take the different characteristics of the controls into account which often appears in complex intervention studies. Garnett *et al.* (2018) conducted a meta-regression analysis of digital behaviour change interventions for controlling alcohol consumption, including a web-based intervention (134). They took a conventional approach to meta-regression and coded only the BCTs that were present in the intervention group and not present in the control group. Their results suggested that interventions that contain BCTs domains *'Behaviour substitution'*, *'Problem solving'* and *'Credible source'* were associated with a decrease in alcohol consumption.

With an increasing number of RCTs available, meta-regression analysis can be useful to identify effective moderators that can be applied in an adaptive intervention that contains decision rules based on a pre-specified set of effective moderators or tailoring variables (65). However, in order to conduct a meta-regression analysis, a large number of synthesised studies from the systematic review is required. This study only used study-level moderators rather than individual-level moderators such as the dose that the participant received. A regression based on the mean dose participants received would likely suffer from aggregation bias, thus giving misleading results (135). Ideally, a meta-analysis of individual participant data is preferred. Finally, due to limitations in the statistical software used, equal weights were assigned to all studies in the multi-level modelling. In other words, more weight was given to smaller studies rather that larger trials.

3.6.3 Implications for practice and further research

With a rapid pace of technological advance, an update search for new trials is necessary. This review included studies published up to October 2015 to inform intervention development. There were only two negative trials of mobile phone applications included in this systematic review. It is expected that recent research will focus on application-based intervention. For example, BinDhim and colleagues have recently published their multi-country RCT based on a smartphone application which resulted in a positive effect of the intervention on smoking cessation (relative risk = 1.68, 95% CI = 1.25 to 2.28) (136). A planned update of the systematic review will be conducted for the publication version of this review.

The meta-regression analysis was typically used to manage the heterogeneity of results from the meta-analysis and to explain what causes the diversity of the results. However, it is expected there is a presence of heterogeneity within the complex interventions and meta-regression analysis can be used as a method to identify components as well as the packages of components as an alternative to the optimising phase of the Multiphase Optimisation Strategy (MOST) approach. With the speed of technology advancement, meta-regression studies (with coded control groups) accelerate the process of the component selection process. However, meta-regression requires a substantial portion of the included literature to observe such an association and detailed descriptions of the intervention and control groups. To illustrate, only one study reported the *BCT Biofeedback* domain (see **Table 3.6**); therefore, it is not possible to determine such an association.

Future mHealth intervention studies should report intervention descriptions and behaviour change techniques used in their studies. A Template for Intervention Description and Replication (TIDieR) checklist provides a guide to the research community to report complex interventions in detail (137). With the availability of a TIDieR checklist, it is expected that the research community will be aware of the importance of detailed descriptions for complex interventions which in turn advance the accumulative knowledge of mHealth behaviour change interventions.

This chapter highlighted the importance of characterising the control groups in meta-regression. Ignoring the diversity of different controls may underestimate the effectiveness of the complex intervention. There are no agreed methods in the research community on how to take the characteristics of the control group into account. Another method for handling this issue in the literature is omitting the components that are contained in both the intervention and control group (134). Further research could investigate the effect of different methods employed.

Most studies in this systematic review had around an equal representation of male and female participants. However, less than 10% of all smokers in Thailand are female. In addition, the majority of mHealth intervention studies were conducted in high-income countries where technology is more advanced than in low- and middle-income countries. Acceptance of technologies may also differ between countries with different income levels. Therefore, the results from this systematic review may not be generalisable to another settings where the prevalence of female smokers is low, and mHealth technology is less developed. Further research such as experimental trials may allow researchers to infer causal effects of mHealth interventions or the packages of intervention components.

3.7 Chapter summary

The current literature suggested that mHealth behaviour change interventions increased the smoking cessation rate compared to no intervention, usual care, or alternative mHealth interventions. However, the heterogeneity between studies included in the systematic review was prominent and questions the usefulness of combining complex intervention studies that are expected to be different. A meta-regression is an alternative to data synthesis which can explain how the effectiveness of those interventions differ. When considering distinct characteristics of the control groups, mHealth interventions that used theory to inform their intervention design, interchange information between provider and receiver, contained BCTs grouped into COM-B behaviour change components, both individually or in combination, resulted in an increased odd of smoking cessation. Additionally, there was a lack of evidence on the effectiveness of specific BCTs in mHelath intervention. This warrants further exploration in an experimental trial to confirm the causal relationship between the behaviour change components in text messages and smoking cessation.

Chapter 4: Development of the content of BCT-enhanced text messages

4.1 Chapter overview

The results from the meta-regression **(Chapter 3)** found that mHealth interventions for smoking cessation that contained BCT grouped into COM-B behaviour change components were associated with an increase in the odds of smoking cessation. Further research to confirm the causal relationship of these behaviour change components on smoking cessation was planned. This chapter explains the development of the content of BCT-enhanced text messages that were planned to be test as a short messaging service (SMS) smoking cessation programme called 'iCanQuit' for three intervention components.

4.2 Aims and objectives

The aim was to develop BCT-enhanced text messages to aid Thai smokers to stop smoking. The objective was to create text messages to support smoking cessation that can be mapped into the BCTTv1 and behaviour change components ('Capability', 'Opportunity', and 'Motivation') (30).

4.3 Intervention design considerations

4.3.1 Language

Texts were generated by Pritaporn Kingkaew (PK) in Thai as this is the native language for Thai people. The rationale for developing the text in Thai prior to in English was due to the character limitation per one SMS (70 characters); translation from English to Thai failed to provide a concise Thai message within this character limit. Subsequently, all texts were then translated into English and proofread by a native Thai person who speaks English fluently.

4.3.2 Frequency and timing

Text messages were designed to provide different messages in Thai twice a day for 30 days at 7:00 AM and 4:00 PM (local time), free of charge. The rationale for sending texts twice a day was to allow for the same frequency of texts planned to be sent from the Thailand National Quitline (TNQ) routine service in the future. The first text message of each day was designed to be sent soon after participants had woken up (their morning cigarette craving). The second text message of each day was designed to be sent before participants finished their school/work at 4:00 PM to serve as reminders before their afternoon craving for cigarettes. In total, 60 BCT-enhanced messages per study group were planned to be sent.

4.3.3 Intervention components

The COM-B system is a behaviour system that focuses on the three essential components of behaviour change: Capability, Opportunity, and Motivation (37). To generate a desired behaviour, capability to engage the behaviour, opportunity to enable the behaviour, and motivation to activate the behaviour should be presented. The results from the meta-regression **(Chapter 3)** found that mHealth interventions for smoking cessation that contained BCTs mapped into all behaviour change components were associated with an increase in the odds of smoking cessation by 1.30 (95% CI: 1.05 to 1.59). However, the results from the meta-regression suggested an association rather than causation. Moreover, studies included in the systematic reviews were conducted in high-income settings and the interventions developed in Western countries may not be feasible or acceptable to the local practice in Thailand. Therefore, there is a need to develop text messages to be tested in further research to confirm the causal relationship of these behaviour change components in text messages on smoking cessation.

With the clear constructs of the COM-B system, it is possible to test behaviour change components in experimental studies. BCTs are viewed as a more of a fine-grain unit of behaviour change and allow researchers to identify the active ingredients used in their interventions (30). **Figure 4.1** shows the link between BCTs and behaviour change components. The design for the intervention aimed to apply BCTs to support smokers' capability to quit smoking, motivation to quit smoking, and to support opportunity to quit smoking.

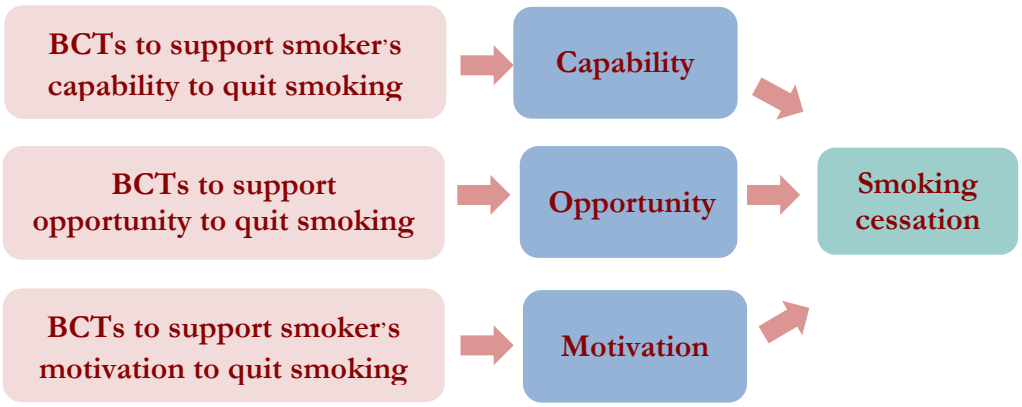


Figure 4.1 The link between behaviour change techniques and behaviour change components

To allow for equal representation of the number of text messages per behaviour change component, the COM group was limited to contain only 20 texts from each behaviour change component. For example, the COM group contained 20 text messages from the 'Capability' group, 20 text messages from the 'Opportunity' group, and 20 text messages from the 'Motivation' group, and the 'C' group contained 20 text messages from the Capability group, with repetition of BCTs. Details of the selection and development of BCT-enhanced text messages are discussed in **Section 4.4**.

4.3.4 Placebo text

For the placebo group, text messages were designed to provide different messages that contained no behaviour change techniques for smoking cessation in Thai for the same interval as the intervention groups (twice a day for 30 days at 7:00 AM and 4:00 PM), free of charge. A total of 60 text messages were designed to provide information and support about diet, exercise, and well-being (see **Appendix M**). This was to avoid incomplete factorial design resulting from a high rate of loss to follow-up when providing no information or no text at all (138).

4.4 Methods

The development of the text message contents involved three steps: 1) selecting BCTs and constructing text messages embedded with behaviour change components; 2) testing whether the content of the BCT-enhanced text messages represented the intended BCTs;

and 3) ensuring that the BCT-enhanced text messages were acceptable among stakeholders in Thailand.

The complexity of behaviour change interventions and insufficient details of reporting intervention content in published literature makes it difficult to understand the effective components of behaviour change interventions (139). A common language—the Behaviour Change Technique Taxonomy version 1 (BCTTv1) (30)—to describe behaviour change techniques (BCTs) will help the future designs of behavioural change interventions. Reporting the intervention content in sufficient detail is very important to allow for knowledge accumulation and future replication. A Template for Intervention Description and Replication (TIDieR) checklist (137)—used to assess the quality of reporting of complex interventions—guided the reports of this study's intervention development (see **Appendix H**).

4.4.1 Step 1: Selecting BCTs and constructing BCT-enhanced text messages

There are 93 defined BCTs according to the BCTTv1 taxonomy (30). Based on the mapping exercise in **Chapter 3**, 23 BCTs were in the capability group, 23 BCTs in the opportunity group, and 47 BCTs in the motivation group; it was not possible to include all listed BCTs. The objective of the first step was to select the BCTs and to construct text messages aimed at behaviour change components.

The selection of BCTs was based on the inclusion and exclusion criteria. For the inclusion criteria, the priority for selection was given to BCTs that had been applied in previous mHealth interventions for smoking cessation identified from the systematic review (see **Chapter 3** for more details), applicable to the Thai context, or contained in the TNQ practices. Some BCTs were selected as an alternative to BCTs identified from the systematic review which were not feasible for delivery via SMS, and allowed for more BCTs within a behaviour change component. For example, BCTs involving incentives (informing about rewards) were used instead of rewards (arranging for actual rewards). The exclusion criteria were 1) BCTs not supported by the systematic review results; 2) BCTs reported in the systematic review but were not feasible for delivery using text messages as a platform; or 3) BCTs which were presented as negative reinforcement statements.

4.4.2 Step 2: Testing whether the content of text messages represented the intended BCTs

The objective of the second step was to determine whether the BCT-enhanced text messages created by PK represent the intended BCTs.

Inter-coder reliability for an agreement was conducted prior to the generation of the full list of text messages. An independent and experienced BCT coder, Fabiana Lorencatto (FL), was invited to code a random sample of text messages. A random sample generator[1] was used to randomly select a number between 1 and 60. The random sample of texts was selected using Microsoft Excel. Both BCT coders (PK and FL) coded the 20 texts for BCTs using the BCTTv1.

Cohen's kappa coefficient (77) was used to determine the inter-rater agreement of at least 1 BCT per message between the two raters (PK and FL). Cohen's kappa coefficient was preferred over the percentage agreement because it takes into account agreement by chance (random agreement). Landis and Koch (1977) suggested the interpretations of kappa coefficient as follows (140): below 0.00 Poor; 0.00 – 0.20 Slight; 0.21 – 0.40 Fair; 0.41 – 0.60 Moderate; 0.61 – 0.80 Substantial; and 0.81 – 1.00 Almost perfect. The analysis was conducted using Stata/IC software (Release 14; StataCorp, 2015) (87).

4.4.3 Step 3: Validate whether the text messages were acceptable in Thai

The objective of the third step was to ensure that the BCT-enhanced text messages were acceptable by key stakeholders in Thailand.

A structured face-to-face focus group discussion using the Nominal Group Technique (141) was conducted to explore the acceptability of the intervention by stakeholders in Thailand. This method was chosen rather than individual face-to-face interviews because the focus group discussion engages people to discuss; it also allows for interaction and group dynamics to play a role in the discussion process (142). Therefore, it enabled opinions to be considered by other members and focused on participants' thoughts

[1] =RANDBETWEEN(1,60)

towards a set of previously developed text messages. Moreover, the Nominal Group Technique was used rather than the traditional focus group method because it is more structured, allowing for everyone in the group to decide and avoid the domination of certain participants. Another advantage of the Nominal Group Technique is that it also increases the stakeholders' ownership of the intervention, ensuring the likelihood of implementing the programme in the future if it is found to improve smoking cessation rates (143). The design for the structured face-to-face focus group discussion is summarised below. The COREQ checklist was used as a guide to report this qualitative study (144), see **Appendix I**.

4.4.3.1 Participant selection

Eligible participants were experts involved with tobacco control in Thailand. The rationale of choosing experts over smokers was to allow for the interventions to be accepted by the local practice. Purposive sampling of participants was used to identify a list of organisations that developed the "Clinical guidelines for smoking cessation in Thailand" (43) and the tobacco control network from those organisations' websites. This sampling method was used to ensure a range of participants from service providers, policymakers, funders, research units, and non-governmental organisations. The identified organisations were: 1) the Thai Health Professional Alliance Against Tobacco; 2) the Thai Physicians Alliance against Tobacco; 3) the Nurse Network on Tobacco Control of Thailand; 4) the Smoke Free Pharmacy; 5) the Action on Smoking and Health Foundation Thailand (ASH Thailand); 6) the Tobacco Control Research and Knowledge Management Center (TRC); 7) the Thailand National Quitline (TNQ); 8) the Bureau of Tobacco Control, Department of Disease Control, Ministry of Public Health; 9) the Thai Health Promotion Foundation; and 10) the developer of the Thai Rai Kwan application.

Invitation letters were sent to each organisation listed above to ask for one or two representatives to participate. The contents of the invitation letter consisted of: 1) a 2-page trial summary, 2) objectives and agenda of the meeting, 3) participant information sheet, and 4) consent form (see **Appendix J**). In Thailand, when invitation letters are sent to organisations, the directors of these organisations typically assigned member(s) of the organisation to attend based on their relevant experience and availability to attend the scheduled meeting. This method of participant selection is preferred to avoid systematic biases in the selection process by the researcher. Therefore, it is unknown to PK whether the participants will know each other.

4.4.3.2 Setting

A structured face-to-face focus group discussion took place at the Health Intervention and Technology Assessment Program (HITAP) meeting room. HITAP is an independent research unit located in the Ministry of Public Health within the Bangkok Metropolitan Region (www.hitap.net/en/). All participants were from Bangkok and the Bangkok Metropolitan Region (within 30 kilometres radius). The meeting room was arranged in a circle with a computer and a projector. A light refreshment was provided to all participants.

4.4.3.3 Data collection

The meeting was held on 4 November 2016 and lasted for 3 hours. The focus group discussion was divided into four sessions with a small 15-minute break after the first 2 sessions. This allowed the participants to have a break as any session longer than 90 minutes may result in a loss of focus. All participants were provided with a pen, presentation slides, voting flags, and a document containing the sets of text messages divided by BCT groups.

PK facilitated the meeting and introduced the research aim and objectives of the focus group discussion. Participants were informed that they would be assessing BCT-enhanced text messages based on the following criteria: 1) scientific grounds, 2) clarity of text messages, 3) unintended consequences, e.g. reminder of smoking, etc., and 4) acceptability to the stakeholders.

Participants were given three voting flags to represent their decisions on each group of text messages. A red flag represented a decision where the text message was unacceptable and required modification. A yellow flag represented a decision where the text message was acceptable but required minor changes in wording. A green flag represented a decision where the text message was acceptable without requiring any further changes.

Participants were provided with a ranking sheet to state their preference for each set of text messages. The text that received the highest preference score was prioritised to be in all treatment groups. **Figure 4.2** shows an example of three sets of text messages within the *BCT Information about health consequences*. Text messages were presented in groups of three texts that represented the same BCT with different style of writing. Out of three text, the one that received the highest vote will be used as the text message in all treatment groups. For example, if the text "It's hard to quit smoking because of nicotine and habits formed

by smoking." received the highest vote, this text will represent *BCT Information about health consequence* in the C, CO, CM, and COM groups. The text that was voted as the second rank will be included in CO and CM group while the third-rank text will be included in the C group only.

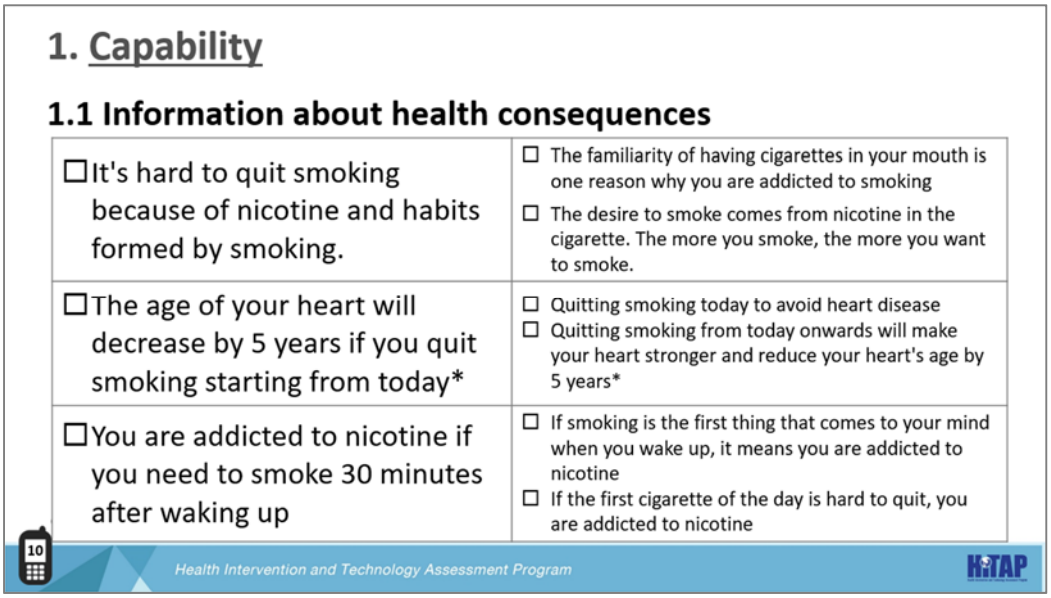


Figure 4.2 Examples of text messages that were presented in the focus group discussion

Individual voting was done openly in each round (a group of three text messages shown). In the case where all participants presented a green flag, the text was automatically accepted with no further changes. However, if there was no consensus on any text message (presenting yellow or red flags), a discussion was held to determine how to improve the message.

Participants were asked for permission to record the audio of the discussions. Voting results for each text message were announced in each round. Fieldnotes were made during the discussion by PK and a HITAP research assistant (Sarayuth Khantha). PK listened to the recorded audio file again after the focus group discussion and summarised the important aspects from the discussion in the meeting minutes. All participants were asked to provide further comments on the findings summarised through the minutes sent via email. Due to the limitation of time allowed for the development of text messages, there were no further revisions by participants.

4.4.3.4 Ethics

Ethical approval for the focus group discussion was granted by the School of Medicine Research Ethics Committee, University of Leeds (MREC16-001), and the Institute for the Development of Human Research Protections, Thailand prior to the focus group discussion (see research ethics in **Chapter 2** and participant information sheet and the consent form in **Appendix J**).

4.5 Results

4.5.1 BCTs included in each behaviour change component

Thirty-nine out of 93 BCTs were identified from this initial step. The majority of BCTs (80%) were supported by previous literature. **Table 4.1** displays the lists of selected BCTs, the rationale for selection, and examples of text messages for each BCT. Eleven BCTs were included in the 'Capability' behaviour change component. Another 11 BCTs were included in the 'Opportunity' behaviour change component while 17 BCTs were included in the 'Motivation' behaviour change component.

Appendix K displays the lists of BCTs that were excluded and the rationale for exclusion. The majority of BCTs that were excluded were not supported by the findings from the systematic review. Some BCTs were not applicable because it was not feasible to deliver them through SMS. For example, BCTs that provided feedback requiring a two-way SMS system where there is communication between the smokers and researchers. Some BCTs required elaborate explanations, and therefore were not feasible to be delivered within the one SMS limit (70 characters).

Table 4.1 Selected behaviour change techniques, rationale for selection, and examples of BCT-enhanced text messages

Behaviour change techniques (n*)	Rationale for selection	Examples of BCT-enhanced text messages
CAPABILITY		
1. Goals and planning		
1.2 Problem solving (n=23)	Supported by the systematic review findings	Drinking at least 8-10 glasses of water a day will help clear nicotine from your system.

Behaviour change techniques (n*)	Rationale for selection	Examples of BCT-enhanced text messages
2. Feedback and monitoring		
2.3 Self-monitoring of behaviour (n=4)	Supported by the systematic review findings	Try to stop smoking as much as you can, and then record how long you were able to stop.
2.4 Self-monitoring of outcome(s) of behaviour (n=2)	Supported by the systematic review findings	Try to record the number of cigarettes you smoke a day.
4. Shaping knowledge		
4.1 Instruction on how to perform the behaviour (n=16)	Supported by the systematic review findings	Try to reduce the number of cigarettes smoked per day. It will help with nicotine withdrawal symptoms.
4.2 Information about antecedents (n=2)	Supported by the systematic review findings	Prepare to quit smoking by recording events that give you urges to smoke every day.
5. Natural consequences		
5.1 Information about health consequences (n=10)	Supported by the systematic review findings	Stop smoking for 6 months and you can see that coughing will have decreased.
8. Repetition and substitution		
8.1 Behavioural practice/rehearsal (n=5)	Supported by the systematic review findings	If quitting smoking now is too hard for you, try reducing the number of cigarettes.
8.2 Behaviour substitution (n=7)	Supported by the systematic review findings	If smoking helps you to relax, try to find new ways to make you relaxed.
8.6 Generalisation of target behaviour	Contained in the TNQ practices	Prepare to quit by trying to abstain from smoking at home like when you have to abstain at your work place or school.
8.7 Graded tasks (n=3)	Supported by the systematic review findings	Prepare to quit by trying to reduce one cigarette a day until your quit date.
12. Antecedents		
12.4 Distraction (n=10)	Supported by the systematic review findings	When you get the urge to smoke, try to distract yourself with music you like instead.
OPPORTUNITY		
3. Social support		
3.1 Social support (unspecified) (n=18)	Supported by the systematic review findings	Quitting smoking is not that difficult. Just find a buddy who wants to also quit and quit smoking together.
3.2 Social support (practical) (n=10)	Supported by the systematic review findings	Quitline 1600 is here to help you plan how to quit smoking.
3.3 Social support (emotional) (n=11)	Supported by the systematic review findings	Quitline 1600 is here to support you when you are feeling down.

Behaviour change techniques (n*)	Rationale for selection	Examples of BCT-enhanced text messages
6. Comparison of behaviour		
6.2 Social comparison (n=11)	Supported by the systematic review findings	Many people quit smoking in a year. If they can, so can you.
7. Associations		
7.1 Prompts/cues (n=4)	Supported by the systematic review findings	Write messages to encourage your abstinence, then place them at home.
11. Regulation		
11.1 Pharmacological support (n=15)	Supported by the systematic review findings	Nicotine replacement therapy can help you with nicotine withdrawal symptoms. Consult a pharmacy near you.
12. Antecedents		
12.1 Restructuring the physical environment (n=6)	Supported by the systematic review findings	Have you thrown away your cigarettes and ash tray today?
12.2 Restructuring the social environment (n=8)	Supported by the systematic review findings	Quitting smoking is not that difficult. Just stay away from friends who smoke for a while.
12.3 Avoidance/ reducing exposure to cues for the behaviour (n=6)	Supported by the systematic review findings	When you start to quit smoking, try to avoid places that remind you of the urge to smoke.
13. Identity		
13.1 Identification of self as role model	Contained in the TNQ practices	All you need is commitment to abstinence. It is a good example to those around you.
13.2 Framing/reframing (n=4)	Supported by the systematic review findings	Change your attitude. Not being able to quit now is not a failure. You just need to try harder.
MOTIVATION		
1. Goals and planning		
1.1 Goal setting (behaviour) (n=11)	Supported by the systematic review findings	Setting a quit smoking date on an important date will motivate you to quit smoking.
1.3 Goal setting (outcome)	Alternative to BCT 1.1 Goal setting (behaviour)	Set your goal. How many cigarettes will you reduce within a week?
1.5 Review behaviour goal(s) (n=9)	Supported by the systematic review findings	If you have set a quit date, see if you have quit smoking already.
1.7 Review outcome goal(s)	Alternative to BCT 1.5 Review behaviour goal(s)	Have you reached your target to reduce smoking today?
1.8 Behavioural contract (n=1)	Supported by the systematic review findings	You can do it. Just make a promise to your loved ones that you will quit in 2 weeks.

Behaviour change techniques (n*)	Rationale for selection	Examples of BCT-enhanced text messages
1.9 Commitment (n=8)	Supported by the systematic review findings	Start quitting now. Make a commitment to your loved ones that you will quit smoking.
5. Natural consequences		
5.3 Information about social and environmental consequences (n=4)	Supported by the systematic review findings	Many people do not like smokers because they feel that they have been hurt indirectly.
9. Comparison of outcomes		
9.2 Pros and cons (n=14)	Supported by the systematic review findings	Compare the pros and cons of quitting smoking. Ask yourself: should you quit?
10. Reward and threat		
10.5 Social incentive	Alternative to BCT 1.4 Social reward	Share your quit smoking journey on Facebook. You will receive a lot of support from your friends.
10.6 Non-specific incentive	Alternative to BCT 1.3 Non-specific reward	You will be able to stay with your loved ones for 10 years longer if you quit smoking today.
10.9 Self-reward (n=8)	Supported by the systematic review findings	Reward yourself if you have reached your target or quit smoking.
11. Regulation		
11.2 Reduce negative emotions (n=9)	Supported by the systematic review findings	Relieve stress from withdrawal symptoms by doing activities you like or talking to your best friend.
13. Identity		
13.5 Identity associated with changed behaviour (n=8)	Supported by the systematic review findings	Tell your friends that you are a person who wants to quit smoking.
15. Self-belief		
15.1 Verbal persuasion about capability (n=16)	Supported by the systematic review findings	You can quit. Keep telling yourself that you can quit smoking.
15.2 Mental rehearsal of successful performance	Alternative to BCT 15.3 Focus on past success	Imagine if you could quit smoking. How happy would you feel?
15.4 Self-talk (n=2)	Supported by the systematic review findings	You can do it. Just tell yourself that you can quit smoking. You can quit. Keep telling yourself that you can quit smoking.
16. Covert learning		
16.2 Imaginary reward	Alternative to BCT 16.1 Imaginary punishment	Imagine if you could quit smoking. How happy would you feel?

*Number of studies reported to contain the select BCTs in their intervention group

BCT: Behaviour change technique; **TNQ**: Thailand National Quitline

4.5.2 Do the text messages represent the intended messages for the selected BCTs?

PK and FL agreed on 16 text messages that had the same BCT. The results from the two coders are presented in **Appendix L**. Inter-coder reliability for BCT coding was calculated using Cohen's kappa and was found to have a substantial level of agreement (k = 0.7820) (see **Table 4.2**). When considering text message number 11, "Set your goal. How many cigarettes will you reduce within a week?", PK only informed FL that the behaviour of interest was smoking cessation without notifying that the number of cigarettes should be coded as 'outcome of behaviour' rather than 'behaviour' itself. If this discrepancy is relaxed, the inter-rater reliability would have been 'almost perfect' (level of agreement of 0.8361).

The discrepancy of BCT coding (including text messages that were coded to have more than one BCT) was explored to determine whether the text messages fell into different behaviour change components for example, motivation instead of opportunity. It was found that none of the discrepancies of BCT coding fell into different behaviour change components.

Table 4.2 Inter-coder reliability for the behaviour change technique coding

Scenario	Agreement	Expected agreement	Kappa	Standard error	p-value
Base case	80%	8.25%	0.7820	0.0630	P < 0.001
Allow for outcome discrepancy	85%	8.50%	0.8361	0.0644	P < 0.001

Note: Substantial level of agreement: 0.61 – 0.80; almost perfect level of agreement: 0.81 – 1.00

4.5.3 Acceptability with Thai smoking cessation stakeholders

Eight participants and one observer attended the focus group. The majority of participants were female (n=7). There was one participant for each organisation from the following organisations: the Thai Health Professional Alliance Against Tobacco; the Thai Physicians Alliance against Tobacco; the Nurse Network on Tobacco Control of Thailand; the Action on Smoking and Health Foundation Thailand (ASH Thailand); and the Bureau of Tobacco Control, Department of Disease Control, Ministry of Public Health. Two participants were

from the TNQ and one participant represented both the Thai Health Promotion Foundation and the TNQ.

Three representatives declined, one female representative from the Tobacco Control Research and Knowledge Management Center because she thought that the agenda of the meeting was not relevant to someone with her expertise; and two representatives from Smoke Free Pharmacy and the developer of the Thai Rai Kwan application because they could not attend the meeting on the specified date/time. One observer from the Thai Physicians Alliance against Tobacco attended the focus group discussion for learning purposes and did not vote.

From the 20 sets of text from the capability group, participants rejected 4 text sets. Ten text sets were accepted with minor changes (in wording) and 6 text sets were mixed in voting (accepted without any changes and accepted with minor changes). The 4 sets of text messages that were rejected were:

- *BCT Instruction on how to perform the behaviour*, "Try to reduce the number of cigarettes per day. It will help with nicotine withdrawal symptoms."
- *BCT Self-monitoring of outcome(s) of behaviour*, "Try to record the number of cigarettes you smoke a day."
- *BCT Behavioural practice/rehearsal*, "If quitting smoking now is too hard for you, try reducing the number of cigarettes."
- *BCT Graded tasks*, "Prepare to quit by trying to reduce one cigarette a day until your quit date".

Participants agreed, after discussion, that texts messages related to the suggestion of reducing the number of cigarettes or using the number of cigarettes as outcomes should be removed from the text set. This was because the aims of this study and the smoking cessation interventions provided by the TNQ is smoking abstinence. The participants also agreed that the primary aim of the test messages was to convince the smokers to quit smoking completely. Therefore, all texts related to the concept about the reduction of the number of cigarette smoked were rejected. From the focus group discussion, *BCT Self-monitoring of outcome(s) of behaviour*, *BCT Behavioural practice/rehearsal*, and *BCT Graded tasks* were removed from the original list of 'Capability' behaviour change component.

From the opportunity group's 20 sets of texts, participants rejected only 2 text sets. Twelve text sets were accepted with minor changes (in wording) and 6 text sets were accepted without any changes. The 2 sets of rejected texts were:

- *BCT Social support (unspecific)*, "Quitting smoking is not that difficult. Just find a buddy who wants to also quit and quit smoking together."
- *BCT Social support (emotional)*, "Recording voices of encouragement from your loved ones will keep you motivated to quit smoking."

Participants agreed, again after discussions, that the first text (specified above) may harm smokers; instead of finding a buddy to quit, participants were worried that the buddy may invite the smoker to smoke again. Participants also thought that the second text above may not be feasible as voice recording functionality might not be available on the smoker's phone. Overall, no BCT was removed from the original list of opportunity behaviour change component

From the 20 sets of text from the motivation group, participants rejected 5 text sets. Nine text sets were accepted with minor changes (in wording) and 2 text sets were mixed in voting (accepted without any changes and accepted with minor changes). Four text sets were accepted without any changes. The 5 sets of text messages that were rejected were:

- *BCT goal setting (outcome)*, "Set your goal. How many cigarettes will you reduce within a week?"
- *BCT review outcome goal(s)*, "Have you reached your target to reduce smoking today?"
- *BCT behavioural contract*, "You can do it. Just make a promise to your loved ones that you will quit within 2 weeks."
- *BCT reduce negative emotions*, "Relieve stress from withdrawal symptoms by doing activities you like or talking to your best friend."
- *BCT reduce negative emotions*, "You can do it. Relieve stress from withdrawal symptoms by meditating for 10 minutes."

BCT goal setting (outcome) and *BCT review outcome goal(s)* were removed as participants agreed that any texts related to the suggestion of reducing the number of cigarettes should be removed. *BCT Behavioural contract* required a higher level of explanation to communicate an adequate level of detail to smokers, and participants decided that the information was unlikely to be sufficient within the 70-character limit per text message. Moreover, *BCT*

Commitment served similar purposes and was sufficient for this level of communication. Therefore, all texts related to *BCT Behavioural contract* were removed.

Finally, texts within *BCT Reduce negative emotion* were classified within the 'Motivation' group. Participants agreed that the texts for this BCT were similar to texts within the 'Capability' group. Therefore, all texts related to *BCT Reduce negative emotion* were removed to avoid the duplication of the two domains ('Capability' and 'Motivation').

Figure 4.3 shows the overall voting results by groups. The majority of votes were accepted with minor changes in wording. Main suggestions were given in the focus group discussion and minor suggestions were written down in the document. Here are some of the main suggestions within the focus group discussion:

> The wording "Nicotine replacement therapy" should be replaced with "smoking cessation medications" in order to include non-NRT medications. All texts related to the Quitline should be modified to match the quotes that the TNQ uses. For example, *"Quitline 1600 is here to help you plan your smoking cessation process"* to *"1600 Quit Smoking hotline. Call free on all mobile networks."*.

Some texts sounded too academic and required modification. For example, *"Nicotine replacement therapy can assist you in quitting smoking by up to 2 times compared to abruptly quitting."* to *"smoking cessation medication can help you successfully quit smoking"*.

For other text messages that required minor changes in wording, suggestions of text modifications were noted in the form and handed to PK at the end of the focus group discussion. Afterwards, the minutes of the meeting were sent to all participants. None of the participants asked for further modification of the text messages. **Table 4.3** reports the final BCTs used in this study. **Appendix M** lists the final text messages for the 'Capability', 'Opportunity', 'Motivation' groups, and details of text messages for each of the intervention arms.

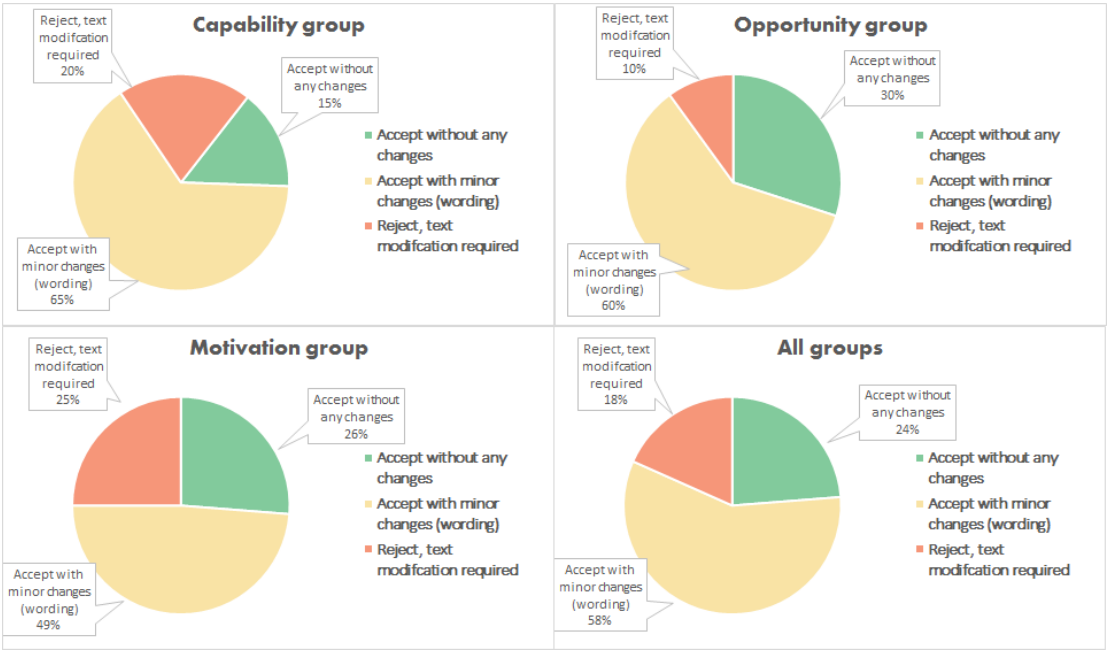


Figure 4.3 Voting results by behaviour change component group

Table 4.3 Final behaviour change techniques included in the study

Capability (n=8)	Opportunity (n=11)	Motivation (n=13)
- Problem solving - Self-monitoring of behaviour - Instruction on how to perform the behaviour - Information about Antecedents - Information about health consequences - Behaviour substitution - Generalisation of target behaviour - Distraction	- Social support (unspecified) - Social support (practical) - Social support (emotional) - Social comparison - Prompts/cues - Pharmacological support - Restructuring the physical environment - Restructuring the social environment - Avoidance/ reducing exposure to cues for the behaviour - Identification of self as role model - Framing/reframing	- Goal setting (behaviour) - Review behaviour goal(s) - Commitment - Information about social and environmental consequences - Pros and cons - Social incentive - Non-specific incentive - Self-reward - Identity associated with changed behaviour - Verbal persuasion about capability - Mental rehearsal of successful performance - Self-talk - Imaginary reward

4.6 Discussion

4.6.1 Main findings

BCT-enhanced text messages were developed based on BCTs that were mapped into three behaviour change components, and were validated by a BCT expert and a panel of Thai stakeholders and users. A total of 240 text messages were developed comprising 60 texts that served as the placebo text group, 60 texts for capability group, 60 texts for opportunity group, and 60 texts for motivation group. From 39 candidate BCTs, 7 BCTs were excluded from the initial list including *BCT 2.4 self-monitoring of outcome(s) of behaviour; 8.1 behavioural practice/rehearsal; 8.7 graded tasks; 1.3 goal setting (outcome); 1.7 review outcome goal(s); 1.8 behavioural contract; and 11.2 reduce negative emotions*. Therefore, a total of 32 BCTs were included in the final set of text messages.

This chapter highlighted the development process of the intervention and illustrated the structured three-phases of intervention development, which can guide other researchers on how to develop BCT-based interventions. The development process of the intervention was similar to CHAT and CHAT-DM, multicentre, single-blinded, two-arm, randomised controlled trials of an automated mobile phone text message-based intervention (145). This intervention development involved a group of experts to refine text messages and allowed users to comment on their text messages prior to its use.

4.6.2 Strengths and limitations

The use of BCTs as the smallest ingredient of behaviour change interventions allowed for the compilation of collective knowledge about the applicability of behaviour change intervention. The development of the intervention based on BCTs at the beginning allowed for unbiased identification of technique used in the study, unlike some previous studies where BCTs were identified at a later stage.

Furthermore, the intervention development involved local stakeholders to increase acceptability of the text messages programme in the future. In this case, the Nominal Group Technique was a very useful decision-making exercise given the limited resources available. It provided information to help inform the decisions and allowed for consensus within a given time. However, it was unexpected that several BCTs would be removed

from the list as a consequence. Removing BCT *graded task* was a surprise to PK as there were studies that contained text messages recommending to reduce the number of cigarettes smoked as an alternative. The third step was vital to the future implementation because the intervention developed for the Quitline would not have been achieved if only the validity of BCTs had been considered and the cultural and contextual aspects were ignored.

There are several limitations on the design of the intervention. Firstly, only one-third of the original text messages were randomly selected and assessed by an independent person. There was no assessment after the full set of text messages had been finalised. The confirmation of active ingredients would have improved if another assessment had been conducted after the full list of text messages was approved. This was due to the resource constraints of the design phase of this PhD as it would have added more time to the development phase and would not have been feasible to continue to test the intervention in the factorial trial. However, the high rates of agreement suggest that PK was able to design the text messages within the intended BCTs and within behaviour change components.

Secondly, there was no user testing and pilot study prior to the full RCT, unlike the intervention development from another research study (145). One of the important aspects of mHealth intervention development is to ensure that the technology is user-friendly and engaging. This evaluation is important at the design stage for mHealth interventions. Due to resource constraints in terms of time and unplanned additional ethical approvals for the added focus group discussion, this study was unable to conduct a usability test of the text message contents among a group of smokers and people who stopped smoking. However, mobile text messages are a more straightforward mHealth intervention, unlike mobile smoking cessation apps where a number of iterations of the intervention should be tested; user testing would definitely play a significant role in the acceptance of these types of interventions. Prior user testing may result in a higher level of engagement to the text messages programme and propensity to share text messages to other smokers may be larger as only 14% of the trial participants shared text messages they received (Chapter 7, **Table 7.3**).

Thirdly, there were limited opportunities for multiple meetings for the acceptability phase. The meeting took 3 hours and even though there were breaks in between sessions, PK was able to see that participants started to lose concentration during the last 30 minutes. It was

suggested by the stakeholders that the session should have begun with the 'Motivation' group rather than the 'Capability' group as most experts were familiar with texts aimed at increasing motivation to quit smoking. More rounds of the expert panel—for example, one session per behavioural component—could also improve the development of text messages.

4.6.3 Implications of research

Behaviour change interventions are usually treated like a 'black box' and replication of an intervention is difficult as details of the intervention development are not explicitly stated. With the availability of the Template for Intervention Description and Replication (TIDieR) checklist, it is expected that future trials will be able to explicitly report details of interventions, hence allowing for future replication. The findings suggest the importance of the contextual aspect of intervention development. Country-specific aspects of intervention development are vital for the acceptance of an intervention for future implementation.

4.7 Chapter summary

This chapter details the development of an automated text message-based intervention to aid Thai smokers to stop smoking. To create text messages aimed at three theory-based behaviour change components ('Capability', 'Opportunity', and 'Motivation'), 32 BCTs were found to be acceptable among the Thai panel and was included in the final set of text messages.

Chapter 5: Methods and data analysis plan for a factorial randomised controlled trial to simultaneously test the effectiveness of BCT-enhanced text messages for smoking cessation in Thailand

5.1 Chapter overview

This chapter focuses on the design of the trial to test the effectiveness of three behavioural change components in BCT-enhanced text messages on smoking cessation in Thailand and the data analysis plan. This trial was designed to be a pragmatic, individually-randomised, controlled trial with a 2×2×2 full factorial design. Two levels (present and absent) of three behavioural components ('Capability', 'Opportunity', and 'Motivation') were considered within text messages to support the smoking cessation process of Thai smokers. Details on the methods and analysis plan are presented.

5.2 Trial aim and objectives

5.2.1 Aim

The aims of this study were to simultaneously test the effectiveness of three intervention components ('Capability', 'Opportunity', and 'Motivation') in text messages for smoking cessation and the influence of the absence and presence of each behavioural component on smoking cessation rates in Thailand.

5.2.2 Primary objective and hypotheses

The primary objective of this study was to simultaneously test whether BCT-enhanced text messages aimed at different behavioural components can improve the 7-day self-reported smoking abstinence rate at 1-month follow-up.

The null hypotheses were:

1) Providing text messages aimed at supporting smokers' **capability** to quit (C, CO, CM, and COM) does not improve 7-day smoking abstinence rate at 1-month follow-up compared to text messages that do not contain the capability component (placebo texts, O, M, and OM)
2) Providing text messages aimed at supporting smokers' **opportunity** to quit (O, CO, OM, and COM) does not improve 7-day smoking abstinence rate at 1-month follow-up compared to text messages that do not contain the opportunity component (placebo texts, C, M, and CM)
3) Providing text messages aimed at supporting smokers' **motivation** to quit (M, CM, OM, and COM) does not improve 7-day smoking abstinence rate at 1-month follow-up compared to text messages that do not contain the motivation component (placebo texts, C, O, and CO)

5.3 Rationale for a factorial experimental design

A randomised controlled trial (RCT) is considered to be the gold-standard for the evaluation of the efficacy/effectiveness of an intervention. A standard two-arm parallel trial is the most common design, where participants are assigned to either an intervention group or a control group. However, this type of RCT only provides an answer to whether the intervention is effective or not. It is not possible to differentiate the treatment effects of multicomponent interventions, e.g. a mobile health (mHealth) behaviour change intervention which can contain many 'active ingredients'. Further scientific contribution to behavioural sciences is limited as it treats an intervention as a package, with unknown active components similar to a 'black box' (146-148). For a standard parallel design, a limited number of experimental conditions can be explored. To test several components of behavioural interventions, more resources are needed for a multi-arm parallel design. For example, if a sample size of 800 is required to test for one condition, an 800×n sample size

is required for 'n' conditions (149). Therefore, the extra resources required for additional experimental groups can be very costly.

The Multiphase Optimisation Strategy (MOST) is a methodological approach to optimise and evaluate multicomponent interventions and consists of three phases: screening, refining, and confirming (150). This approach utilises experimental designs to screen for potentially effective intervention components prior to testing in an RCT (151), and has been used in optimising packages for smoking cessation (152-155). Experimental designs that are recommended for optimising the effectiveness of multicomponent interventions in the MOST approach include full factorial, fractional factorial, and 'sequential, multi assignment, randomised trial' (SMART) (156). These types of designs are a more efficient approach compared to a parallel design or multi-arm design. For example, a factorial design requires the same sample size as a parallel design (and less compared to a multi-arm design) for the same statistical power (149).

A full factorial design considers all possible experimental conditions. For example, a 2×2×2 (2^3) full factorial design involves three experimental conditions (factors) with two levels of each condition. A total of eight experimental conditions can be achieved within this design. A full factorial design allows the effects of each behavioural component in text messages to be separately compared with text messages that do not contain the components.

A fractional factorial design is a subset of experimental conditions of the full factorial design. For example, a 2^{3-1} fractional factorial design involves a chosen subset of experimental conditions from three experimental conditions (factors) with two levels of each condition, resulting in four experimental conditions. The fractional factorial design provides the same statistical power as the full factorial design with fewer resources needed to develop experimental conditions (interventions). However, this design requires careful consideration of the subset selection. The main assumption of a fractional factorial design is that the effect of interaction between factors is zero or negligible and the main effect of a factor is confounded with an interaction of factors (157). Interactions indicate that the effect of one component is not equal to the sum of the individual effects.

Moreover, the different resources used between full factorial and fractional factorial designs are the costs of the initial design of the intervention. If the cost for each condition to be implemented is relatively high, e.g. testing different platforms for providing interventions, a fractional factorial design may be more appropriate. Since there are no

published studies investigating whether an interaction between behavioural change components are negligible and there were no extra costs to develop all experimental conditions in this study, the use of a full factorial design was considered to be more appropriate.

The SMART is a special variation of the factorial experiment of multi-stage and multi-component treatments (158). This design is suitable for adaptive interventions or just-in-time adaptive interventions that have time-varying components (e.g. dose-response or stage of change). In this case, the interventions were designed to be a fixed set of text messages aiming to test behaviour change components (see **Chapter 4** for intervention development). In the case where tailored design features (e.g. text messages to support smoker's stage of change) are of interest, the SMART design may be more appropriate to assess the effectiveness of the interventions.

5.4 Trial design and methods

5.4.1 Overview

A pragmatic, definitive, individually-randomised, controlled trial with 2×2×2 full factorial design was used to simultaneously assess the effectiveness of three behavioural change components (capability/opportunity/motivation) enhanced text messages for smoking cessation (main effects) and the influence of each behavioural change component in text messages on smoking cessation rates (interactions). This trial was designed to be a pragmatic trial that measured the effectiveness of text messages in the routine practice of the Thailand National Quitline (TNQ). The TNQ is the only national agency that provides telephone counselling for smoking cessation and participants were recruited nationwide.

Consenting participants were randomised to receive one of eight sets of behaviour change component enhanced text messages (placebo texts, C, O, M, CO, CM, OM, and COM) in an equal allocation ratio (1:1:1:1:1:1:1:1) via a web-based programme. Placebo texts refer to text messages that do not contain any behavioural change for tobacco cessation. 'C' stands for messages aimed at increasing smokers' capability to quit. 'O' stands for messages aimed at increasing opportunity to support smoking cessation. 'M' stands for messages aimed at increasing motivation to quit. Combinations of C, O, and M stand for messages aimed at increasing more than one components, e.g. COM stands for messages aimed at

all behavioural components. Age groups and intention-to-quit smoking are used as stratification factors for the randomised block design. The participants were blinded from group allocation by withholding information about the content or intention of the different sets of text messages. Data collection was conducted at baseline and again 1 month later, after participants had received all text messages. Though an objective measurement—biochemical verification of abstinence—and a longer follow-up duration (6-month or 12-month) is recommended to be used as a primary endpoint (159), the long-term follow-up was beyond the scope of this PhD.

5.4.2 Reporting guideline and protocol registration

There were no published reporting guidelines specific to randomised controlled trials with a factorial experimental design (160). Therefore, the Consolidated Standards of Reporting Trials (CONSORT) and its supporting papers (161-163)—the most recent recommendations for reporting randomised trials—were used as a guide to report this trial design **(Appendix O)**, complemented by the Medical Research Council (MRC) guidance for reporting process outcomes (164) and recommendations from previous research about key methodological issues for factorial trials (160, 165). The International Council for Harmonisation (ICH) guidance on Statistical Principles for Clinical Trials was also used to guide the statistical analysis plan (166).

The protocol was registered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry to support transparency in research (ISRCTN16022919), available from http://www.isrctn.com/ISRCTN16022919. The ISRCTN registry was chosen as it is an open-access database with a primary focus on clinical trial studies and is recognised by the World Health Organization (WHO) and International Committee of Medical Journal Editors.

5.4.3 Trial participants and study settings

Smokers from across Thailand who wanted to quit smoking were identified from the TNQ database or through online database hosted by Bristol Online Survey (BOS). Once eligible smokers were identified from the TNQ database, the quitline staff briefly informed them about the trial. The list of eligible smokers who were interested in participating was sent by secure file transfer to the chief investigator, Pritaporn Kingkaew (PK), weekly. An

information sheet and a consent form were sent to these interested smokers via mobile phone, email, or post, depending on their preference for communication method. Eligible smokers who completed self-administered baseline questionnaires from online BOS database were also recruited. This route was used to allow smokers that sought smoking cessation support via national public health campaigns. An option for online registration is similar to 'call back services' (the routine service provided by TNQ) where smokers can provide information and the TNQ can call them back.

The inclusion criteria were tobacco smokers: (1) residing in Thailand who wanted to quit smoking, (2) who owned a mobile phone with at least the ability to send and receive SMS text messages, and (3) who are able to read and write Thai. The inclusion criteria were modified to allow for any smokers rather than smokers who did not set a quit date within a month in order to meet the target sample size in response to changing circumstances in TNQ practices (see **Chapter 6** for the rationale).

Participants were enrolled into the trial after giving informed consent. All participants then completed a baseline questionnaire either via a telephone interview or a self-completed online questionnaire (see research ethics approval for this trial in **Chapter 2** and participant information sheet and the consent form in **Appendix P**).

5.4.4 Randomised interventions

5.4.4.1 Design of mobile health interventions

All texts were designed to be a fixed intervention. No provision was made for tailoring functionality, either based on the smoker's characteristics or preferences. In addition, the intervention was unable to adapt to participants' progress automatically (no dynamic function). These advanced designs are resource intensive and are not feasible for implementation in resource-limited settings. Due to limited resources available for this PhD, the automated text message-based intervention in this study was developed to be a one-way communication pathway that can be feasibly delivered at scale. This means that text messages are sent by the provider only and there is no function to allow for participants to reply to the provider or chief investigator, Pritaporn Kingkaew (PK).

5.4.4.2 Content of BCT-enhanced text messages

The methods for the development of the BCT-enhanced text messages are detailed in **Chapter 4**. Eight experimental conditions were tested which considered two levels (present and absent) of three behavioural components ('Capability', 'Opportunity', and 'Motivation') in the text messages; **Table 5.1** shows the design matrix of the full factorial design. Participants were randomised to receive one of eight sets of text messages that contained different behavioural components, which were:

1) **Placebo texts:** messages containing no behaviour change techniques for smoking cessation
2) **C:** BCT-enhanced text messages to support smokers' capability to quit
3) **O:** BCT-enhanced text messages to support smokers' opportunity to quit
4) **M:** BCT-enhanced text messages to support smokers' motivation to quit
5) **CO:** BCT-enhanced text messages to support smokers' capability and opportunity to quit
6) **CM:** BCT-enhanced text messages to support smokers' capability and motivation to quit
7) **OM:** BCT-enhanced text messages to support smokers' opportunity and motivation to quit; and
8) **COM:** BCT-enhanced text messages aimed at all behavioural change components

Table 5.1 Design matrix of 2×2×2 factorial design and content of text messages within interventions that were randomised

Experi-mental group	Content of text messages (factor)			Abbreviation
	Capability	Opportunity	Motivation	
1	No (-)	No (-)	No (-)	Placebo
2	Yes (+)	No (-)	No (-)	C
3	No (-)	Yes (+)	No (-)	O
4	No (-)	No (-)	Yes (+)	M
5	Yes (+)	Yes (+)	No (-)	CO
6	Yes (+)	No (-)	Yes (+)	CM
7	No (-)	Yes (+)	Yes (+)	OM
8	Yes (+)	Yes (+)	Yes (+)	COM

All participants were scheduled to receive a free automated text message twice a day at 7:00 AM and 4:00 PM for 30 days, for a total of 60 text messages per participant. All participants

received text messages throughout the study period. For the placebo text group, participants received text messages that contained no behaviour change techniques for smoking cessation. This was to avoid using an incomplete factorial design resulting from a high rate of loss to follow-up (138). Participants recruited via the TNQ received counselling services and were encouraged to set a quit date within a month. They also received routine follow-up telephone calls from the TNQ at 7-day, 15-day, and 1-month intervals after their quit date for practical and emotional support. For participants who refused to set a quit date, no routine follow-up telephone calls were made by staff from the TNQ.

Two additional text messages were sent to serve as the research process on how to opt out from receiving text messages and how to contribute data. The first text, *"You will receive messages for 30 days. To stop, contact 0891643777."*, was sent to all participants as a welcome message to the trial, and included contact information if the participant wanted to stop receiving these messages. A final message, *"Thank you for joining iCanQuit. Please answer the questionnaire at https://leeds.onlinesurveys.ac.uk/icanquit-1-mo to improve the quality of this program.",* was sent 30 days after the first text was sent to thank each participant for their participation and to ask them to complete the online follow-up questionnaire.

5.4.4.3 Online platform to deliver text messages

Sending text messages via mobile phones is a viable platform for conveying messages directly to individuals. Short Message Service (SMS) is a service for providing short messages over mobile phone networks. Text messages can be sent directly to mobile phone users manually via a mobile device as a one-to-one message or can also be sent in bulk. Sending text messages in bulk, via an SMS gateway, is much more efficient compared to a one-to-one message. This method is expected to minimise human error from manual operations.

An SMS gateway is a device or service that allows for an exchange of information between senders and mobile networks and is considered to be the fastest and most reliable method to send text messages in bulk (167). SMS gateways have been used in many fields such as SMS mobile marketing, mobile banking, etc. SMS gateway service providers can send text messages in bulk to many mobile users both locally and worldwide, depending on the services they provide.

There are numerous SMS gateway providers available in Thailand and worldwide. There are three main reasons why a provider in Thailand was chosen. First, SMS gateway providers must abide by Thai laws and regulations. Second, SMS gateway providers should be able to send text messages via available mobile network operators in Thailand (True Move-H, DTAC, and AIS) since mobile networks are different between countries (e.g. O2, Vodafone in the UK). Third, the price ranges of SMS from Thai-based SMS gateway companies are generally lower than abroad as the price of sending SMS is based on the local rate, not the roaming rate.

ThaibulkSMS was chosen to be the only SMS provider in this study because it provides a competitive price, follows Thailand's SMS marketing regulations, and has an online security safeguard (SSL Greenbar certified by VeriSian Inc.). It was also selected by the TNQ for future implementation. ThaibulkSMS connects to all Thai mobile network operators with the ability to accommodate application programming interface (API). API is a set of functions and procedures that enables a third-party programme to gain access to facilities within an application. It allows different applications and devices to be able to connect and exchange information, serving as a translator. Finally, ThaibulkSMS enables block list management in the event where participants would like to stop receiving text messages. There is no record on whether participants open the text messages, only the delivery status. Depending on the subscription package, the delivery status of text messages can be tracked using the "cooperate package". The delivery statuses of text messages include:

1. **Delivery:** the message has been received at the destination mobile number
2. **Waiting:** the message is being sent (waiting for status reply)
3. **Fail operator:** unable to send the message (mobile network operator outages)
4. **Anti-spam:** the destination mobile number has informed the mobile network not to receive SMSs from this channel
5. **Blocklist:** the mobile number is registered on a blacklist
6. **Fail mobile:** unable to send the message (failure from the destination mobile number, e.g. out of network range, memory full, etc.)

5.4.5 Randomisation

5.4.5.1 Type of randomisation

Randomisation, or random allocation, of treatments to participants is one of the key characteristics of an RCT. The aim is to avoid selection bias, which can occur if recruiters decide which treatment group participants should be placed in. Also, when randomisation is performed appropriately, it ensures a balance of both known and unknown factors between treatment groups (168). The simplest form of randomisation is a coin toss, where a participant has a 50% chance of receiving one treatment or the other. However, an imbalance in the number of participants in each treatment arm can occur.

To ensure a balance in sample size across treatment groups and across stratification factors, stratified permuted block randomisation—a form of restricted randomisation—was used in this trial. It was suggested that the number of stratification factors should be kept to a minimum as adjusted models may lead to a high type I error rate (169). Longitudinal data from the International Tobacco Control (ITC) Southeast Asia studies in Thailand suggested that older age and intention-to-quit smoking were found to be predictors of quit attempts (170, 171); both factors were associated with a higher likelihood of quit attempts and smoking cessation. To minimise treatment allocation imbalance between experimental groups across important prognostic factors, age group (≤30, 31-40 and >40) and intention-to-quit scores (1-5 and 6-10) were used as stratification factors resulting in a total of 6 strata. Age was categorised into three groups according to the proportion of TNQ smokers who were recruited to a previous study (40). Mixed intention-to-quit scores were observed in the previous TNQ study, where 41% of the respondents had low-moderate intention-to-quit; the scores were divided in half to represent the low intention-to-quit and high intention-to-quit groups (40).

5.4.5.2 Sequence generation

The sequence list for random allocation was a computer-generated schedule, produced in Stata/IC software (Release 14; StataCorp, 2015) (87). A permuted-block random schedule with an equal block of size 16 was generated (eight experimental conditions twice). There were six sets of random lists (6 strata) according to age group (≤30, 31-40 and >40) and intention-to-quit scores (1-5 and 6-10).

5.4.5.3 Allocation concealment mechanism

Though the ThaiBulkSMS allows users to send automated multiple text messages to multiple numbers at the same time, allocation concealment is not achievable with this function. **Figure 5.1** shows a simple function to send one text message to the mobile user(s).

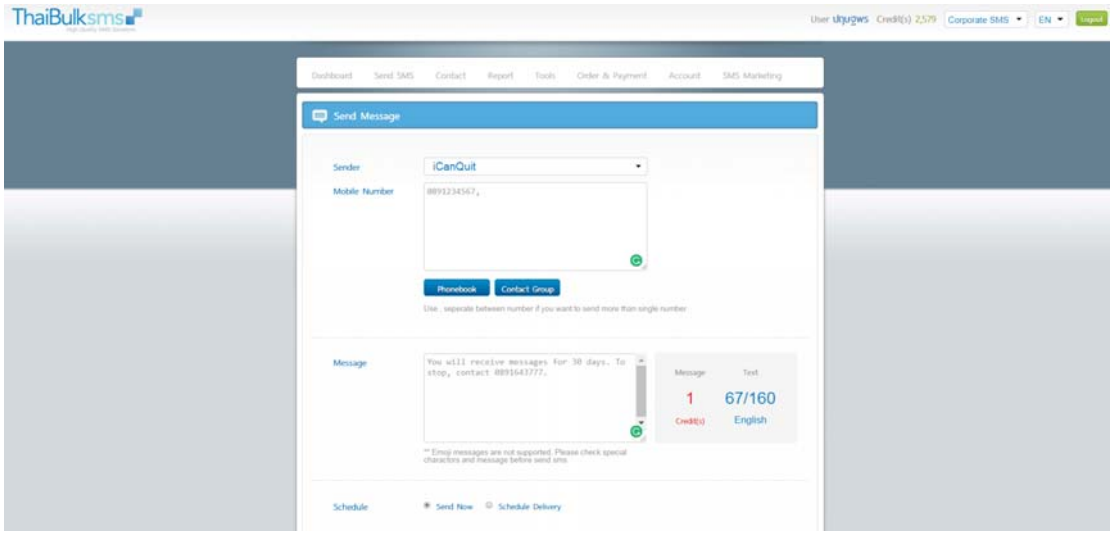


Figure 5.1 ThaiBulkSMS user interface for sending text messages

A programme was developed to provide automated text messages through ThaiBulkSMS while withholding group allocation and minimising human error caused by providing the intervention manually. The system architecture of providing text messages to smokers is illustrated in **Figure 5.2**. Text messages are sent via ThaiBulkSMS - which serves as a gateway provider that links to Thai mobile operators. The mobile operators then send text messages to mobile users. Information about the delivery status is then sent back to ThaiBulkSMS. The computer icons on the far left of the figure represent an additional online website that links to the ThaiBulkSMS website via API.

This programme needed to serve two functions: allowing for block randomisation and blinding of the treatment group allocation. **Figure 5.3** shows the programming flow. Required input information included name of the participant, phone number, date of information submission, age, and intention-to-quit. Based on the age and intention-to-quit groups (block group), the programme selected intervention groups from the random list. Scheduled text messages were then sent to ThaiBulkSMS via API. To send SMS via the ThaiBulkSMS website, input information included a phone number, all intended text messages (63 texts per number), a sender name (iCanQuit), and scheduled date and time

for each text. An external programmer was hired to write this programme. The programme is available online via website http://stopsmokephd.esy.es/. This programme took one month to develop, with an additional 2 weeks of piloting to ensure the correct sequences were generated by the programme. **Appendix L** shows the details of the programme in non-technical language.

An independent researcher, who was not involved in the allocation of interventions or the assessment of outcomes, produced the random allocation sequence list. The randomisation list was directly transferred to the programmer who developed a web-based programme. PK initiated the intervention by submitting participant's information including name, mobile number, age, intention-to-quit and the submission date to the web-based programme. The programme then automatically submitted scheduled text messages to the SMS gateway provider, ThaiBulkSMS. Participants were randomly assigned to receive one of eight set of text messages in an equal allocation ratio via the web-based programme. Group allocation for each participant was concealed from PK.

5.4.6 Blinding of randomised interventions

Blinding of participants or outcome assessors from the randomised intervention reduces biases in reported outcomes (172). Trial participants, interviewers (the outcome assessors), and PK were blinded to treatment allocation. Trial participants were blinded from group allocations by withholding information regarding the different sets of text messages being studied, or the rationale for these. Measures to ensure that the interviewers and PK were blinded to treatment allocation consisted of the following: 1) group allocation was generated by a research assistant who was not involved in the outcome assessment at 1-month follow-up; 2) allocation of treatment groups was kept in a separate file, and was not shared with PK or the interviewers; and 3) statistical analyses were conducted by PK, who was blinded to the allocation group until the data (primary outcome) were collected and cleaned.

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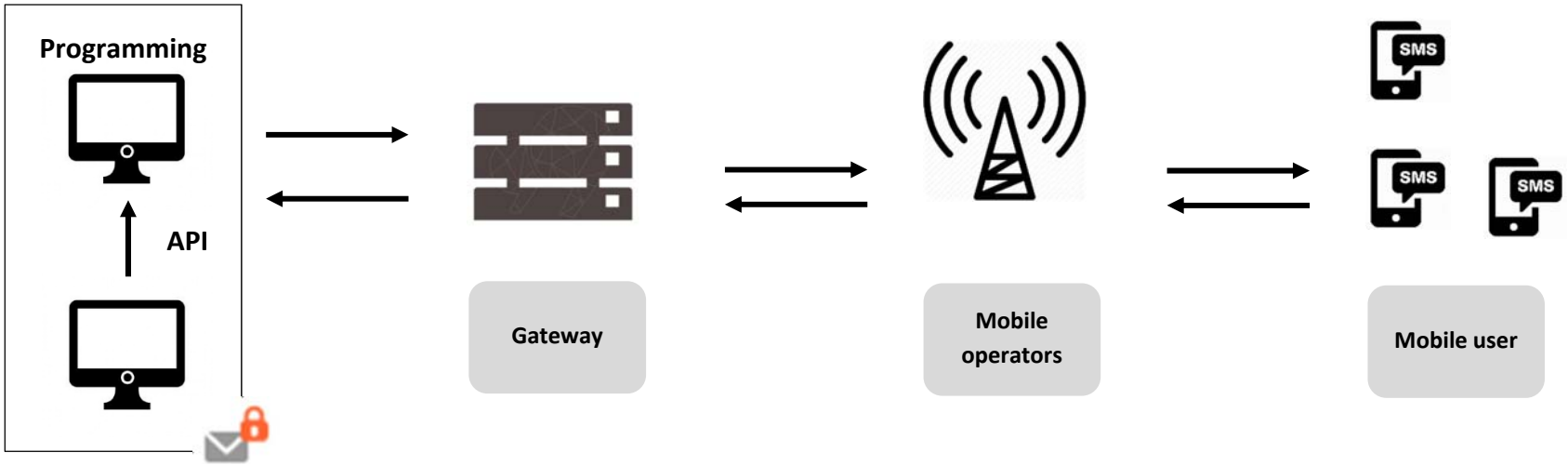


Figure 5.2 System architecture of providing text messages to smokers

Input information
1. Phone number (identifier)
2. Date of information submission
3. Age
4. Intention to quit
5. Name

Select random list
Input: Age and intention to quit
Output: Block group e.g. listage1int1, listage2int1, etc.

Automated function
Set of text messages (60+3 texts) based on intervention group within block group

Output/ Input for ThaiBulkSMS
1. Phone number
2. Set of text messages
3. Sender name (iCanQuit)
4. Scheduled date and time

Figure 5.3 Programming flow

5.4.7 Definition of the primary outcome

The primary outcome in this study was self-reported 7-day point prevalence abstinence at 1-month follow-up. Point prevalence abstinence measures whether a smoker has stopped smoking at the point of follow-up (173), i.e. not a puff for the past 7 days on the follow-up date.

Since participants in this study did not need to have a designated quit date prior to the trial entry, prolonged prevalence abstinence—where a smoker has stopped smoking for the whole period at a given point of follow-up—was not a logical outcome for this study. Hughes *et al.* (2010) conducted a systematic review to investigate whether there was a difference in reporting point prevalence or prolonged prevalence. They found that point prevalence and prolonged prevalence were closely related and, in fact, interchangeable; the effect size was similar between the two measurements when an odds ratio was used to measure the effect size, better than when the percentage change in abstinence between intervention and control groups was used (174).

5.4.8 Sample size calculation

A sample size was calculated to determine the number of participants needed for detecting the main effects of the three behavioural change components in text messages on self-reported 7-day point prevalence abstinence at 1-month follow-up. There were three main effects of smoking cessation from providing text messages to support smoker's capability to quit, opportunity to quit, and motivation to quit. The meta-regression analysis (see **Chapter 3**) was conducted to determine the association of increasing effect size of mHealth interventions containing BCTs mapped into the 'Capability', 'Opportunity', and 'Motivation' groups (odds ratio = 1.30, 95% CI: 1.05 to 1.59). The meta-analysis of mHealth interventions for tobacco cessation showed that the odds ratio was 1.41 (95% CI: 1.19 to 1.67) at 1-month follow-up. The effect size of 1.5 was used as the sample size calculation for a more conservative approach.

The study was designed to have 80% power (Z_β) to detect a difference in the main effects using a two-sided test to compare two sample proportions. For a two-sided test, the level of statistical significance (α) was set at 0.05. The sample size calculation to detect a difference between two proportions is given by: (175)

$$n = \frac{[p_1(1-p_1)+p_2(1-p_2)]\left(z_{1-\propto/2}+z_\beta\right)^2}{(p_1-p_2)^2}$$

where p_1 was the baseline probability of a successful outcome for the control group and p_2 was the probability of a successful outcome for the experimental group.

An odds is the probability that the event will occur divided by the probability that the event will not occur. Since it was expected that 16% of smokers in Thailand had attempted to quit smoking without any assistance (p_1 = 0.16) (Thai National Statistics) and given that the odds ratio was 1.5, the probability of smoking cessation in the experimental group was expected to be 22% (p_2 = 0.22).

The sample size was estimated to be 626 people for the experimental group and 626 for the control group to detect a 6% difference in the main effects (corresponding to an odds ratio of 1.5). For example, from **Table 5.1**, text message groups 2, 5, 6, and 8 were the experimental group containing 'Capability' texts, and text message groups 1, 3, 4, and 7 were the control group (did not contain 'Capability' texts).

A retention rate of Thai participants from the International Tobacco Control Southeast Asia Survey was 77.9% (170); therefore, it was expected that around 75% of the participants would complete the trial. The target sample size should therefore be increased to 1,670 people to provide 1,252 evaluable participants, accounting for this 78% rate of loss-to-follow-up. For this factorial design, the same sample size was applied and divided equally for each intervention (149, 176). For the eight experimental conditions, the sample size for each group was thus 208.

The sample size calculation used in this study only considered the main effect of each component, and hence did not take interaction into account, even though it is recommended that the size of interaction should be assessed (160, 165, 177). From the systematic review (**Chapter 3**), this study was the first to test the main effects of behaviour change components in text messages. Thus, it was unknown whether there would be an interaction between treatment arms, so an assumption was made that there would be no interaction, i.e. the treatment effect of providing 'Capability' texts does not depend on whether participants received messages from other groups. For a trial to detect any interaction, a larger sample size is usually required. Montgomery (2003) suggested that for the same magnitude of effects between the main effects and any interaction, the total

sample size would need to be increased 4-fold (149). Since the total sample size calculation for this study would subsequently need to be 6,680, which was not feasible.

5.5 Data collection

5.5.1 Questionnaire development

Numerous factors perceived as external to the intervention can impede or strengthen the effects of a complex intervention (164). The logic model is a systematic method for identifying how a programme might work and what factors could potentially be attributed to an effective programme (178). The model was adopted in an evaluation of text messages and was recommended for use to understand the intervention pathways (179). The model was used to systematically illustrate the causal assumptions underlining the expected outcome of the text message programme and to provide a framework for questionnaire development (**Figure 5.4**). This was used to provide a deeper understanding of the role of other factors that may impact the outcome. Hence, it was used not only to measure smoking status as an outcome but also to explain possible variations in outcomes through the evaluation of implementation, mechanism of change, and context.

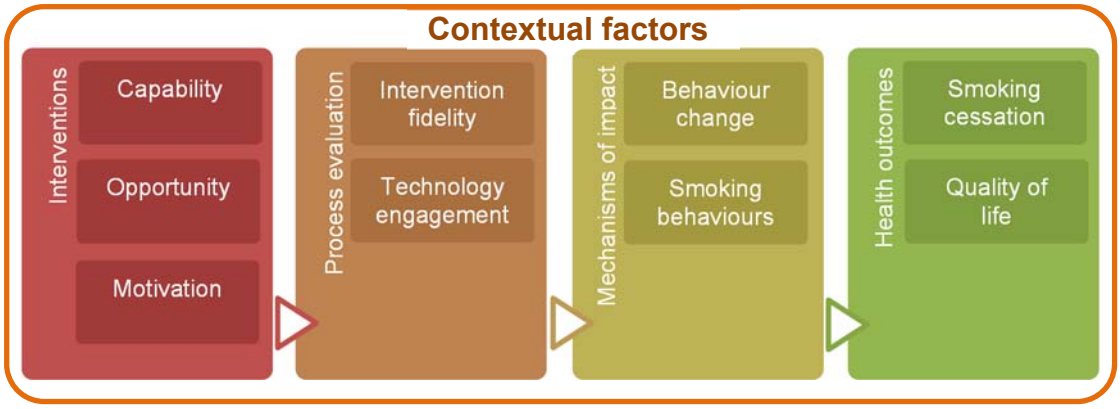


Figure 5.4 Logic model for the evaluation of the text messaging intervention

5.5.1.1 Screening measures

For participants screened via the TNQ, their name, contact details, TNQ identification number, quit date, and status of smoking were obtained from the TNQ after permission was granted. For participants registering online, no information about participants' name or quit dates were collected.

5.5.1.2 Baseline measures

1) Baseline characteristics

A systematic review conducted by Vangeli *et al.* (180) identified predictors of quit attempts and quit attempt success. The following variables were shown to be statistically significant predictors of quit attempts and quit attempt success in at least one of the eight eligible studies in that review: gender, age, education, income, home smoking ban, and smoking behaviours (cigarette dependence, number of cigarettes per day, age when started smoking, past attempts to quit, duration of quitting smoking in the past, wish to quit, motivation to quit score, intention-to-quit, and confidence of success in quitting).

Additional variables that were included in other smoking cessation intervention studies were also included in the baseline data collection such as employment status, any medical illness, family medical history (of smoke-related illnesses), duration of smoking, and smoker's smoking network (180). To understand the context of smokers and the characteristics of those who stopped smoking, these variables were included in the questionnaires as observed variables.

2) Mobile phone usage

To understand the baseline use of mobile phone technology, the following variables were also included in the questionnaire: type of mobile phone, attachment to their mobile phones (for example, whether they carry their mobile phone at all times), frequency of using text messaging, frequency of using instant messages, frequency of using mobile applications for health-related communication and non-health related communication, and time spent on mobile phones.

5.5.1.3 Process evaluation

Process evaluation means an evaluation of programme implementation to assess intervention fidelity and quality of implementation. Process evaluation can help understand why a trial fails and also provide policymakers and practitioners with knowledge of how the intervention can be replicated and for implementing complex interventions (164). Components to measure process evaluation in the literature vary across the type of interventions used and the stage at which the process evaluation was conducted (164). To provide greater confidence in the trial conclusion in terms of effective programme

implementation, a quantitative process evaluation was conducted by measuring intervention fidelity and participant engagement with technology.

1) Measuring intervention fidelity

Intervention fidelity involves reach, dose delivered, received dose effectiveness, recruitment, and context (181). With advances in technology, intervention fidelity can now be measured objectively. The ThaiBulkSMS service provider provided a delivery status report for each text message that was scheduled to be sent. The number of texts received was measured at the end of the trial when PK became unblinded to the group allocation. In total, it was expected that a complete intervention fidelity status would be 60 text messages per participant. Thus, a binary variable was created for status indicating whether 60 text messages had been received by the participant.

Even though the participant might receive all the text messages, they might not open or even read them. Unlike instant messages services, the status of whether a person actually opens or reads the text is not available for SMS. The self-reported questionnaire at 1-month follow-up asked whether participants had received all the text messages and whether they had opened and read them. The question provides an overall status on whether the participant received, opened, and read the text messages. The intervention was designed in this manner as measuring all 60 text messages was not possible on this platform; moreover, there would be a burden to research participants if they had to answer a questionnaire every day, and this burden may increase the loss to follow-up rate.

2) Technology engagement

Technology engagement, a more specific component of digital health intervention, is one of the key areas in the evaluation of mHealth interventions (182). It plays a vital role in the success of this programme as it is possible that a less engaging SMS message schedule can impede the effectiveness of behaviour change interventions. However, a taxonomy and model for effective engagement—a sufficient level of intervention engagement to achieve positive outcomes (183)—is still under development.

Technology engagement was measured from the self-reported questionnaire at 1-month follow-up using the three main components of technology engagement: likes, shares, and subscribes. Whether one likes the programme or not is relatively subjective. Respondents often endorse a statement rather than disagree with it (57) and it was expected that the direction of question wording would vary. Therefore, a set of statements about the

programme was created comprising three questions with negative statements and three questions with positive statements about the programme. Second, propensity to share information was measured by asking participants whether they had shared text messages with other people. Third, the question about re-engagement with mHealth was measured by asking about their likelihood to subscribe to similar programmes in the future.

5.5.1.4 Mechanisms of impact

Mechanisms of impact—to address the question of whether the delivered intervention has produced any change (164)—were observed through intended behaviour change and smoking behaviours to support smoking cessation as proximal outcomes.

1) Intended behaviour change

There is no existing questionnaire developed to measure 'Capability', 'Opportunity', and 'Motivation' of the COM-B system as this is still in an emerging area. Thus, a questionnaire was developed to measure the COM-B domains related to smoking behaviour. It reflected each function of the COM-B component, hence a total of 6 questions were identified. Each item was rated on a scale of 1 to 10, with 10 being strongly agree and 1 being strongly disagree. **Table 5.2** shows the questions that were used to evaluate intended behaviour change.

Table 5.2 Statements to measure intended behaviour change for smoking cessation

COM-B domain	Function of the components	The statement
Capability	Knowledge	I know that smoking can harm myself and others around me.
	Skill and ability	I have enough knowledge and required skills to be able to quit smoking such as how to deal with cravings.
Opportunity	Environmental context	I know that many things have been done in our society to stop people from smoking such as banning smoking in public places, sales restrictions, stop smoking campaigns, etc.
	Social support	I have received enough support (from my family, friends, and the government) to quit smoking.
Motivation	Evaluation of desire behaviour	My life will be better off if I quit smoking.
	Desire and impulse	It is important to me that I should quit smoking now.

Intention-to-quit smoking has been found to be associated with smoking cessation (e.g. among Chinese people (184), and among Thai and Malaysian people (170)) (180). An intention-to-quit scale is preferable over the 'stage of change' due to theoretical and methodological problems with the concept of 'stage of change' (185). An increase of one point on the 1-10 intention score increased the odds of being abstinent at follow-up by 20%. Moreover, the TNQ already collects intention-to-quit smoking on a scale of 1 to 10 at the point of care (40).

Self-efficacy—one's beliefs in one's own ability to execute something (186, 187)—has been widely used to explain behaviour. High self-efficacy towards a behaviour is associated with a tendency to change that behaviour. A recent meta-analysis showed that higher self-efficacy is associated with future smoking cessation, though the association is minimal (188, 189). Moreover, self-efficacy was associated with higher abstinence rates in Thai smokers (171). A Smoking Abstinence Self-efficacy Questionnaire has been shown to have discriminant validity and is feasible for use in clinical settings (190). This questionnaire contains six items regarding smoking situations where respondents assess their confidence in the ability to remain abstinent. The questionnaires were translated into Thai by two bilingual translators (initial translation by PK and rechecked by Thanut Tritasavit).

2) Smoking behaviours

A number of smoking behaviours have been shown to be statistically significant predictors of quit attempt and smoking cessation (180), namely: cigarette dependence, number of cigarettes smoked per day, age at smoking initiated, number of past attempts to quit, duration of quitting smoking in the past, wish to quit, motivation to quit score, intention-to-quit, and confidence of success in quitting.

Nicotine dependency has also been shown to be associated with smoking cessation rates. There are a number of questionnaires to assess nicotine dependence among smokers (191). The Thai clinical guidelines (43) recommend that the Fagerström Test for Nicotine Dependence (FTND) (192) should be used in clinical settings. The FTND, a validated questionnaire available in Thai (43), was used as a tool to assess dependence on nicotine.

3) Alcohol drinking behaviour

Alcohol drinking behaviour is known to be associated with smoking behaviour in Thailand; a positive association was found between alcohol and tobacco consumption (47, 193). The Alcohol Use Disorders Identification Test (AUDIT), a validated 10-item questionnaire

developed by the WHO, measures alcohol consumption, drinking behaviour, and alcohol-related problems (194). The AUDIT score ranges from 0 to 40, with higher scores representing a higher dependence on alcohol. A score of 8 or above indicates harmful or hazardous alcohol use. This questionnaire has been validated and translated into Thai (195).

5.5.1.5 Health outcome measures

1) Primary outcome

The primary outcome for this study was self-reported 7-day point prevalence smoking abstinence at 1-month follow-up based on the question: "How many cigarettes did you smoke in the past 7 days?". Three choices: 0, 1-5, and more than 5 were used in the questionnaire because the Russell Standard accommodates studies that assess smoking outcomes at follow-up times longer than 1 month (159). To determine a positive outcome, a response of zero cigarettes indicated smoking abstinence.

2) Quality of life

Health-related quality of life examines the impact of current health status on quality of life. It has been used as a health outcome when conducting an evaluation of health care interventions in Thailand as recommended by the Thai National Health Technology Assessment guidelines (196). For the future economic evaluation of text messages to support smoking cessation in Thailand, the EQ-5D—a standardised measurement of generic health-related quality of life that provides a single index value for health status—was used (197). Health-related quality of life states consist of 5 dimensions including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D-5L, a recently developed EQ-5D (current name EQ-5D-3L), consists of 5 levels of severity for each domain (instead of 3 levels in the previous version). Index values attached to the EQ-5D health states are based on a Thai population value study (198). Registration for the use of EQ-5D-5L questionnaires was required prior to conducting this trial (Registration ID: 14129).

5.5.2 Pilot test and revision

The objective of the pilot test was to assess the understanding of questions in the questionnaire. The time taken to complete each questionnaire was also recorded. A full set of questionnaires in Thai were read by two academic staff (Songyot Pilasant, a researcher

who was not involved in the trial, and Sarayuth Khuntha, a research assistant of this trial) and one administrative staff member (non-academic staff) at the Health Intervention and Technology Assessment Program (HITAP). Their comments were used to modify the wording of the questionnaire. Some questions that were perceived to contain academic language were modified into lay terms. The final version of the questionnaires (English version) that was used can be found in **Appendix Q**.

5.5.3 Assessment instrument

Data collection tools included a baseline questionnaire and a 1-month follow-up questionnaire. These questionnaires were designed to be self-administered either via the post or online. Online questionnaires were created using secure Bristol Online Survey (BOS) accounts through subscriptions at the University of Leeds. The baseline questionnaire is available at https://leeds.onlinesurveys.ac.uk/icanquitbaseline and the 1-month follow-up questionnaire is available at https://leeds.onlinesurveys.ac.uk/icanquit-1-mo.

The order of questions in the online and interview formats were standardised and prioritised the primary outcomes and other smoking behaviours. It then followed with baseline characteristics of the participant to serve as a break between sets of questions. Subsequently, questions on mobile usage, drinking behaviour, and quality of life were asked as it is perceived as less relevant to the participants. For the baseline questionnaire, the layout consisted of: 1) smoking behaviour; 2) baseline characteristics; 3) mobile phone usage; 4) drinking behaviour; and 5) quality of life. For the follow-up questionnaire, the layout consisted of: 1) smoking behaviour; 2) process outcomes; 3) drinking behaviour; and 4) quality of life.

For the limited time available for this PhD, pre-coded closed questions were perceived as the most feasible option for collecting over 3,000 observations (baseline and follow-up questionnaires). The data collected for this study and its timing is shown in **Table 5.3**. The answers were recorded electronically when a participant answered the online questionnaire. Data from the BOS were then exported into a Microsoft Excel file with coded responses, which was then imported into the statistical analysis software. All survey data and backups are stored on servers located at the University of Bristol, United Kingdom.

Table 5.3 Data collection and timing of assessment

Assessment	Timeline		
	Screening	**Baseline**	**1-month**
Thailand National Quitline routine data collection			
TNQ identification number	x		
Ownership of mobile phone	x		
Name	x		
Contact details: Phone number (and email address/mailing address)	x		
Questionnaire			
Baseline characteristics:			
Age		x	
Gender		x	
Marital status		x	
Religion		x	
Parental status		x	
Employment		x	
Education		x	
Co-morbidities		x	
Family medical history (smoke-related illnesses)		x	
Socio-economic status		x	
Household income		x	
Smokers among friends and family		x	
Mobile phone usage:			
Type of mobile phone owned		x	
Carry mobile phone at all times		x	
Frequency of text message usage		x	
Frequency of instant messaging services usage		x	
Frequency of using mobile apps for health-related communication and non-health related communication		x	
Time spent on mobile phone		x	
Smoking behaviour:			
Smoking status		x	x
Daily/ occasional smoking status		x	x
Number of tobacco products used per day		x	x
Age started smoking		x	
Duration of smoking		x	
Fagerstrom Test for Nicotine Dependence		x	x
History of quitting smoking in the past		x	x
Methods used to assist smoking cessation		x	x
Behaviour change:			
Behaviour to support smoking cessation		x	x
Willingness to quit in the next month		x	x
Intention to quit (185)		x	x
Smoking cessation self-efficacy (199)		x	x
Process evaluation:			
1) Intervention fidelity			

Assessment	Timeline		
	Screening	Baseline	1-month
Text received status			x
Open and read text status			x
2) Technology engagement			
Text messages received status			x
Text messages open and read status			x
Shared text messages status			x
User engagement scale			x
Drinking behaviour: AUDIT scores		x	x
Quality of life: EQ-5D-5L		x	x

5.6 Trial period

Participants were recruited from 16 January 2017 to 14 January 2018. All participants were contacted for 1-month follow-up, completed on 20 February 2018. The original plan was to recruit participants from December 2016 until June 2017. However, due to the modification of the trial, ethical amendments had to be sought prior to data collection, adding an extra month. The original plan was to utilise 6 months for recruiting; however, this trial suffered from recruitment issues (see issues and strategies to manage in **Chapter 6**).

5.7 Adherence to the protocol

5.7.1 Research visit window definitions

All follow-up data from the questionnaire were planned to be collected within one week of the expected date wherever possible. However, an additional period of one week was allowed when participants preferred to answer via telephone interviews or the post to allow time for additional administration.

5.7.2 Departure from randomised intervention policy

A programme via http://stopsmokephd.esy.es/ was linked with the ThaiBulkSMS website to ensure stratified random allocation. The programme was tested to ensure the correct sequences of text messages were inserted into the ThaiBulkSMS website. An audit of the stratification random allocation was performed two weeks after the first participant was

allocated to the intervention group (prior to the online questionnaire for 1-month follow-up) to ensure the correct intended allocation.

5.7.3 Departure from intended intervention

Participants were expected to receive 60 text messages. However, they may not have received all intended text messages due to, for example, mobile network failure. The delivery status of text messages was retrieved from a report from the SMS gateway provider's website (ThaiBulkSMS) at the end of 1-month follow-up.

5.7.4 Withdrawal and loss to follow-up

5.7.4.1 Withdrawal from intervention and follow-up

Participant withdrawal from receiving the intervention occurred when a participant contacted the TNQ or PK and requested to stop receiving text messages. The number of withdrawals from the intervention was reported. When a participant requested to withdraw from the intervention, the participant was invited to complete the follow-up questionnaire. If they declined, the number of withdrawals from the follow-up was reported.

5.7.4.2 Loss to follow-up

Any failure of attempts to obtain follow-up data, following a maximum of three phone call reminders to complete the questionnaire, was recorded. The number of losses to follow-up was reported.

5.8 Statistical analysis plan

5.8.1 Statistical considerations

5.8.1.1 Blinding of the statistical analysis

The statistical analysis plan was written and finalised before unblinding to the treatment group. Data were cleaned prior to linking treatment allocations to participants. PK created a dummy dataset for treatment allocation only and a Stata command file for statistical analysis prior to unblinding to the treatment group. This was to ensure blinding throughout the data cleaning process as descriptive analyses can be conducted unblinded, then matched

to intervention allocation. In the case where the blinding of PK was no longer feasible, it was planned to be reported.

5.8.1.2 Software

All data collected from the online questionnaire were entered and checked using Microsoft Excel. Once all datasets were locked, they were transferred to the statistical analysis software. All analyses were undertaken using Stata/IC software (Release 14; StataCorp, 2015) (87).

5.8.1.3 Populations to be examined

- **Screening sample:** All participants who were screened to be included in the trial. This information was reported on the CONSORT diagram.
- **Intention-to-treat sample:** The intention-to-treat (ITT) sample is defined as all participants who were randomised into the trial, regardless of the follow-up data available and the groups to which they were randomised.
- **Per-protocol sample:** Per-protocol sample is defined as all participants who were randomised into the trial and received 60 intended text messages, with all follow-up data available.

5.8.1.4 Timing of analysis

All analyses were conducted at the end of the 1-month follow-up period.

5.8.1.5 Stratification in the analysis

Stratification factors—age group (18-30, 31-40, and above 40 years) and intention-to-quit (1-5 and 6-10)—were included in the model for all analyses regardless of their prognostic value. Stratification factors were considered as design factors. An adjusted analysis will give valid inference because for an unadjusted analysis without stratification factors, the standard errors for the treatment effect are subject to bias, resulting in wide confidence intervals, low type I error rates, and a reduction in power (169).

5.8.1.6 Method for handling dropouts and missing data

There are three mechanisms governing the missingness of data: 1) missing completely at random (MCAR); 2) missing at random (MAR); and 3) missing not at random (MNAR)

(200). Missing completely at random means the probability of missing data on an outcome (for example, smoking status at follow-up time point) is unrelated to the true value of the outcome or to other observed variables. Missing at random means the missingness of observations depends only on observed quantities; in other words the missingness can be predicted with reasonable accuracy based on other observed variables. The probability of missing data on an outcome is unrelated to the true value when adjusting for predictors of missingness. Missing not at random means the missingness of observations depends only on unobserved variables.

Missing data should be managed systematically to minimise bias, maximise the use of information available, and manage uncertainty from the missing data. The management method depends on the missing data pattern and type of missing variables. The simplest method to deal with missing data is to exclude observations with missing variables or a complete case analysis. For data missing completely at random, there would be no bias using the complete case analysis. The only disadvantage is that the precision of estimates will be reduced due to a decrease in sample size. However, missing completely at random is not a valid assumption in the addiction field (201-203). Missing data on smoking status from smoking cessation trials is sometimes managed by assuming that the participant is now smoking, so one popular approach to deal with missing data is to assume that all missing participants are still smokers (159). This method will not provide valid standard errors, confidence interval or p-values (204).

Therefore, data is assumed to be missing at random in this study. Tests of predictors of the missingness of smoking status at 1-month follow-up will be conducted using a t-test for continuous variables or chi-square test for categorical variables. In the case where a missing pattern is arbitrary and many types of data are missing, multiple imputations by chained equations (MICE) was used to impute missing variables (205). Multiple imputations for missing data were conducted by generating the imputed datasets from variables in the main analysis such as treatment group, stratification factors, and the predictors of missingness of smoking status that report statistically significant results at p=0.1 (with a priority to include 0.05 first) (206). Multiple values were imputed rather than a single value to reflect uncertainty. For missing item data and missing scale data in outcomes derived from a scale such as the AUDIT, EQ-5D-5L, or FTND, multiple imputation methods for item-level missing data were used (207).

5.8.1.7 Analytical methods

All analyses were conducted using either a complete case analysis or a multiple imputations (MI). The complete case analysis used a complete data set, and thus reduced sample size and power. Missing data were imputed more than once (m=50 datasets) to reflect uncertainty about the missing values (205). The estimates from all datasets were pooled for each outcome according to Rubin's rule (208).

5.8.2 Descriptive analysis of participant characteristics

A CONSORT diagram (161-163) was used to report the flow of participants in each stage including enrolment, allocation, follow-up, and analysis. Baseline information was summarised by the total number of participants and by the experimental conditions (8 groups). All continuous variables were reported using means and standard deviations; for data that were not normally distributed, medians and inter-quartile ranges were used instead. The Shapiro-Wilk W test, appropriate for samples between 4 and 2000 (209), was used to test for the normality of continuous variables. For binary variables and categorical variables, frequencies and percentages were presented. The number of missing data items at baseline are reported in the baseline characteristic table (**Chapter 7, Table 7.2**). However, it should be noted that the presentation of descriptive statistics should be compared between the presence and absence of each intervention component ('Capability', 'Opportunity', and 'Motivation'). For example, 'Capability' contained experimental conditions C, CO, CM, and COM, whereas the control for 'Capability' contained experimental conditions placebo, O, M, and OM. Regardless, the presentation of the 8 experimental conditions would provide more information and hence more transparency.

When participant randomisation and blinding has been fully achieved, the use of significance tests for detecting baseline differences between treatment groups is inappropriate, philosophically unsound, and potentially misleading (210-212). Statistical testing for baseline differences to determine whether randomisation was successful or whether baseline differences should be taken into account is a misconception that still exists (213), and the CONSORT statement recommends against significance testing of baseline difference in RCTs (162). Adjusting for baseline differences, rather than for all prognostic factors, should be performed.

5.8.3 Primary analysis of self-reported 7-day point prevalence abstinence at 1-month follow-up

Logistic regression was used to estimate self-reported 7-day point-prevalence abstinence at 1-month follow-up. The main model included all three main effects of each behaviour change component, interaction terms between behaviour change components, and stratification factors as follows:

$$\begin{aligned} logit(y_i) = \ & \beta_0 + \beta_1 C_i + \beta_2 O_i + \beta_3 M_i + \beta_4 C_i * O_i \\ & + \beta_5 C_i * M_i + \beta_6 O_i * M_i + \beta_7 C_i * O_i * M_i \\ & + \beta_8 Agegr_i + \beta_9 Intgr_i + e_i \end{aligned}$$

where logit is the logarithm of the odds, β_0 is the constant term in the model representing the baseline (log) odds; β_1, β_2, and β_3 are coefficients corresponding to the (log) odds of the main effects attributed to component C, O, and M, respectively; β_4, β_5, and β_6 are coefficients corresponding to the (log) odds of the 2-way interactions between C and O, C and M, and O and M, respectively; β_7 is the coefficient corresponding to the (log) odds of the 3-way interaction of components C, O, and M; β_8 and β_9 are coefficients corresponding to the (log) odds of age group and intention-to-quit group, respectively. Interaction terms were included to provide unbiased estimates if important interactions exist (214, 215).

5.8.4 Sensitivity analysis of self-reported 7-day point prevalence abstinence at 1-month follow-up

A sensitivity analysis of the primary outcome was conducted using a logistic regression model to estimate self-reported 7-day point-prevalence abstinence at 1-month follow-up under 4 scenarios. First, the main model was fit using the per-protocol sample (participants receiving the intended 60 text messages). Second, the main model was fit using the sample of participants who reported that they received text messages. Third, the main model was fit using the sample of participants who reported that they read the text messages. Fourth, the main model was then adjusted for factors that may affect the smoking cessation rate. These potential covariates included gender, marital status, parental status, medical illness, time spent using a mobile phone, whether the participant opened and read their text

messages, behaviour to support smoking cessation, baseline smoking cessation self-efficacy scores, baseline number of tobacco products used per day, baseline FTND scores, and baseline AUDIT scores.

5.8.5 Subgroup analysis of self-reported 7-day point prevalence abstinence at 1-month follow-up

For the subgroup analysis, a logistic regression was used to estimate self-reported 7-day point-prevalence abstinence at 1-month follow-up, irrespective of whether there was a significant treatment effect on the primary outcome. The model included all three main effects of each behaviour change component, interaction terms between behaviour change components, stratification factors, and pre-specified interaction terms between behaviour change components and the following subgroups:

- **Baseline intention-to-quit score:** 1-5 (low) versus 6-10 (high)
- **Age:** 18-30, 31-40, and above 40
- **Gender:** male versus female
- **Baseline FTND scores:** 0-2 (low dependence) versus 3-10 (high dependence) (191)
- **Baseline number of tobacco products used per day:** ≤5 (light smoker) versus >5 (heavy smoker) (216)
- **Baseline AUDIT scores:** <8 (non hazardous and harmful use of alcohol) versus ≥8 (hazardous and harmful use of alcohol) (194)

5.8.6 Secondary analysis

Other measured outcomes were analysed based on appropriate regression analyses depending on the distribution of data. For continuous data with censored values, a censored Poisson regression model was used. For count data, a negative binomial regression model was used. The main model included all three main effects, interaction terms between treatment groups, stratification factors, and the baseline value of that outcome.

5.9 The pragmatic nature of this trial

Clinical trials have traditionally been categorised as either pragmatic trials, where the effectiveness of an intervention is measured, or explanatory trials—where the efficacy of an intervention is measured (217). However, this is not a simple dichotomy and there can be some degree of overlap. The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) was developed as a tool to assess and display where the clinical trial lies on the pragmatic and explanatory spectrum (218). The second version of the PRECIS (PRECIS-2) is a validated version that includes 9 domains to determine the pragmatism of a trial using a 5-point Likert scale where 1 = very explanatory and 5 = very pragmatic (219, 220). A higher score therefore represents a more pragmatic trial.

This trial was designed to measure the effectiveness of each component of a set of text messages in the routine practice of the TNQ. This trial was designed to be more pragmatic with a score of 38. The PRECIS-2 wheel below shows that this trial had a more pragmatic nature (**Figure 5.5**). The rationales for each score is presented in **Table 5.4**

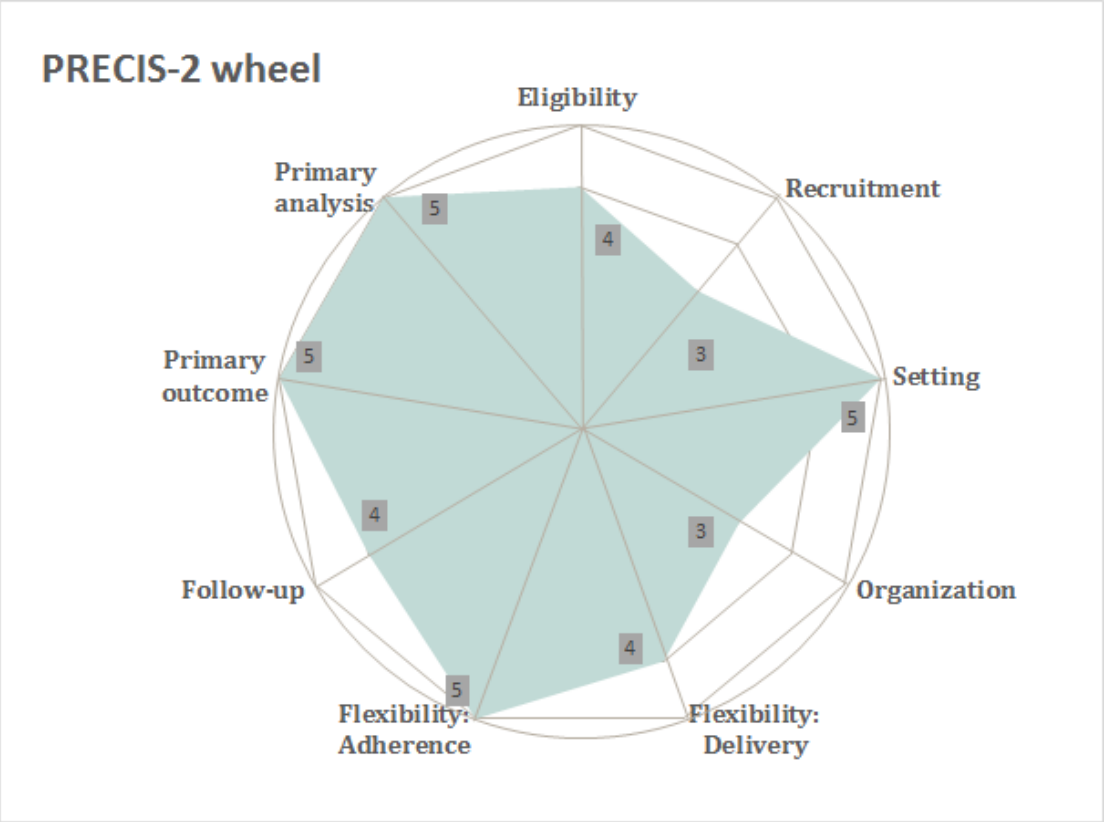


Figure 5.5 PRECIS-2 wheel scheme for this trial

Table 5.4 The PRECIS-2 scores and rationale for each domain for this trial.

Domain	Score	Rationale
Eligibility	4	The intervention is intended for smokers who want to quit smoking to help them quit smoking. Trial participants were similar to those under the usual care of the TNQ except that they needed to consent to participate in the trial. The intervention was limited to participants who owned a mobile phone with the ability to send and receive SMS. This is not limited to the nature of the future users of this intervention.
Recruitment	3	Recruitment was conducted through the TNQ and online channels. Extra effort was made through online advertisement.
Setting	5	The identical setting to usual care where smokers receive support for smoking cessation from the TNQ.
Organisation	3	The SMS messages to support smoking cessation to TNQ callers were planned to be sent. However, additional resources, in terms of financial resources and an IT system, are needed to deliver and randomise the intervention.
Flexibility: Delivery	4	The SMS to support smoking cessation for TNQ callers were planned to be sent 2 times a day. There was no restriction on any co-interventions for smoking cessation. However, the platform used to deliver the intervention is different from the one provided by the TNQ due to stratification purposes.
Flexibility: Adherence	5	There is no intervention to increase adherence to the intervention.
Follow-up	4	The follow-up takes place after receiving the intervention for 1 month. The number of follow-up calls is less than the usual monitoring provided by the TNQ (3 times in a month). However, more information is collected at 1-month follow-up for this trial.
Primary outcome	5	The primary outcome is smoking cessation status, an outcome of importance to both trial participants and to smokers worldwide.
Primary analysis	5	Analysis using intention-to-treat, with all available data

Chapter 6: Recruitment to a factorial randomised controlled trial: challenges and strategies to improve trial recruitment

6.1 Chapter overview

When the factorial randomised controlled trial (**Chapter 5**) was implemented, the actual recruitment rates were lower than the rates required to complete the study in the given time frame. Therefore, it was necessary to systematically identify the problems that held back recruitment and find methods to improve it. This chapter presents the challenges and strategies to improve participant recruitment for the study. This chapter outlines the initial recruitment plan and internal pilot phase. Then, the methods to overcome the recruitment challenges and results are presented and discussed.

6.2 Background

6.2.1 Recruitment challenges

Recruiting participants to trials can be extremely challenging and poor recruitment is a major threat to trial success (221). Resources are wasted in trials that fail to reach recruitment targets as they risk being unable to answer their objectives reliably. Of the 151 RCTs that were publicly funded by the UK National Institute for Health Research-Health Technology Assessment Programme between 2004 to 2016, only 56% of the studies achieved the final recruitment target sample size (222).

There is little evidence to guide trialists on decisions about effective methods to improve trial recruitment (223). Many systematic reviews that aimed to identify methods to improve recruitment to trials used quantitative data analysis (224-228). The emerging evidence-base on strategies to support recruitment is of variable quality (227). Strategies that were evaluated using a high-quality study design and associated with an increase in recruitment rates are telephone/SMS reminder, opt-out consenting procedures, and open trial design

(225). The updated systematic review study by the same author in 2017 reported similar recommendations (226). Bower and colleagues surveyed recruitment and retention strategies that trialists in the UK implemented and suggested that interventions to improve recruitment and retention can be grouped into eight categories (229):

1) **Patient contact:** any interventions that promote the research information to participants including an appropriate design of information to participant, research advertisement, and reminders;
2) **Patient convenience:** any interventions that aim to ease the process of trial participation such as a flexible appointment or reducing any research burden by shortening unnecessary tasks;
3) **Support for recruiters:** any interventions that support recruitment staff such as training or 'Question and Answer' sessions;
4) **Monitoring and systems:** any interventions to reduce the current workload of recruitment;
5) **Incentives:** any interventions that provide direct or indirect benefits to participants or recruitment staff;
6) **Design:** any issues involving the design of research such as altering research design, widening the eligibility criteria, and piloting research;
7) **Resources:** any additional resources such as networks; and
8) **Human factors:** the relationship between the research team and recruitment team such as having regular contacts.

It is recommended that trialists should have a systematic way of identifying effective recruitment strategies (226). However, findings from these studies may not be transferable to complex trial designs or to where research context and cultures differ.

6.2.2 Initial participant recruitment plan

Trial participants were recruited from two sources: the Thailand National Quitline (TNQ) and online registration via completion of the baseline questionnaire (see **Figure 6.1**). The focal route for participant recruitment was through the TNQ. TNQ staff assessed smokers' eligibility and offered them the opportunity to be recruited into the trial. The original eligibility criteria were: "(1) Thai smokers who received a single brief counselling session for smoking cessation from the TNQ; (2) did not set a quit date within one month; (3)

owned a mobile phone with at least the ability to send and receive SMS text messages; and (4) be able to read and write Thai".

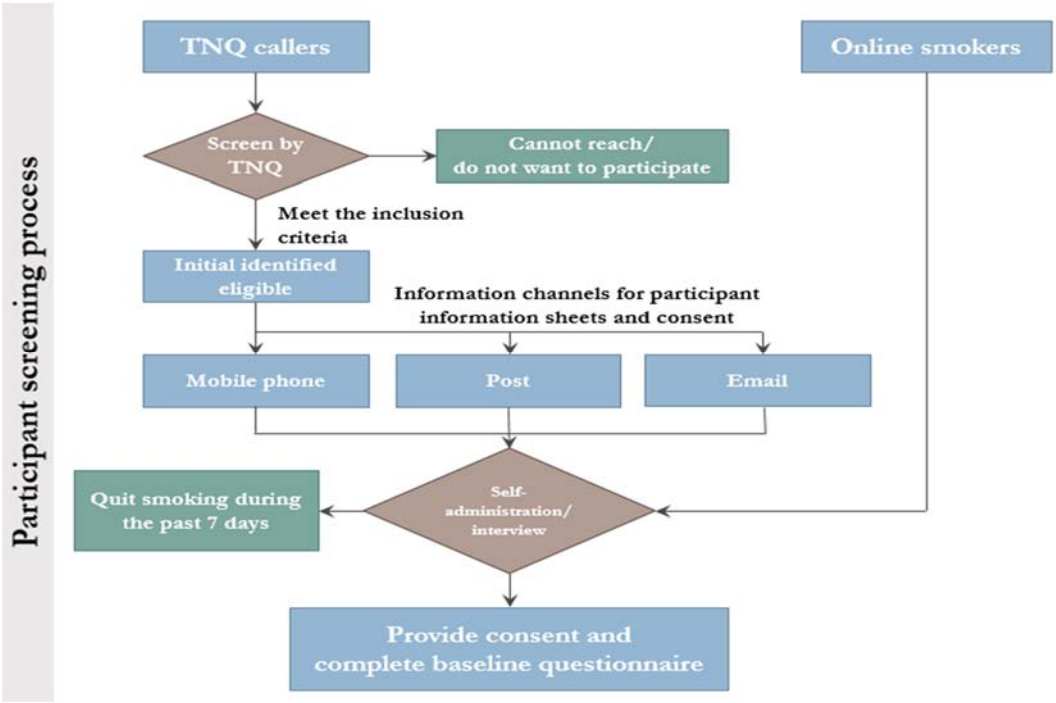


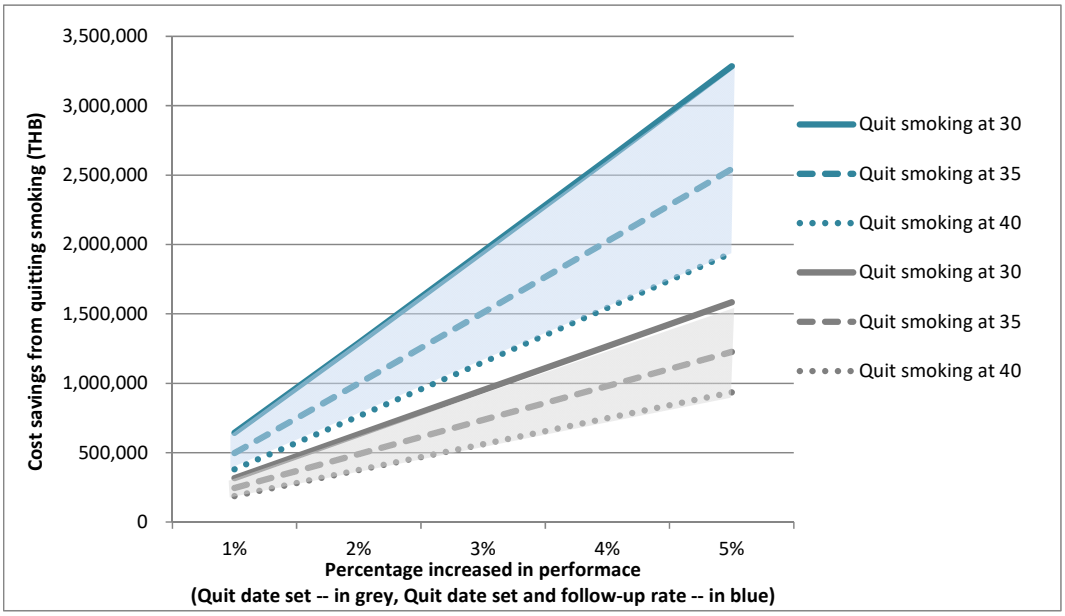
Figure 6.1 Initial participant recruitment flow

The rationale for the criteria on 'did not set a quit date within one month' was because when smokers refuse to set a quit date or receive a follow-up service, they will no longer receive support via follow-up services from the TNQ. An increase in smokers who set a quit date within one month by 5% has been estimated to generate a cost-savings of 1-1.5 million THB a year for the Thai society. Moreover, the cost-savings would be around 2-3 million THB based on a 5% increase in people allowing for a follow-up (**Figure 6.2**).

Once eligible smokers were identified, the TNQ staff briefly informed them about the trial. The list of eligible smokers who were interested in participating were sent by secure file transfer to the chief investigator, Pritaporn Kingkaew (PK), weekly. Depending on their preference for communication method (mobile phone, email or post), an information sheet and a consent form were sent to those smokers.

Online registration through completion of the baseline questionnaire was offered to smokers across Thailand as well. The availability of online registration was similar to the routine call back services provided by the TNQ where smokers provided their details and TNQ staff contacted them back. Since 53% of the Thai population have internet access (55), this route also allowed smokers who were more familiar with the online platform to

seek smoking cessation support from national public health campaigns to be recruited into the trial.



Source: Author

Figure 6.2 Estimated cost saving from quitting smoking when the performance of the Thailand National Quitline increases by 1-5%

6.2.3 Internal pilot phase for trial recruitment

6.2.3.1 Expected recruitment rate

Recruitment progression criteria were used to determine the trial progress; criteria were based on the expected number of smokers consenting to participate in the trial. From October 2015 to January 2016, an average of 1,800 smokers called the TNQ for smoking cessation support per month (see **Figure 6.3**). However, around 30% did not set a quit date within one month (the target population) (40). Therefore, it was expected that 530 smokers would be asked to participate in the trial each month or approximately 123 smokers per week. Of the 92,045 smokers that called the TNQ, 58,190 smokers had completed quit counselling (40); thus, it was assumed that two-thirds of the smokers agreed to participate. The sample size calculation identified 1,670 smokers needed to be recruited into this trial (more details about the method is given in **Chapter 5**). Therefore, the initial plan was to recruit 76 participants per week and completed within 22 weeks.

Source: Thailand National Quitline [Data received: 8 September 2016]

Figure 6.3 The number of callers reported from the Thailand National Quitline

6.2.3.2 Internal pilot results

This trial suffered recruitment problems similar to other related research studies based on a systematic review (222). It was initially observed during the internal pilot phase that the recruitment rate was significantly lower than what was expected. Only 34 smokers showed initial interest for participating in the trial through the TNQ, and there was no consenting participant via the online platform during the first week of recruitment. Only 10 participants were recruited during this period (accounting for 13% of the weekly target, 10/76). During the first month of recruitment, the rate per week continued to decrease compared to the weekly target (**Figure 6.4**). Using a linear extrapolation of an average of 6 participants recruited weekly, the expected number of participants recruited at the end of 22 weeks would have been only 10% of the target sample size.

No pre-agreement of "stop/amend/go" progression criteria—whether to stop the trial, amend the protocol or proceed the trial recruitment (230)—was agreed upon prior to the start of the trial. Research advertisement was the only plan to improve the recruitment rate as determined in the Research Ethic applications. The recruitment materials (see **Appendix R** for the "Recruitment material-v1") were planned to be advertised in public health online domains such as http://www.hitap.net if the recruitment rate was less than the expected

number per week. Therefore, to meet the recruitment target, it is essential to systematically identify the problems that hold back recruitment and the methods to improve it.

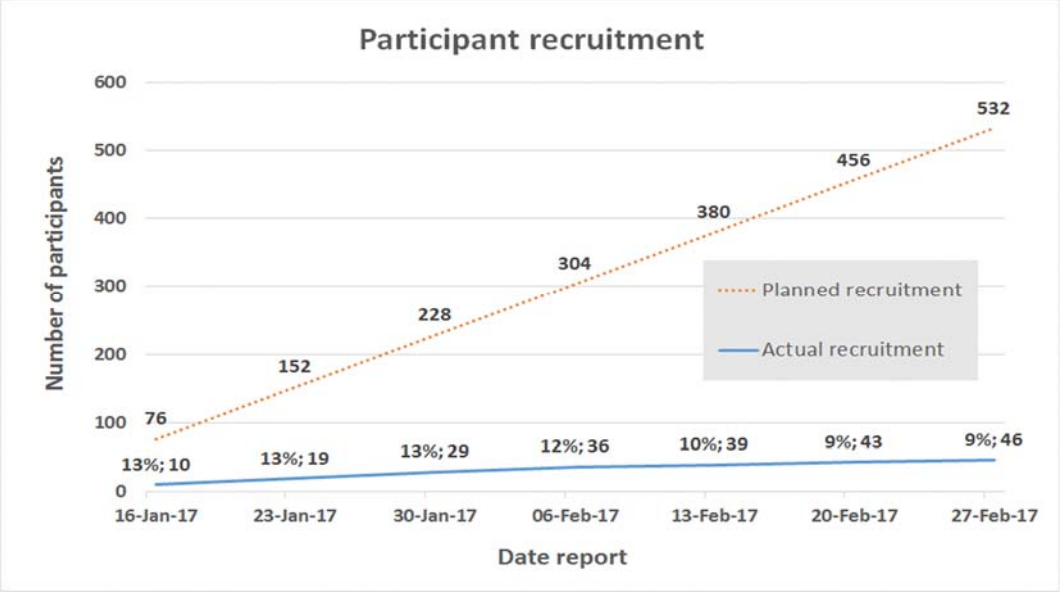


Figure 6.4 The number of participants recruited from the first two months

6.3 Aim and objectives

The aim was to improve the recruitment rate for the factorial RCT. The objectives were to: 1) deconstruct the problem of recruitment and explain any hidden issues why the recruitment rates were not as high as expected; 2) identify strategies to overcome poor recruitment; and 3) implement effective strategies to achieve the target sample size.

6.4 Methods

An analytical problem-solving process was used to characterise and solve the recruitment challenges. This method was used as it is intuitive and can be achieved within the limited time frame of a PhD. First, barriers to participant recruitment were systematically identified from a series of consultations with the TNQ staff and Health Intervention and Technology Assessment Programme (HITAP) communications team throughout the recruitment period. Second, a rapid literature review focusing on published systematic reviews and meta-analysis studies was conducted using Pubmed to identify evidence-based strategies to overcome these problems. Strategies to improve recruitment rate were identified and mapped into the eight categories suggested by Bower and colleagues (2014) (229). Third,

the strategies to improve recruitment rate were implemented in stages. Priority was given to the most feasible strategies for implementation that were supported by the literature. Recruitment strategies were evaluated against weekly recruitment rates. When the target recruitment did not meet expectations, strategies perceived to be more resource-intensive were implemented sequentially.

6.5 Results

6.5.1 Barriers to recruitment and evidence to support

6.5.1.1 Problems related to recruitment within routine service

The recruitment process of this trial was initially proposed to be embedded in the routine service of the TNQ. However, it was treated as an ad-hoc study due to a competing trial conducted by the TNQ. The TNQ conducted a study which had started recruitment from September 2016 to June 2017. This competing non-randomised study aimed to compare three different methods of providing services: usual counselling, counselling plus SMS, and SMS based on TNQ user preference. The objective was to look at the feasibility, smoking cessation rates, and user preferences of the three services. The inclusion criteria for the competing study included: 1) first-time TNQ callers or those who had called the TNQ for more than one year; 2) consent to be a part of the research; and 3) set a quit date (any dates but mostly not more than one month). The target sample size of the competing study was 650 smokers.

Only four out of seven TNQ call-takers were allocated for this trial, and no TNQ counsellors were involved. The recruitment for this trial was assigned to the call-taker as extra work in addition to their routine work; therefore, the call-taker only recruited smokers after their working hours. Since there was a competing trial occurring simultaneously, time allocation for the two projects was unknown.

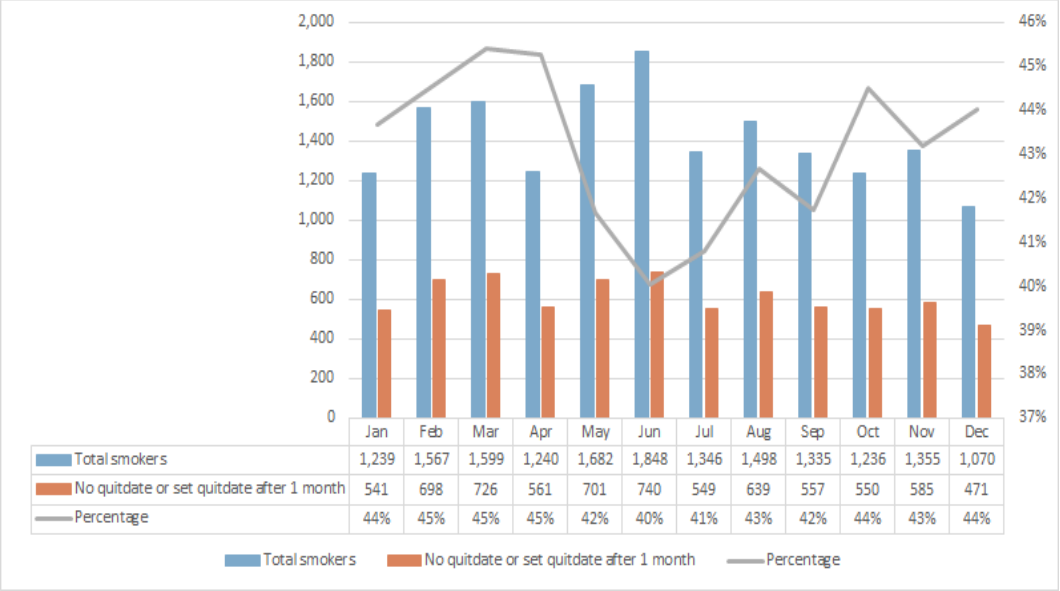
In addition, there was a gap of around 7 and up to 10 days between the initial invitation to the trial by the TNQ, and the consent process and data collection for baseline information by PK. Often, smokers expressing initial interest had already quit smoking or were no longer willing to participate in the study.

6.5.1.2 Fewer eligible participants

The number of smokers who met the initial eligibility criteria was decreasing each week. In addition, the number of smokers who called the TNQ was decreasing. The average rate of smokers who called the TNQ was 1,800 per month from October 2015 to January 2016 (**Source:** TNQ); however, this dropped by 21% to an average of 1,418 per month from January to December 2016 (see **Figure 6.5**).

The contextual change within the TNQ's practice also reduced the proportion of smokers who did not set a quit date. Due to the TNQ's competing study, TNQ staff had been pursuing all smokers to set a quit date. From the report in 2016, around 43% of the smokers did not set a quit date; this figure represents the proportion before the competing study began (**Figure 6.5**).

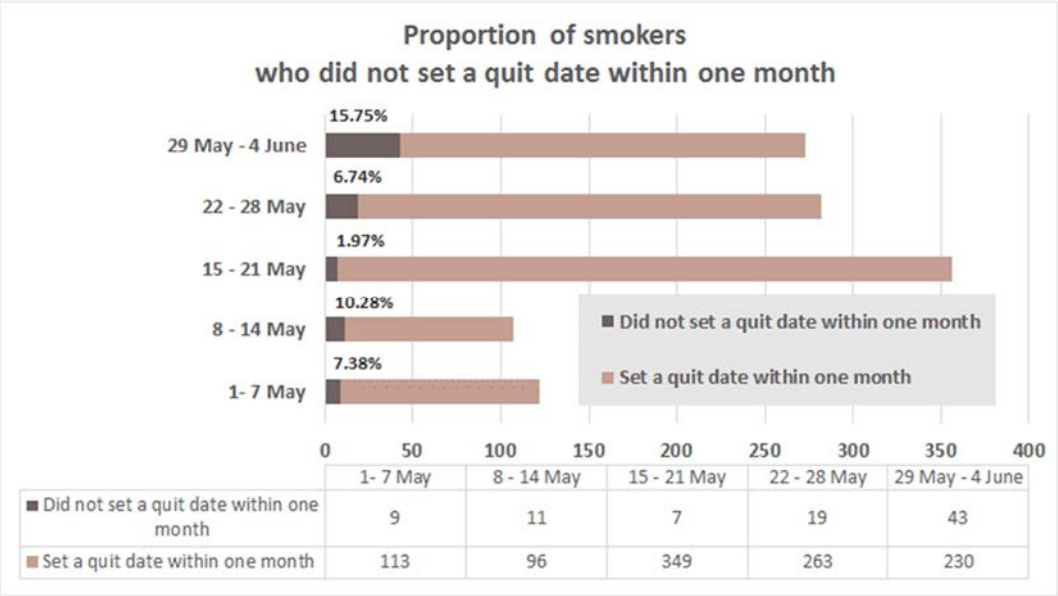
However, based on data retrieved from the TNQ in May 2017, there were 1,140 smokers who showed interest in receiving SMS and only 89 smokers did not set a quit date within one month; this accounted for only 8% of the smokers that were eligible to participate in the trial. **Figure 6.6** shows the proportion of smokers who did not set a quit date within one month. Therefore, the target sample size would not have been reached within the time frame of the PhD if the original inclusion criteria were continued.



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total smokers	1,239	1,567	1,599	1,240	1,682	1,848	1,346	1,498	1,335	1,236	1,355	1,070
No quitdate or set quitdate after 1 month	541	698	726	561	701	740	549	639	557	550	585	471
Percentage	44%	45%	45%	45%	42%	40%	41%	43%	42%	44%	43%	44%

Source: Thailand National Quitline [Data received: 22 February 2017]

Figure 6.5 Number of smokers who called the Thailand National Quitline, eligible smokers and the percentage of eligible smokers



	1- 7 May	8 - 14 May	15 - 21 May	22 - 28 May	29 May - 4 June
Did not set a quit date within one month	9	11	7	19	43
Set a quit date within one month	113	96	349	263	230

Source: Thailand National Quitline [Data received: 4 May to 5 June 2017]

Figure 6.6 Number of smokers who called the Thailand National Quitline and the proportion of smokers who did not set a quit date within a month

6.5.1.3 Impractical data collection methods and research burden to participants

From the internal pilot phase, the data collection process was not convenient for the participants. During the first month, of the 72 smokers interested in the trial, 35 preferred to receive trial information via mobile phone, 32 via post, and five via email. Three smokers returned a completed questionnaire via post. Two questionnaires never reached HITAP, and PK had to conduct telephone interviews as a result. Three smokers completed online questionnaires and no questionnaires were returned via email.

When PK conducted reminder telephone calls, the majority of smokers did not want to complete the online questionnaire but still wanted to receive text messages. Reasons included: 1) not being used to using an online platform; 2) not having Internet access on their phone; and 3) unable to complete the online questionnaire on their own. It was also found that a telephone interview was the preferred method for questionnaire completion. Therefore, telephone interviews for data collection were conducted instead. A team of interviewers was trained by PK prior to conducting the interviews.

The participant information sheet was also considered long and unattractive. Some participants reported feeling overwhelmed, and they decided not to take part because there was too much information on the participant information sheet and consent form. One

participant refused to take part stating: "I am too lazy to read [all the information given to me]".

Another piece of information showing the unattractiveness of participant information sheets was the number of people who clicked each page of the online questionnaire. From the Bristol Online Survey web report on 13 February 2017, there were 2,232 people interested in the trial and only 103 people decided to continue to the consent page (4.6% of the total). Overall, 52 people consented to the trial, and three people completed the online-based questionnaire. HITAP's communications team suggested that when dealing with an online platform, information provided should be simple, clear, and easy to read. Subsequently, the text on the first page was reduced and a link to the full information was added.

6.5.2 Strategies to overcome recruitment problems

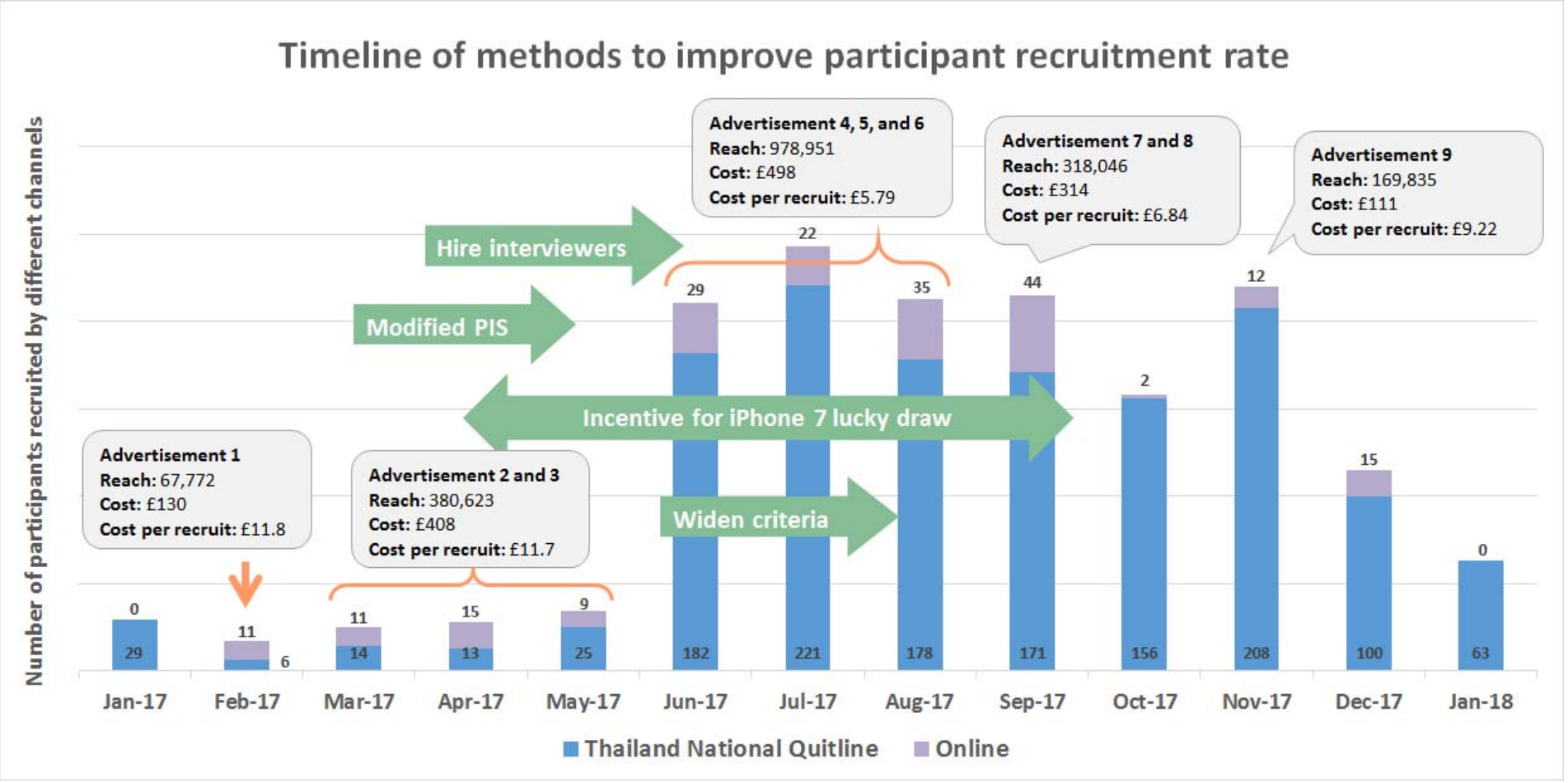
Barriers to recruitment and all possible strategies to overcome problems were mapped into Bower's recruitment strategy categories (229). **Table 6.1** summarises the barriers to participant recruitment, strategies to improve recruitment rate, and implemented strategies. Additional rationale for trial advertisement, incentives for participants, modification of methods to recruitment, and change in the eligibility criteria are provided in the next section.

Strategies that were more feasible in terms of implementation were implemented first including intensive online advertisements, improving trial management such as developing regular communications between PK and the recruitment team, and providing additional incentives such as financial support to the recruiting unit. Strategies that required research ethics approval, such as modification of the information sheet and consent form and allowing for telephone interviews, were implemented after the amendment was sought (detailed in **Chapter 2**). Strategies that were perceived to be more resource-intensive, such as embedding the recruitment process into the TNQ practice and widening eligibility criteria, were implemented at a later stage. **Figure 6.7** shows the timeline of implemented strategies and improvements in participant recruitment rates per month.

Table 6.1 Methods being implemented and other possible strategies to increase recruitment rates

Barriers to trial recruitment	Strategies to improve recruitment	Implemented strategies
Problems related to recruitment within routine service	**Incentives:** incentives to recruitment site	- Knowledge transfer for future implementation of text messages programme for the TNQ - Monthly funding support (10,000 THB per month (£233) in total for 12 months was allocated to the TNQ - Co-authorships for future publications
	Human factors: regular communication with the recruitment unit to improve attitude toward the trial	- Regular contact with recruitment staff (formal communication via email every week for report and informal communication via LINE, an instant messaging service) - Email the progress of participants that are actually recruited every week, as a reply email (instead of simply thank you)
	Support for recruiters: training	- Conversation dialogue in Thai and training had been provided prior to the recruitment
	Monitoring and system: revise recruitment flow	- Embedded the recruitment process into routine practice. This was done after the competing trial was completed. - The recruitment lists were sent to PK more often than at weekly intervals (3-4 times a week)
Fewer eligible participants	**Patient contact**: trial advertisement through networks and social media	- Expand network to advertise the research, e.g. smoking cessation clinics, rehabilitation clinics, and pharmacy networks - Series of research advertisement through paid Facebook advertisement (EC amendment 2: 14/03/2017)

Barriers to trial recruitment	Strategies to improve recruitment	Implemented strategies
	Incentives: provide an incentive for trial participation	- Provide a random draw for a smart phone for participants who consented to participate and completed the baseline questionnaire (EC amendment 2: 14/03/2017)
	Design: widen participant inclusion criteria	- Modify the inclusion criteria to allow for more smokers be able to participate in the trial by relaxing the criteria of setting a quit date within a month. (EC amendment 3: 08/06/2017)
Impractical data collection methods/ research burden to participants	**Patient contact:** modify the participant information sheet	- Shorter version of participant information sheet to fit within the size of a phone's screen (see **Appendix P**). However, due to the limitation of BOS online survey functionality, inserting text in figures are not allowed. Therefore, only text was used. (EC amendment 2: 14/03/2017)
	Patient contact: modify the consent form	- Alter the design of the consent form by using opt-out click instead of opt-in click for all consent statements to reduce the time required to complete the questionnaire (EC amendment 2: 14/03/2017)
	Patient convenience: participant burden	- Allow for data collection via telephone interviews with flexible appointments (including weekends) (EC amendment 2: 14/03/2017)
	Support for recruiter: recruiting and training telephone interviewers	- Recruit interviewers to conduct telephone interviews with participants who preferred to answer via telephone with flexible appointments - Conversation dialogue and training had been provided prior to the recruitment - Group conversation in LINE was created for any questions arising from the interview
	Monitoring and systems	- Weekly report has been set up. Issues at the beginning of the trial were discussed via the LINE group.



PIS: participant information sheet

Figure 6.7 Timeline of methods to improve trial participant recruitment and monthly participant recruitment number

6.5.2.1 Trial advertisement through social media

Social media marketing has become a marketing channel for the modern era (231). Social media is widely used in Thailand; the majority of Thai internet users now use social networking, accounting for 92% of Thai internet users (54). Facebook is a social networking service that is the number one leading social network in Thailand (232), with 45 – 50 monthly active users in Thailand (233). Therefore, Facebook can be used as a marketing tool for commercial goods and research (234), with a few examples of studies recruiting trial participants via an online platform (235-238).

Advertisements were placed on Facebook through paid advertisements (https://www.facebook.com/business) from February to November 2017. Content details are shown in **Table 6.2** and **Appendix R**. The objective of the first three advertisements (**Traffic**) was to increase the number of people clicking the advertisement link to reroute to the participant information sheet webpage. The objective of the rest of the advertisements (**Brand Awareness**) was to increase the reach of the ads to a target group. Given the budget pre-set for each advertisement, the cost per 1,000 people reached decreased from over a Great British Pound (GBP) to less than 1 GBP. Payment by reach was more cost-effective compared to payment by link clicks; therefore, this method for advertisement was continued until the end of the advertisement period.

In addition to paid advertisements, research advertisement materials for this trial **(Appendix R)** were sent to the online media and Facebook pages of health professional networks for smoking cessation such as the QuitSmokingThailand, Byebyeburi, QuitforKing, ThaiHealth, RxSmokeFree, etc. prior to the nationwide 'World No Tobacco' campaign (31 May 2017).

Table 6.2 Facebook advertisement

No.	Key message	Target population	Budget per day (THB)	Payment	Length (days)	Costs	Reach	Cost per 1000 reach
1.	Invitation to participate in research	Thai men and women aged 18-65+	200	Traffic (Pay per link click)	28	130	67,772	1.92
2.	Incentive for iPhone 7 lucky draw	Thai men and women aged 18-65+	200	Pay per link click	46	366	325,569	1.12
3.	Campaign for stop smoking on the Thai New Years	Thai men and women aged 18-65+	200	Pay per link click	10	43	55,054	0.78
4.	Add HITAP as an organisation who conducted research	Thai men and women aged 18-65+	600	Brand awareness Pay per reach	14	202	532,412	0.38
5.	Same content as Ad number 4	Thai men and women aged 18-65+	600	Pay per reach	15	202	480,526	0.42
6.	Same content as Ad number 4	Thai men aged 18-65+	600	Pay per reach	6	95	159,208	0.60
7.	Last chance to get lucky draw	Thai men aged 18-65+	600	Pay per reach	14	202	239,780	0.84
8.	Last chance to get lucky draw	Thai men aged 18-50	1000	Pay per reach	4	113	155,666	0.72
9.	Last change to receive free text messages to help stop smoking	Thai men aged 18-50	200	Pay per reach	23	111	169,835	0.65

6.5.2.2 Provide incentives for participants

Clinical trials often offer a financial incentive for participants who consent. An appropriate amount of incentives can be given to trial participants in recognition of the research burden. Financial incentives were reported to improve recruitment rates (RR 12.95, 95% CI 1.71 to 98.21) (225), and the willingness to participate increased with the amount of payment (225). An RCT to evaluate the effect of a £100 incentive reported an increase in the number of participants signing a consent form by 5.1% (239). A prize draw also improved the consent rate in an intervention trial specific to smoking cessation (240); it was reported to increase the consent rate by a factor of 1.36 (95% CI 1.13 to 1.64) compared to no incentive (224).

There was no financial support from the trial funder because a financial incentive was not designed in the original protocol. Therefore, the funding for this study's financial incentive was sought from HITAP. However, a generous amount of incentive for all participants was not financially feasible. A small payment such as 100 baht (£2) or a Lotus/Tesco supermarket cash card were considered as other options; however, it was expected that the amount of administrative workload would increase. In addition, postal addresses for all participants would be required, and a receipt from each participant is also required for research reimbursement from the funder. Therefore, a lucky draw for a more enticing incentive such as a smartphone for one participant was more feasible compared to providing all participants with a small payment. With approval from HITAP, an iPhone 7 was used as an incentive for the lucky draw. The information about the lucky draw was inserted into the research advertisement in the above section from April to September 2017 (the first extension for trial recruitment).

6.5.2.3 Modified methods to recruit participants

A telephone interview was added to the recruitment method due to the low number of self-administered online questionnaires. Additional resources were required as interviews typically lasts for 30-40 minutes per baseline questionnaire. Interviewers were recruited and trained by PK. A written protocol with conversation dialogue was provided to all interviewers. The protocol for follow-up required at least three attempted contacts per participant, with different dates and times per call. A pre-arranged time for telephone interviews was allowed for participants during the weekends and after normal working hours.

Initial screening via the TNQ continued until the end of April 2017. Of 115 smokers identified from the TNQ, 67 preferred to receive trial information via mobile phone, 42 via post, and six via email. The majority of smokers were interviewed, and five smokers answered the questionnaire online. No additional questionnaires were sent back to PK via post or email.

After the TNQ completed their recruitment for their competing trial, PK discussed options of increasing the recruitment rate with the head of the TNQ recruitment staff and director of the TNQ. It was agreed among all parties that the recruitment process could be incorporated into the TNQ's routine practice. Both TNQ call-takers and counsellors subsequently offered the trial information to all smokers (see **Figure 6.8**). After the TNQ counsellor provided 20-30 minutes quit counselling as a part of routine practice, smokers were offered to receive trial participant information to be recruited to the trial. In addition, the initial recruitment workload of TNQ staff was reduced by removing the options of preferred methods to receive trial information. An automated invitation text message was sent out to all participants. Any participant who did not complete the online questionnaire would be contacted by telephone.

6.5.2.4 Widen the eligibility criteria

Modification of the eligibility criteria was reserved as a last resort for increasing the recruitment rate. The rationale for modification was to widen the eligibility criteria so that more potential participants could be eligible for the trial. The low recruitment rate was estimated to justify this modification. As of May 2017, there were 117 participants in the trial. This accounted for only 8% of the cumulative target sample size. Using linear prediction, only 19% of the target sample size would be achieved at the end of the 1-year recruitment period, suggesting a failed trial because the sample size would be too small to answer the research question. However, the trade-off for this change was that one of the secondary outcomes (self-reporting of setting a quit date) became unfeasible

The inclusion criteria was modified from *"(1) Thai smokers who received a single brief counselling session for smoking cessation from the TNQ and (2) did not set a quit date within one month"* to *"Smokers residing in Thailand who wanted to quit smoking"* because it would allow for a wider audience than the previous restricted criteria. It included any smokers with or without a pre-set quit date. After the Ethical amendments were granted, the new criteria were implemented at the beginning of June 2017.

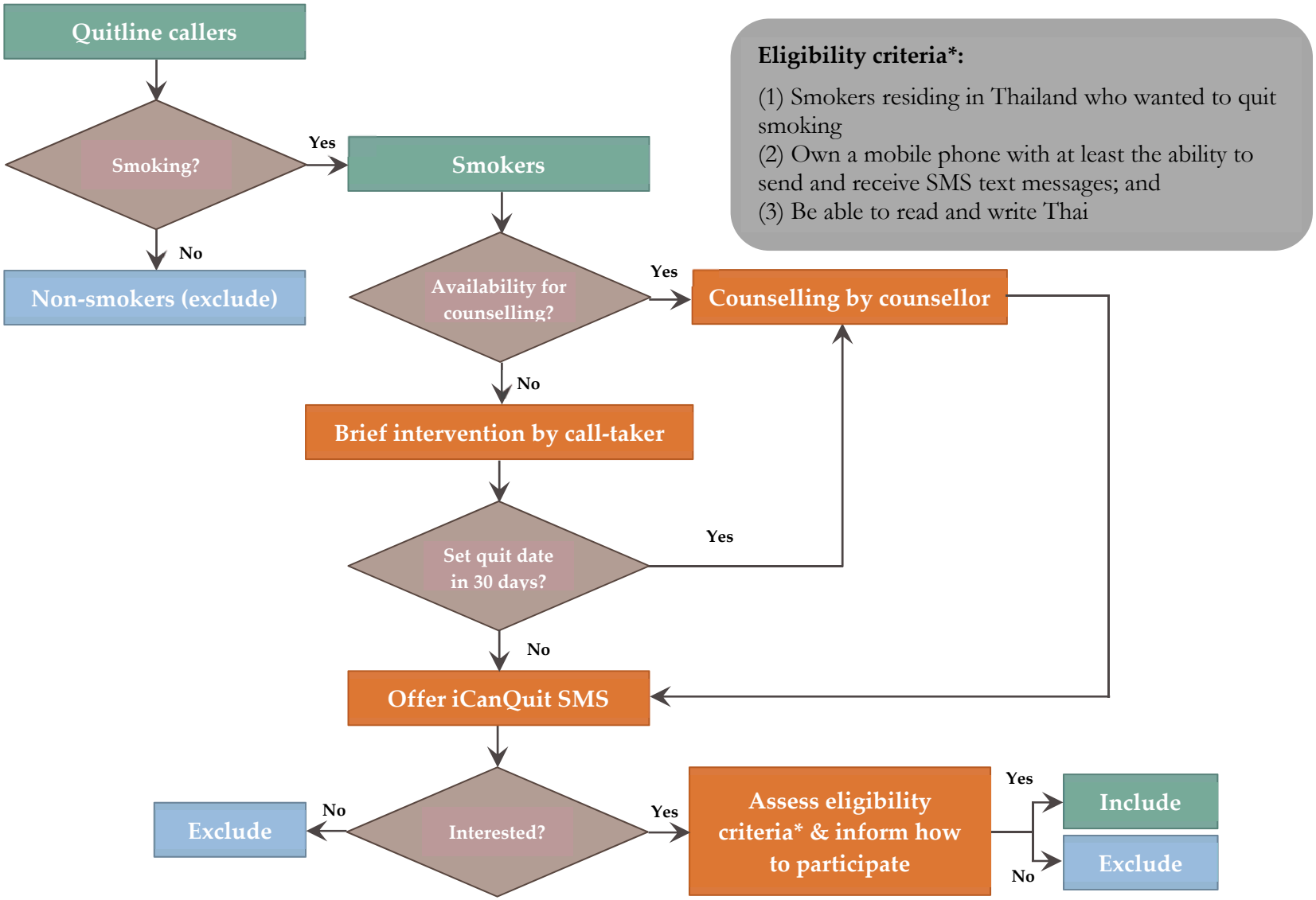


Figure 6.8 TNQ modified participant recruitment flow

6.5.3 Trial recruitment results

During the first four months (February to May 2017) of implementing strategies to improve the recruitment rate, the recruitment rate remained low, and the target sample size was not achievable. An extension of 6 months was made to the original plan because the recruitment was not achievable (see **Figure 6.9**). In the end, participants were recruited from 11 January 2017 to 14 January 2018, with a final recruitment number of 1,571 smokers (94% of the cumulative target sample size). **Figure 6.10** shows the monthly cumulative number of participants recruited by the TNQ and online registration via the BOS online survey (online platform). 1,366 participants (87%) were recruited via the TNQ and 205 participants were recruited via online.

A noticeable impact was observed during the modification of the eligibility criteria and the methods of recruitment. The recruitment rate improved from 34 participants recruited per month in May to 211 participants in June (a 5-fold increase). There was a peak in the number of people who showed interest in the trial during June 2016. **Figure 6.11** shows a graph of the number of participants recruited into the trial and the number of people who showed interest over time. This peak was an effect from the nationwide 'World No Tobacco' campaign to promote people to stop smoking, implemented from the middle of May to the beginning of June (external to this trial). As such, there was an influx of callers to the TNQ, resulting in a two-month waiting list for telephone counselling from the TNQ. However, the number of people who called the TNQ decreased over time once again after the national campaign.

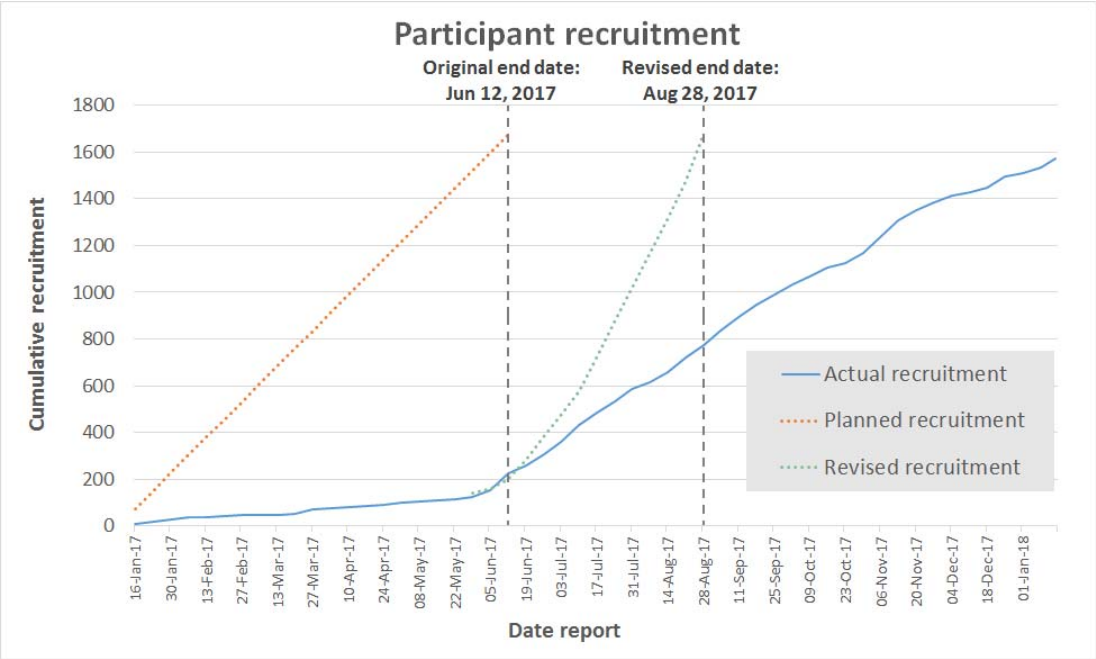
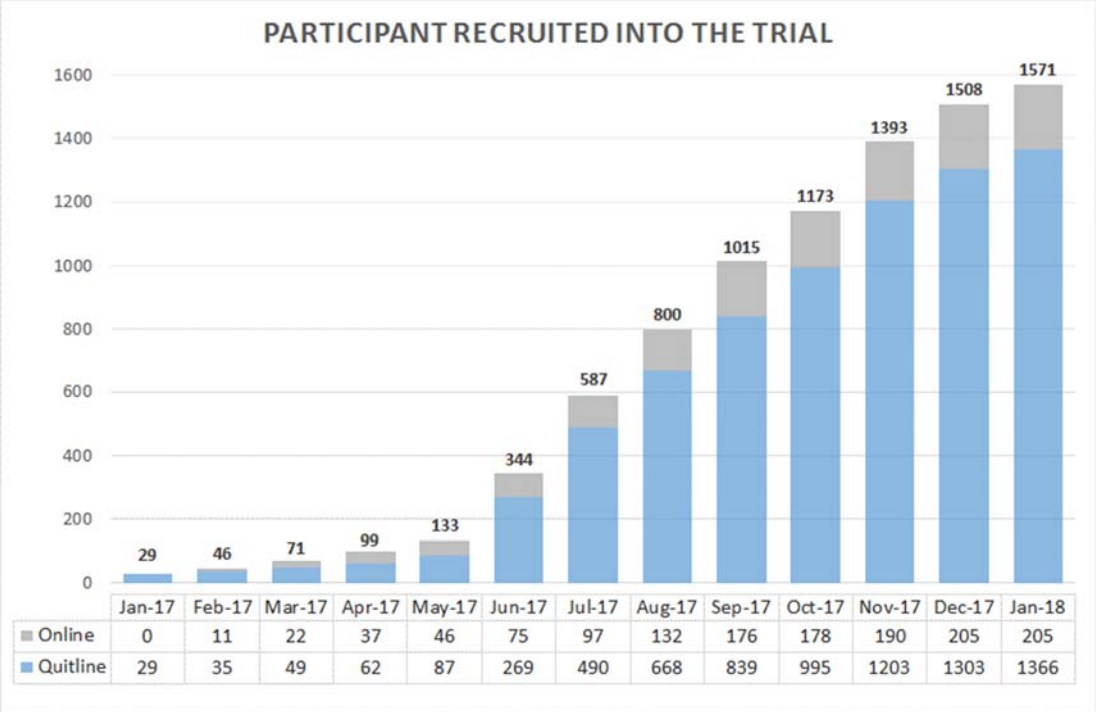


Figure 6.9 Cumulative planned, revised, and actual recruitment to the trial



	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18
Online	0	11	22	37	46	75	97	132	176	178	190	205	205
Quitline	29	35	49	62	87	269	490	668	839	995	1203	1303	1366

Figure 6.10 Cumulative number of participants recruited via the Quitline and online channels

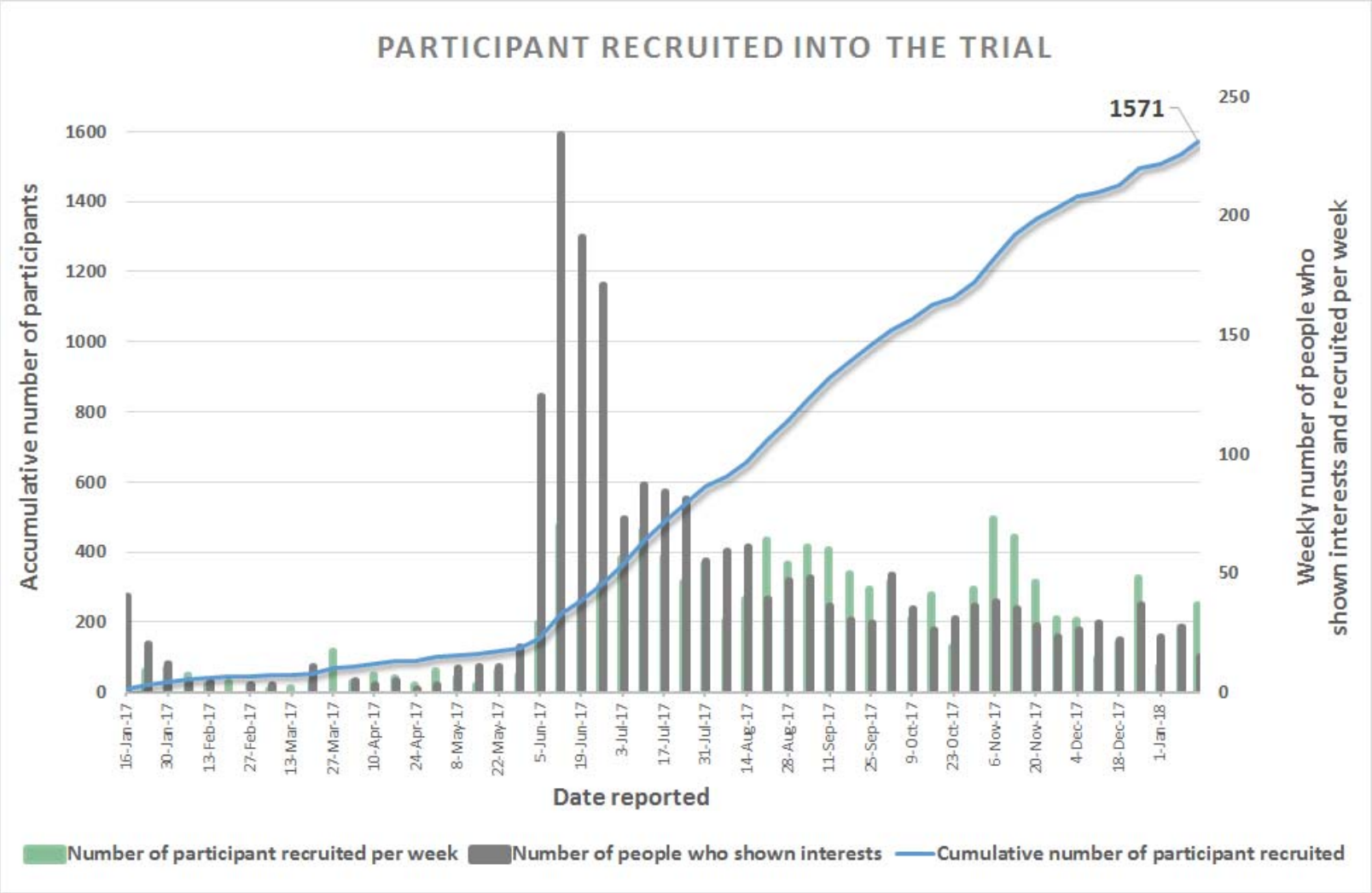


Figure 6.11 Number of participants recruited into the trial against the number of people who showed interests

6.6 Discussion

6.6.1 Main findings

This chapter provides a descriptive account of recruitment strategies and lessons learned from the recruitment processes. Monitoring and evaluation of recruitment strategies to reach the target sample size were vital to the trial's success. From the internal pilot phase, the competing trial and the contextual changes in TNQ practices were likely to be the leading causes of the initial low recruitment rate. It also evident that Thai smokers were not familiar with online self-administered questionnaires despite the fact that internet access to the Thai population was high. Many strategies with supporting evidence to improve recruitment rate were implemented in this trial, yet it failed to provide a sufficient number to meet the target sample size. The relaxation of inclusion criteria, modification of recruitment methods, and extension of the recruitment period based on the new recruitment rate projection were necessary to complete the trial within the given time frame for the PhD. The final recruitment period was extended by six months, and 1,571 participants were recruited in the trial, accounting for 94% of the target sample size.

Only three effective recruitment strategies and interventions are currently supported by high-quality evidence (226). While providing incentives to trial participants has been shown to improve in the literature (225), it failed to significantly improve the recruitment rate for this trial. However, this chapter did not aim to provide a formal evaluation with hypothesis testing for effective recruitment strategies. It merely suggests that interventions to improve trial recruitment are subject to trial context, settings, and culture. Huang and colleagues also recognised that there is no single solution to overcome the problems, and each trialist faces different problems due to the diversity of the trial design and research context (241).

This trial suffered from many predictable and unpredictable challenges throughout the recruitment period. Improving recruitment rates can be very challenging and resource-consuming, especially when the trial investigates prevention interventions rather than treatment interventions (242). The major problems of the recruitment of this study were due to policy environment change over the course of the study. The overly-optimistic recruitment rate was another factor. An influx of smokers from the nationwide 'World No Tobacco' campaign gave a seasonal over-optimistic figure; as a result, the trial was extended twice. Also, it might have increased the proportion of smokers who are more motivated to

quit, as observed from the decrease in the percentage of smokers who did not set a quit date within a month (**Figure 6.5**).

6.6.2 Strengths and limitation of the study

Continuous piloting, monitoring and evaluation of recruitment strategies are vital to a trial's success. A pilot study can be helpful to predict the recruitment rate in the research setting (243). This trial included an internal pilot phase for estimating the trial recruitment rate. An estimation of the expected recruitment rate was also calculated from previous research and data from the TNQ. White and Hind (2015) suggested this method as the inappropriate anchor estimates by focusing on positive past experiences (243). It is crucial to conduct an internal pilot study properly, and new information may become available during the trial that may be considered sufficient to require changes to the trial design (230). An external pilot trial is another alternative but is also resource-intensive. A review of publicly funded trials in the UK suggested that there is little benefit of conducting an external pilot trial and recommended an internal pilot trial be conducted instead (244).

6.6.3 Implications for practice and further research

The objective of implementing recruitment strategies in most clinical trials is to improve their recruitment rate so that the research does not end up worthless, especially publicly-funded research. However, it is evident that better reporting for overcoming recruitment challenges in the literature is needed. Research proposals should consider including methods to test different recruitment strategies. Huang and colleagues proposed a strategic recruitment planning framework including three dimensions: 1) trial design and protocol development; 2) trial feasibility and site selection; and 3) communication between research teams (241). Future research with a large sample size should consider embedding a trial into the study to improve recruitment rates and advance research in this field.

Examples of collective research to help trialists in understanding this field have been initiated such as Trial Forge (https://www.trialforge.org/pathway/) and The Prioritising Recruitment in Randomised Trials study (PRioRiTy) (https://priorityresearch.ie/the-questions/). This chapter highlights the two unanswered important questions by the PRioRiTy, the first question being "How can randomised trials become part of routine care and best utilise current clinical care pathway?" (223). Integrating the recruitment process

into routine practices and decreasing the workload of research administration are the keys to success. However, this also requires a commitment from the director of the recruitment unit and staff at all operational levels. Regular contact with the staff at the operational level played a major factor to the success of the TNQ recruitment process modification.

The second unanswered question from the PRioRiTy is "What are the advantages and disadvantages to using technology during the recruitment process?" (223). Online self-administered questionnaires are another great opportunity to collect and manage data in this digital era; however, it requires a fair amount of digital literacy by the population of interest. To rely on technology for the recruitment process poses a risk to the success of the trial. The participants in this trial were relatively young, educated, and owned a smartphone (see **Chapter 7**); however, the majority of the participants preferred to be recruited and followed up by telephone interview.

6.7 Chapter summary

The evidence supporting recruitment strategies remains limited as the majority of trials do not test them. This chapter outlined the challenges and strategies to tackle the recruitment challenges for the factorial randomised trial in Thailand. Several methods to improve the recruitment rate were implemented yet failed to provide any significant results. The contextual change to the trial is likely to play a major role in this recruitment challenge. Therefore, the eligibility criteria were relaxed in order to meet the required sample size. This analytical problem-solving process may offer an alternative method to identify and select effective strategies to support recruitment.

Chapter 7: Results of a factorial randomised controlled trial to simultaneously test the effectiveness of BCT-enhanced text messages for smoking cessation in Thailand

7.1 Chapter overview

To assess the effectiveness of three intervention components ('Capability', 'Opportunity', and 'Motivation') individually and in combination, a 2×2×2 full factorial RCT was conducted by randomly providing combinations of BCT-enhanced text messages for smokers under the Thai pragmatic research setting. This chapter reports the flow of trial participants, the process evaluation, and the results from statistical analyses. The results of the intervention components and combinations required to improve smoking cessation rate at 1-month follow-up are presented and discussed.

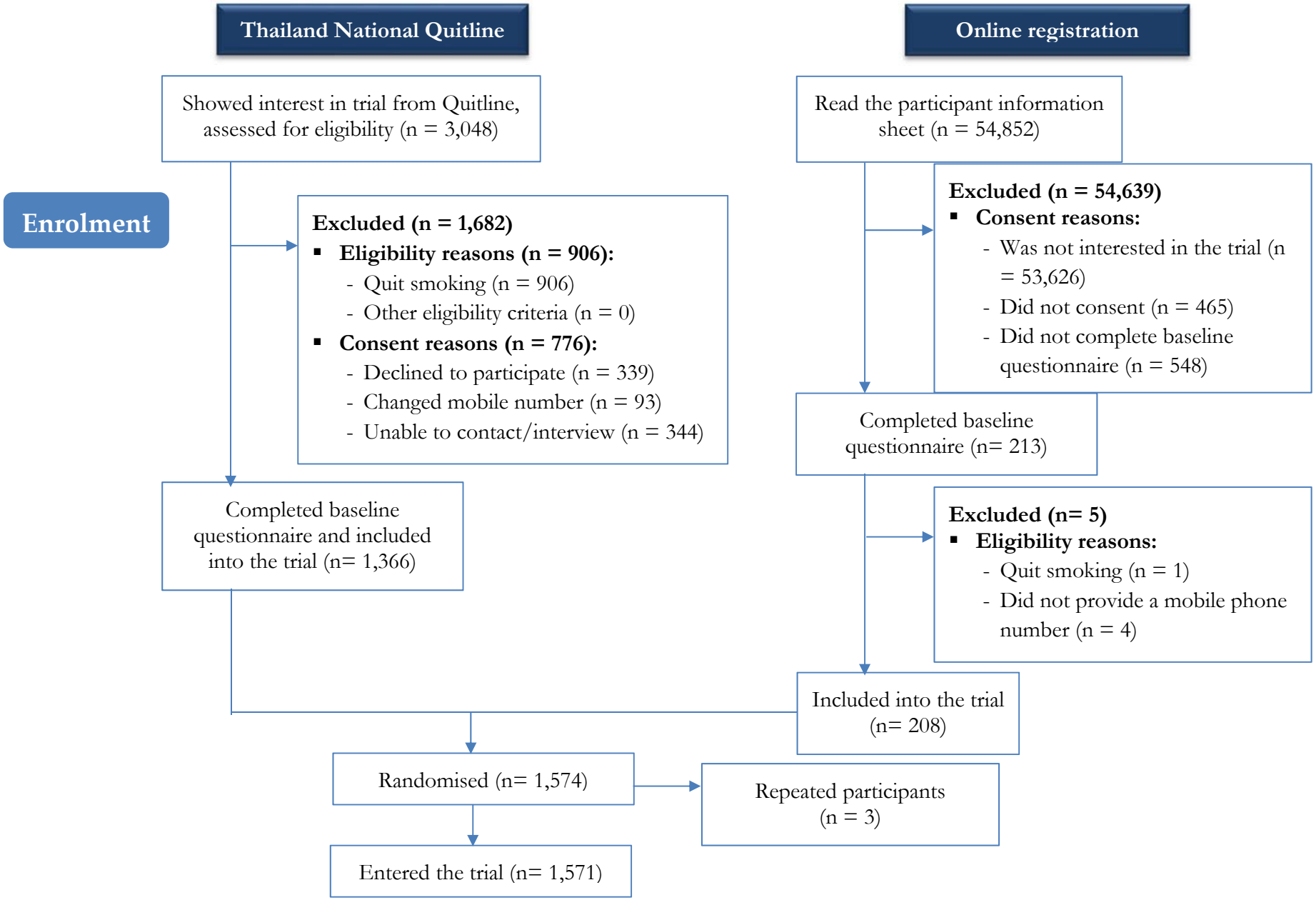
7.2 Recruitment, treatment allocation, and retention

Participant recruitment occurred between 11 January 2017 and 14 January 2018. An extension of 6 months was made to the original plan because the number of participants recruited was only 133 (8%) out of the target sample size of 1,670 after four months. A revised plan to improve the recruitment rate was designed and implemented sequentially (see details in **Chapter 6**). A CONSORT diagram reporting the flow of participants at each stage including enrolment, allocation, follow-up, and analysis is presented in **Figure 7.1**.

Participants were recruited from the Thailand National Quitline (TNQ) and online registration (self-completion of an online-based questionnaire). The majority were

recruited from the TNQ, accounting for 87% of the total sample. Of 3,048 people who showed initial interest via the TNQ, 1,682 (55%) were excluded from the trial. Reasons for the exclusion were 'already quit smoking' (54%), 'no longer interested' (20%), 'changed contact number' (6%), 'unable to contact/interview' (20%). Finally, 1,366 smokers (45%) completed the baseline questionnaire and enrolled in the trial. From the online registration, the participant information sheet was read 54,852 times. Most people (98%) read the trial information (participant information sheets) but did not move on to the consent form page. There were 465 people (0.9%) who did not provide consent, and 548 people (1%) did not complete the baseline questionnaire. In total, 208 smokers completed the baseline questionnaire and enrolled in the trial. However, there were three repeat cases identified from the participant database (participants who provided different mobile numbers). These three numbers were removed from the trial. Thus, a total of 1,571 participants (94% of the original target sample size) were enrolled.

Each participant randomly received one of the eight allocated text messages (placebo, C, O, M, CO, CM, OM, and COM). There were 16 participants (1%) who did not receive any text messages due to a technical error. Two participants (0.1%) asked to stop receiving the intervention because they found the texts to be bothersome. After providing text messages to participants for 30 days, the 1-month follow-up was completed on 22 February 2018. A total of 1,310 participants (83%) reported their smoking status and 1,197 (76%) completed the 1-month follow-up questionnaire (secondary outcomes available). An intention-to-treat (ITT) sample included all participants (n=1,571) and this was used for the primary analysis. There were 1,260 participants who received the intended 60 text messages; this sample was identified as the per-protocol sample.


Thailand National Quitline
Online registration
Enrolment
Showed interest in trial from Quitline, assessed for eligibility (n = 3,048)
Excluded (n = 1,682)
Eligibility reasons (n = 906):
- Quit smoking (n = 906)
- Other eligibility criteria (n = 0)
Consent reasons (n = 776):
- Declined to participate (n = 339)
- Changed mobile number (n = 93)
- Unable to contact/interview (n = 344)
Completed baseline questionnaire and included into the trial (n= 1,366)
Read the participant information sheet (n = 54,852)
Excluded (n = 54,639)
Consent reasons:
- Was not interested in the trial (n = 53,626)
- Did not consent (n = 465)
- Did not complete baseline questionnaire (n = 548)
Completed baseline questionnaire (n= 213)
Excluded (n= 5)
Eligibility reasons:
- Quit smoking (n = 1)
- Did not provide a mobile phone number (n = 4)
Included into the trial (n= 208)
Randomised (n= 1,574)
Repeated participants (n = 3)
Entered the trial (n= 1,571)

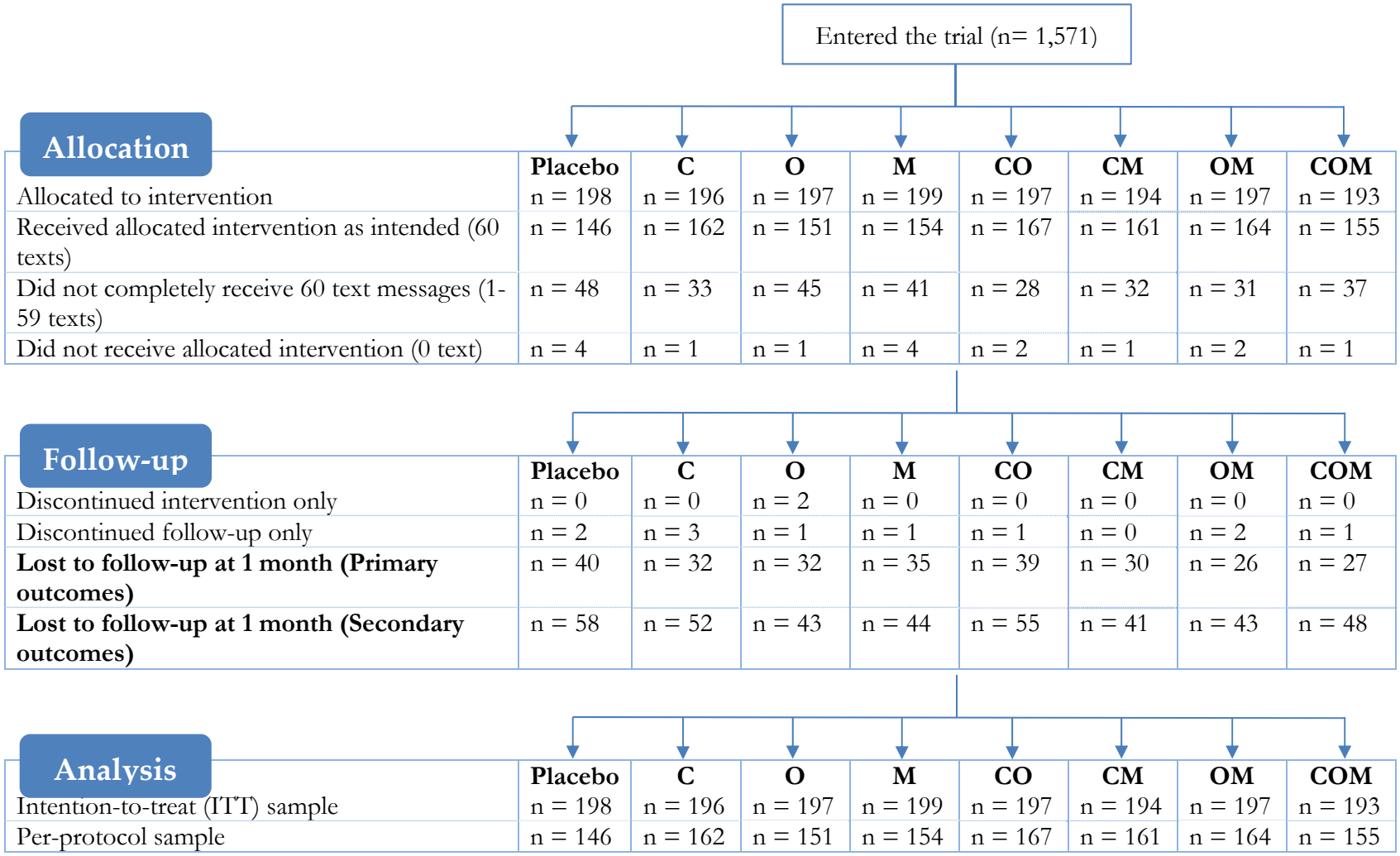


Figure 7.1 CONSORT flow diagram showing the flow of participants to the 8 experimental groups (Placebo, C, O, M, CO, CM, OM, and COM).

7.3 Participant characteristics

Overall, almost half (46%) of the participants were aged under 30 years, 21% of the participants were aged between 31-40 years, and 33% were aged above 40 years. Around 83% of the participants had high (between 6 to 10) intention-to-quit (ITQ) scores at baseline. A balance in sample size through stratified block randomisation among experimental conditions was noted. The sources of participant recruitment and source of data collection were not used as stratification factors but a balance in sample size across the different experimental conditions was also observed. **Table 7.1** reports the total sample and allocation of the 8 experimental conditions among the different design choices of the trial.

Baseline characteristics of smokers who enrolled and received text messages are summarised in **Table 7.2**. Overall, all experimental groups had similar characteristics at baseline. Around 81% of the participants were daily smokers with an average of 8 tobacco products used per day. The average level of nicotine dependence was 3 (moderate nicotine dependence). 91% of the participants had tried to quit before in the past 6 months and 96% were willing to quit smoking in the next month.

On average, the participants spent a median of 4 hours (IQR: 1 - 6.5 hours) daily on their phones. Around 87% of the participants used smartphones, 34% had never used text messages, and 15% had never used instant messages. About 74% and 16% of participants reported that they had used mobile apps for non-health-related and health-related purposes, respectively.

Approximately 43% of participants reported that they did not drink any alcohol in the past 12 months. In addition, the mean AUDIT score was 6.21. In general, the quality of life of the participants was high with an average EQ-5D-5L score of 0.94 and an average visual analogue scale of 78. Around one-third of the participants reported having one or more medical illnesses.

When comparing participant characteristics with available information from the Thai national census data (31), participants in this trial were generally younger and had a higher level of education than the national average. Twenty-seven percent of smokers in this trial were under the age of 24, compared to 12% in the Thai national statistics (illustrated in

Figure 7.2) (31). Furthermore, more females (10% versus 5%) and a higher proportion of unemployed people (17% versus 10%) were observed. When considering smoking behaviour, there was a slightly lower proportion of daily smokers (81% versus 88%) and the number of tobacco products smoked per day (10 versus 11), and a much higher proportion of people with previous quit attempts (91% versus 33%) when compared to the national data.

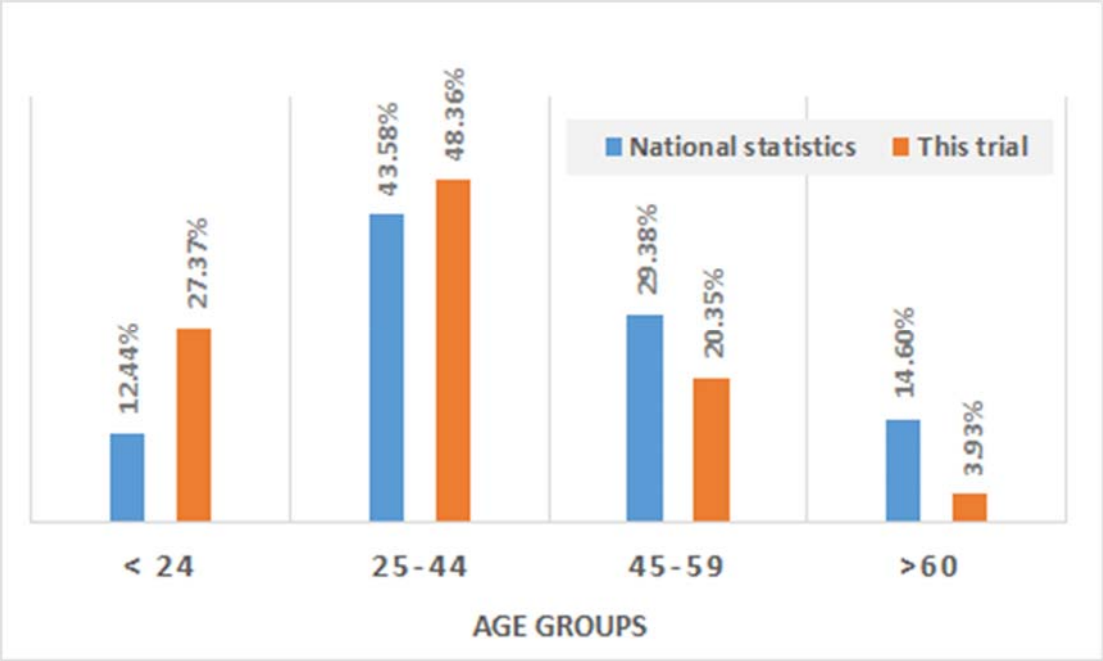


Figure 7.2 Age group comparison between the trial sample and the Thai national census data

7.3.1 Baseline characteristics of participants with smoking status at 1-month follow-up and missing outcome variable

Approximately 17% of participants (n=261) did not report smoking cessation at 1-month follow-up. Participants with complete smoking status at 1-month follow-up were older (35.55 versus 33.23 years, p = 0.010), more educated (22.82% versus 13.90%), started smoking at an older age (17.07 versus 16.50, p-value = 0.046), and had higher capability score at baseline (16.95 versus 16.23, p-value = 0.001) compared to participants that were lost to follow-up. Moreover, participants that received all intended text messages (85.27% versus 54.79%, p-value < 0.001), carried their phone at all times (91.99% versus 87.16%,

p-value = 0.012), used instant text messages more frequently (70.22% versus 65.77%, p-value = 0.025), and were recruited via Quitline (87.86% versus 82.38%, p-value 0.016) were less likely to be lost to follow-up at 1 month.

Table S1 reports the association of all baseline characteristics with the missingness of smoking status (see **Appendix S**). All variables that contained information about the missing data and were statistically significant ($p<0.05$) or marginally significant ($p<0.1$), namely ITQ scores at baseline, duration of smoking (years), quality of life, having children at home, smoker network, and type of mobile phone, were included in the multiple imputation process.

Table 7.1 Allocation of experimental conditions by trial design choices

Design choices	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
1. Stratification at randomisation, n (%)									
Age at randomisation									
less than 30 years old	716 (45.58%)	89 (44.95%)	89 (45.41%)	89 (45.18%)	90 (45.23%)	88 (44.67%)	90 (46.39%)	91 (46.19%)	90 (46.63%)
31-40 years old	336 (21.39%)	43 (21.72%)	42 (21.43%)	44 (22.34%)	43 (21.61%)	43 (21.83%)	40 (20.62%)	41 (20.81%)	40 (20.73%)
above 40 years old	519 (33.04%)	66 (33.33%)	65 (33.16%)	64 (32.49%)	66 (33.17%)	66 (33.50%)	64 (32.99%)	65 (32.99%)	63 (32.64%)
Intention-to-quit group									
Low (score: 1 – 5)	267 (17.00%)	34 (17.17%)	33 (16.84%)	34 (17.26%)	35 (17.59%)	33 (16.75%)	32 (16.49%)	33 (16.75%)	33 (17.10%)
High (score: 6 – 10)	1304 (83.00%)	164 (82.83%)	163 (83.16%)	163 (82.74%)	164 (82.41%)	164 (83.25%)	162 (83.51%)	164 (83.25%)	160 (82.90%)
2. Source of participant recruitment, n (%)									
Thailand National Quitline	1366 (86.95%)	171 (86.36%)	178 (90.82%)	175 (88.83%)	170 (85.43%)	166 (84.26%)	172 (88.66%)	169 (85.79%)	165 (85.49%)
Online	205 (13.05%)	27 (13.64%)	18 (9.18%)	22 (11.17%)	29 (14.57%)	31 (15.74%)	22 (11.34%)	28 (14.21%)	28 (14.51%)
3. Source of data collection, n (%)									
Self-administered via online questionnaire	325 (20.69%)	42 (21.21%)	33 (16.84%)	37 (18.78%)	42 (21.11%)	44 (22.34%)	45 (23.20%)	43 (21.83%)	39 (20.21%)
Interview	1246 (79.31%)	156 (78.79%)	163 (83.16%)	160 (81.22%)	157 (78.89%)	153 (77.66%)	149 (76.80%)	154 (78.17%)	154 (79.79%)

Table 7.2 Baseline characteristics of participants who enrolled and received text messages

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Demographic variables									
Age at randomisation (years), mean (sd), n	35.17 (13.39), 1,571	34.93 (13.64), 198	35.12 (13.14), 196	35.02 (13.42), 197	35.46 (14.16), 199	35.12 (13.55), 197	35.21 (13.10), 194	35.57 (13.12), 197	34.90 (13.16), 193
Gender, n (%)									
Female	154 (9.80%)	16 (8.08%)	17 (8.67%)	19 (9.64%)	20 (10.05%)	26 (13.20%)	20 (10.31%)	22 (11.17%)	14 (7.25%)
Male	1417 (90.20%)	182 (91.92%)	179 (91.33%)	178 (90.36%)	179 (89.95%)	171 (86.80%)	174 (89.69%)	175 (88.83%)	179 (92.75%)
Marital status, n (%)									
Single, widowed, separated/divorced	806 (51.30%)	111 (56.06%)	100 (51.02%)	106 (53.81%)	101 (50.75%)	101 (51.27%)	98 (50.52%)	93 (47.21%)	96 (49.74%)
Married/with a partner	742 (47.23%)	83 (41.92%)	95 (48.47%)	86 (43.65%)	95 (47.74%)	94 (47.72%)	93 (47.94%)	102 (51.78%)	94 (48.70%)
Religion, n (%)									
Others (Islam, Christianity, others, none)	89 (5.67%)	6 (3.03%)	13 (6.63%)	14 (7.11%)	14 (7.04%)	11 (5.58%)	13 (6.70%)	10 (5.08%)	8 (4.15%)
Buddhism	1482 (94.33%)	192 (96.97%)	183 (93.37%)	183 (92.89%)	185 (92.96%)	186 (94.42%)	181 (93.30%)	187 (94.92%)	185 (95.85%)
Education level, n (%)									
Primary school and below	300 (19.10%)	42 (21.21%)	38 (19.39%)	33 (16.75%)	40 (20.10%)	39 (19.80%)	39 (20.10%)	37 (18.78%)	32 (16.58%)

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Secondary or high school completed	914 (58.18%)	106 (53.54%)	122 (62.24%)	113 (57.36%)	119 (59.80%)	116 (58.88%)	115 (59.28%)	116 (58.88%)	107 (55.44%)
College/University and above	329 (20.94%)	46 (23.23%)	32 (16.33%)	46 (23.35%)	39 (19.60%)	41 (20.81%)	37 (19.07%)	39 (19.80%)	49 (25.39%)
Employment status, n (%)									
Unemployed	270 (17.19%)	37 (18.69%)	33 (16.84%)	37 (18.78%)	37 (18.59%)	32 (16.24%)	28 (14.43%)	32 (16.24%)	34 (17.62%)
Employed	1280 (81.48%)	160 (80.81%)	161 (82.14%)	157 (79.70%)	159 (79.90%)	162 (82.23%)	163 (84.02%)	161 (81.73%)	157 (81.35%)
Quintile of asset index (socio-economic status), n (%)									
SES 1	635 (40.42%)	85 (42.93%)	75 (38.27%)	87 (44.16%)	89 (44.72%)	67 (34.01%)	74 (38.14%)	80 (40.61%)	78 (40.41%)
SES 2	320 (20.37%)	44 (22.22%)	38 (19.39%)	36 (18.27%)	38 (19.10%)	44 (22.34%)	37 (19.07%)	46 (23.35%)	37 (19.17%)
SES 3	180 (11.46%)	22 (11.11%)	30 (15.31%)	17 (8.63%)	18 (9.05%)	23 (11.68%)	24 (12.37%)	23 (11.68%)	23 (11.92%)
SES 4	13 (0.83%)	4 (2.02%)	0 (0%)	2 (1.02%)	1 (0.50%)	1 (0.51%)	2 (1.03%)	1 (0.51%)	2 (1.04%)
SES 5	72 (4.58%)	8 (4.04%)	10 (5.10%)	14 (7.11%)	15 (7.54%)	11 (5.58%)	8 (4.12%)	3 (1.52%)	3 (1.55%)
Monthly household income in Thai Baht, mean (sd), n	49,945.70 (531,907.90), 1,452	36,703.30 (54,789.20), 182	31,342.42 (37,303.03), 182	36,880.03 (54,650.77), 184	31,786.10 (37,771.67), 187	32,616.99 (35,361.23), 183	47,603.85 (223,391.31), 182	34,858.89 (51,397.11), 180	154,066.86 (1,523,760.97), 172
Number of illnesses, n (%)									
None	995 (63.34%)	124 (62.63%)	121 (61.73%)	130 (65.99%)	132 (66.33%)	105 (53.30%)	125 (64.43%)	133 (67.51%)	125 (64.77%)
1 or more	576 (36.66%)	74 (37.37%)	75 (38.27%)	67 (34.01%)	67 (33.67%)	92 (46.70%)	69 (35.57%)	64 (32.49%)	68 (35.23%)

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Numbers of smoke-related diseases in family, n (%)									
None	1368 (87.08%)	173 (87.37%)	167 (85.20%)	173 (87.82%)	173 (86.93%)	169 (85.79%)	171 (88.14%)	174 (88.32%)	168 (87.05%)
1 or more	203 (12.92%)	25 (12.63%)	29 (14.80%)	24 (12.18%)	26 (13.07%)	28 (14.21%)	23 (11.86%)	23 (11.68%)	25 (12.95%)
Having children at home, n (%)									
No	875 (55.70%)	124 (62.63%)	111 (56.63%)	106 (53.81%)	103 (51.76%)	104 (52.79%)	110 (56.70%)	97 (49.24%)	120 (62.18%)
Yes	681 (43.35%)	74 (37.37%)	84 (42.86%)	87 (44.16%)	94 (47.24%)	92 (46.70%)	81 (41.75%)	97 (49.24%)	72 (37.31%)
Numbers of smoker network, n (%)									
None	367 (23.36%)	46 (23.23%)	50 (25.51%)	42 (21.32%)	53 (26.63%)	41 (20.81%)	44 (22.68%)	51 (25.89%)	40 (20.73%)
1 or more	1204 (76.64%)	152 (76.77%)	146 (74.49%)	155 (78.68%)	146 (73.37%)	156 (79.19%)	150 (77.32%)	146 (74.11%)	153 (79.27%)
Smoking behaviour									
Type of smoker, n (%)									
Non-daily smoker	295 (18.78%)	41 (20.71%)	38 (19.39%)	40 (20.30%)	41 (20.60%)	30 (15.23%)	36 (18.56%)	34 (17.26%)	35 (18.13%)
Daily smoker	1270 (80.84%)	157 (79.29%)	157 (80.10%)	155 (78.68%)	158 (79.40%)	167 (84.77%)	158 (81.44%)	162 (82.23%)	156 (80.83%)
Number of tobacco products used per day, mean (sd), n	9.75 (8.44), 1,554	9.74 (8.11), 194	9.16 (7.79), 193	9.74 (8.42), 195	9.15 (8.55), 195	10.21 (9.10), 195	9.82 (8.03), 194	9.75 (8.34), 197	10.40 (9.14), 191

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Fagerstrom Test for Nicotine Dependence score, mean (sd), n	3.23 (2.35), 1,524	3.25 (2.35), 190	3.19 (2.43), 190	3.10 (2.33), 195	3.28 (2.42), 194	3.12 (2.41), 189	3.32 (2.28), 187	3.19 (2.31), 192	3.43 (2.29), 187
Age when started smoking (years), mean (sd), n	16.98 (4.26), 1,563	17.52 (5.33), 198	16.87 (4.65), 194	17.08 (3.59), 196	16.45 (4.02), 198	17.28 (4.44), 197	16.96 (4.30), 193	16.69 (3.26), 196	16.97 (4.14), 191
Duration of smoking (years), mean (sd), n	17.32 (12.69), 1,563	16.58 (12.44), 198	16.89 (12.23), 193	16.74 (12.84), 196	18.86 (14.24), 197	17.39 (12.90), 197	17.51 (12.11), 194	17.28 (12.92), 196	17.29 (11.76), 192
History of previous quit attempts in the past 6 months, n (%)									
No	121 (7.70%)	15 (7.58%)	18 (9.18%)	20 (10.15%)	10 (5.03%)	16 (8.12%)	16 (8.25%)	13 (6.60%)	13 (6.74%)
Yes	1432 (91.15%)	181 (91.41%)	176 (89.80%)	176 (89.34%)	184 (92.46%)	179 (90.86%)	175 (90.21%)	182 (92.39%)	179 (92.75%)
Number of methods used to assist smoking cessation, mean (sd), n	0.78 (0.83), 1,571	0.87 (0.85), 198	0.92 (0.93), 196	0.80 (0.89), 197	0.74 (0.82), 199	0.71 (0.80), 197	0.81 (0.76), 194	0.58 (0.72), 197	0.79 (0.85), 193
Duration of quit attempts in the last 6 months (days), mean (sd), n	20.12 (84.42), 1,558	23.65 (116.27), 196	23.06 (132.63), 195	14.57 (40.30), 195	19.50 (56.30), 195	13.77 (31.76), 194	15.12 (46.92), 194	21.98 (87.29), 196	29.32 (101.35), 193
Number of reasons for not being able to quit smoking, mean (sd), n	2.69 (1.89), 1,571	2.70 (1.99), 198	2.71 (1.90), 196	2.59 (1.79), 197	2.74 (2.03), 199	2.68 (1.73), 197	2.82 (1.95), 194	2.42 (1.73), 197	2.87 (1.96), 193
Behaviour change to support smoking cessation, mean (sd), n									

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Capability to quit smoking	16.84 (3.23), 1,556	16.49 (3.20), 198	17.05 (2.98), 193	17.24 (3.11), 195	16.82 (3.42), 197	16.40 (3.66), 193	17.06 (3.07), 193	17.09 (2.83), 197	16.53 (3.43), 190
Opportunity to support smoking cessation	16.86 (3.83), 1,558	16.30 (3.98), 198	16.96 (3.79), 193	17.03 (3.93), 196	17.04 (3.88), 198	16.28 (3.99), 194	17.34 (3.40), 192	17.05 (3.81), 196	16.93 (3.76), 191
Motivation to quit smoking	18.89 (2.64), 1,555	18.51 (3.18), 196	19.09 (2.68), 195	19.02 (2.30), 196	18.92 (2.46), 198	18.69 (3.05), 195	19.09 (2.22), 192	18.88 (2.58), 194	18.94 (2.47), 189
Smoking abstinence self-efficacy score	40.66 (13.92), 1,543	39.77 (13.95), 196	40.93 (14.14), 191	41.07 (13.72), 195	42.54 (13.63), 196	39.86 (14.12), 192	41.21 (14.16), 190	39.62 (14.26), 193	40.22 (13.39), 190
Intention-to-quit score	8.12 (2.13), 1,571	8.09 (2.13), 198	8.13 (2.13), 196	8.15 (2.11), 197	8.20 (2.20), 199	7.89 (2.19), 197	8.17 (2.12), 194	8.25 (1.98), 197	8.06 (2.18), 193
Willing to quit in the next month, n (%)									
No	28 (1.78%)	3 (1.52%)	2 (1.02%)	0 (0%)	3 (1.51%)	5 (2.54%)	7 (3.61%)	3 (1.52%)	5 (2.59%)
Yes	1511 (96.18%)	189 (95.45%)	187 (95.41%)	193 (97.97%)	193 (96.98%)	188 (95.43%)	184 (94.85%)	191 (96.95%)	186 (96.37%)
Mobile phone usage									
Minutes per day spent on mobile phone, mean (sd), n	282.56 (293.79), 1,558	318.79 (468.37), 198	255.36 (224.15), 193	248.22 (220.34), 197	261.62 (256.37), 197	279.82 (254.22), 194	275.41 (279.87), 194	320.98 (311.73), 195	300.38 (247.75), 190
Type of mobile phone owned, n (%)									
Simple mobile phone (no internet capabilities)	174 (11.08%)	26 (13.13%)	21 (10.71%)	19 (9.64%)	25 (12.56%)	24 (12.18%)	21 (10.82%)	23 (11.68%)	15 (7.77%)
Smartphone	1364 (86.82%)	167 (84.34%)	173 (88.27%)	176 (89.34%)	165 (82.91%)	169 (85.79%)	170 (87.63%)	170 (86.29%)	174 (90.16%)
Frequency of text messaging, n (%)									

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Multiple times per day	374 (23.81%)	42 (21.21%)	45 (22.96%)	49 (24.87%)	60 (30.15%)	48 (24.37%)	43 (22.16%)	42 (21.32%)	45 (23.32%)
Everyday	349 (22.22%)	49 (24.75%)	43 (21.94%)	52 (26.40%)	49 (24.62%)	35 (17.77%)	38 (19.59%)	38 (19.29%)	45 (23.32%)
Weekly	299 (19.03%)	37 (18.69%)	40 (20.41%)	35 (17.77%)	28 (14.07%)	42 (21.32%)	39 (20.10%)	40 (20.30%)	38 (19.69%)
Never	536 (34.12%)	69 (34.85%)	65 (33.16%)	61 (30.96%)	62 (31.16%)	68 (34.52%)	73 (37.63%)	77 (39.09%)	61 (31.61%)
Frequency of using instant messages, n (%)									
Multiple times per day	1081 (68.81%)	140 (70.71%)	128 (65.31%)	141 (71.57%)	137 (68.84%)	138 (70.05%)	126 (64.95%)	131 (66.50%)	140 (72.54%)
Everyday	181 (11.52%)	18 (9.09%)	21 (10.71%)	24 (12.18%)	23 (11.56%)	17 (8.63%)	26 (13.40%)	28 (14.21%)	24 (12.44%)
Weekly	60 (3.82%)	7 (3.54%)	12 (6.12%)	8 (4.06%)	6 (3.02%)	7 (3.55%)	10 (5.15%)	7 (3.55%)	3 (1.55%)
Never	234 (14.89%)	31 (15.66%)	30 (15.31%)	24 (12.18%)	33 (16.58%)	32 (16.24%)	29 (14.95%)	31 (15.74%)	24 (12.44%)
Frequency of using mobile apps for health-related communications, n (%)									
Multiple times per day	67 (4.26%)	9 (4.55%)	15 (7.65%)	6 (3.05%)	9 (4.52%)	7 (3.55%)	10 (5.15%)	3 (1.52%)	8 (4.15%)
Everyday	54 (3.44%)	5 (2.53%)	5 (2.55%)	10 (5.08%)	5 (2.51%)	6 (3.05%)	3 (1.55%)	13 (6.60%)	7 (3.63%)
Weekly	110 (7.00%)	13 (6.57%)	13 (6.63%)	18 (9.14%)	20 (10.05%)	10 (5.08%)	10 (5.15%)	17 (8.63%)	9 (4.66%)
Never	1323 (84.21%)	169 (85.35%)	161 (82.14%)	161 (81.73%)	163 (81.91%)	171 (86.80%)	169 (87.11%)	163 (82.74%)	166 (86.01%)
Frequency of using mobile apps for non-health related communications, n (%)									

Baseline characteristic	Total (n=1,571)	Experimental conditions							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Multiple times per day	918 (58.43%)	109 (55.05%)	108 (55.10%)	127 (64.47%)	110 (55.28%)	124 (62.94%)	106 (54.64%)	115 (58.38%)	119 (61.66%)
Everyday	156 (9.93%)	18 (9.09%)	20 (10.20%)	20 (10.15%)	17 (8.54%)	15 (7.61%)	24 (12.37%)	22 (11.17%)	20 (10.36%)
Weekly	82 (5.22%)	10 (5.05%)	10 (5.10%)	13 (6.60%)	11 (5.53%)	7 (3.55%)	9 (4.64%)	13 (6.60%)	9 (4.66%)
Never	403 (25.65%)	59 (29.80%)	55 (28.06%)	37 (18.78%)	60 (30.15%)	49 (24.87%)	53 (27.32%)	47 (23.86%)	43 (22.28%)
Alcohol drinking behaviour									
Drinking status, n (%)									
Never	669 (42.67%)	84 (42.64%)	80 (41.03%)	85 (43.15%)	93 (46.73%)	76 (38.58%)	83 (42.78%)	87 (44.16%)	81 (42.19%)
Drinks alcohol	899 (57.33%)	113 (57.36%)	115 (58.97%)	112 (56.85%)	106 (53.27%)	121 (61.42%)	111 (57.22%)	110 (55.84%)	111 (57.81%)
AUDIT scores, mean (sd), n	6.21 (7.87), 1,530	6.26 (7.97), 194	6.46 (8.33), 186	6.42 (8.28), 191	6.03 (8.19), 195	6.56 (7.49), 193	5.45 (7.04), 188	6.55 (8.07), 193	5.95 (7.55), 190
Quality of life									
EQ-5D-5L scores, mean (sd), n	0.94 (0.09), 1,545	0.94 (0.11), 195	0.94 (0.10), 192	0.95 (0.08), 193	0.95 (0.09), 196	0.94 (0.08), 196	0.95 (0.08), 190	0.94 (0.09), 193	0.95 (0.09), 190
EQ visual analogue scale, mean (sd), n	78.10 (16.01), 1,560	79.76 (15.53), 197	77.99 (15.13), 193	76.65 (17.99), 196	78.78 (16.12), 197	77.55 (15.14), 196	78.30 (17.48), 192	77.70 (15.58), 197	78.03 (14.94), 192

7.4 Process evaluation

7.4.1 Intervention fidelity

7.4.1.1 Local context affecting intervention fidelity

The ThaiBulkSMS (SMS gateway provider) reported **'anti-spam'** status for 6 out of the first 10 participants that were randomly allocated to experimental groups. This meant that 60% of the participants would not receive any text messages due to their presence on the automatic block list (the "Black List"). In Thailand, the National Broadcasting and Telecommunications Commission—responsible for managing and regulating the telecommunications business—launched the 'stop SMS spam' policy as part of the consumer protection policy in March 2013. This policy allows mobile phone users who wished to stop SMS advertisements via an interactive voice response (IVR) system (*137#), both free and paid SMS. An infographic for this policy is available at http://tcp.nbtc.go.th/website/home/ vdo/834/th (in Thai).

Pritaporn Kingkaew (PK) was not aware that when a mobile number registered with *137, not only will it block current SMS advertisements but all future SMS advertisements as well. This issue was taken to the ThaiBulkSMS because this was a research-based SMS programme and all participants consented to receive SMS from 'iCanQuit'—a new username that was approved by mobile operators on 24 November 2016. The only way to resolve this problem was to apply for the White List by contacting all mobile phone operators who operate the anti-spam system. Subsequently, this process took over three weeks to receive approval from all mobile network operators so that text messages could be sent through to pre-registered 'anti-spam' numbers.

While waiting for the approval, the first text message thanking participants for participating in the trial was sent manually via ThaiBulkSMS to identify the 'anti-spam' status of a particular mobile phone number. If the status showed 'anti-spam', those numbers were withheld from the randomised process until the White List was granted. For mobile numbers that were already randomised and showed the 'anti-spam' status, all text messages were sent again with no requirement to unblind the experimental group. This was feasible due to the design feature of the online platform to accommodate participants who change their mobile numbers. The 'Previous Mobile No.' function was used to retrieve input

information from the mobile number; then the 'Message No.' was reset to 1 to submit the allocated text messages.

7.4.1.2 Reported text messages received

Intervention fidelity was measured objectively from the delivery status reported from the ThaiBulkSMS and subjectively from the self-reported follow-up questionnaire. From the web log, 1,260 participants (80%) received all 60 text messages as intended, 200 participants (13%) received 51-59 texts, and 16 participants (1%) never received any texts (see details in **Figure 7.3**). However, on average, 97% of the participants reported that they had received text messages. **Table 7.3** shows the intervention fidelity by experimental groups.

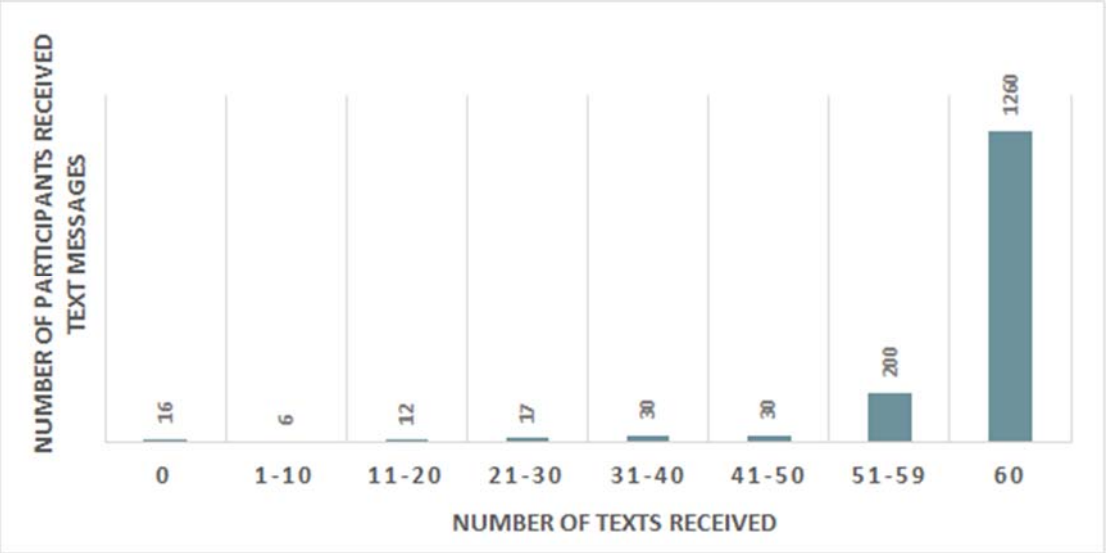


Figure 7.3 The number of participants logged as receiving text messages, by number of texts received

7.4.2 Technology engagement

Table 7.3 shows the technology engagement indicators stratified by experimental groups. Overall, 94% of the participants reported that they had opened (and read) the text messages, while 14% said that they had shared these texts with other smokers. A low level of engagement was observed in participants receiving placebo text messages. Overall, 89% of the participants in the placebo group opened and read their text messages and 9% shared these text messages with other people. Also, the user engagement scale was the lowest among all experimental groups and they were the least likely to subscribe to similar text message programmes in the future.

Table 7.3 Process evaluation results by experimental condition

Process outcomes	All (N = 1571)	Experimental condition							
		Placebo (n=198)	**C** (n=196)	**O** (n=197)	**M** (n=199)	**CO** (n=197)	**CM** (n=194)	**OM** (n=197)	**COM** (n=193)
Intervention fidelity									
Status report from ThaiBulkSMS (%, n)									
Received 60 allocated text messages	80.20%, 1,260	73.74%, 146	82.65%, 162	76.65%, 151	77.39%, 154	84.77%, 167	82.99%, 161	83.24%, 164	80.31%, 155
Received 1-59 allocated text messages	18.78%, 295	24.24%, 48	16.84%, 33	22.84%, 45	20.60%, 41	14.21%, 28	16.49%, 32	15.74%, 31	19.17%, 37
Did not receive any allocated text messages	1.02%, 16	2.02%, 4	0.51%, 1	0.51%, 1	2.01%, 4	1.02%, 2	0.52%, 1	1.02%, 2	0.52%, 1
Reported they received text messages (subjective) (%, n)	97.35%, 1,208	93.84%, 146	99.32%, 147	99.36%, 156	96.82%, 157	95.21%, 146	98.69%, 153	98.06%, 155	97.30%, 148
Technology engagement									
Opened and read text status (%, n)	94.33%, 1,165	88.72%, 133	96.53%, 144	96.10%, 154	92.05%, 151	94.89%, 137	95.33%, 150	97.37%, 152	93.06%, 144
Shared text with others (%, n)	14.12%, 1,154	9.02%, 133	16.67%, 144	9.09%, 154	18.24%, 148	16.42%, 134	14.09%, 149	15.13%, 152	14.29%, 140
User engagement scale (1 – 60) (mean (sd), n)	50.99 (8.60), 1,103	49.51 (9.77), 116	51.94 (8.52), 137	51.16 (8.85), 150	51.77 (8.01), 142	51.62 (7.77), 130	50.88 (8.51), 144	50.60 (8.70), 147	50.26 (8.60), 137
Likelihood of subscribing to similar programme in future (1 – 10) (mean (sd), n)	6.62 (3.31), 1115	6.34 (3.24), 119	6.91 (3.15), 139	6.55 (3.46), 150	6.69 (3.27), 143	7.32 (3.05), 131	6.31 (3.49), 148	6.20 (3.48), 148	6.71 (3.22), 137

7.5 Primary outcome: self-reported 7-day point prevalence abstinence at 1-month follow-up

7.5.1 Descriptive summary of the primary outcome

Overall, 521 participants (40%) reported 7-day smoking abstinence at 1-month follow-up. **Table 7.4** summarises the outcome data at 1-month follow-up by the 8 experimental conditions. Participants who were allocated to receive placebo text messages reported a cessation rate of 39%. A higher rate of smoking abstinence was observed in participants that received BCT-enhanced text messages containing one behaviour change component (C, O, or M). Among those who received at least one behaviour change component, there was a decreasing trend in abstinence rate among those who received an increasing number of behaviour change components. Moreover, participants who were allocated to CO and COM conditions reported a lower abstinence rate than the placebo group. **Figure 7.4** reports the 7-day point prevalence abstinence self-reported at 1-month follow-up by the number of behaviour change components received.

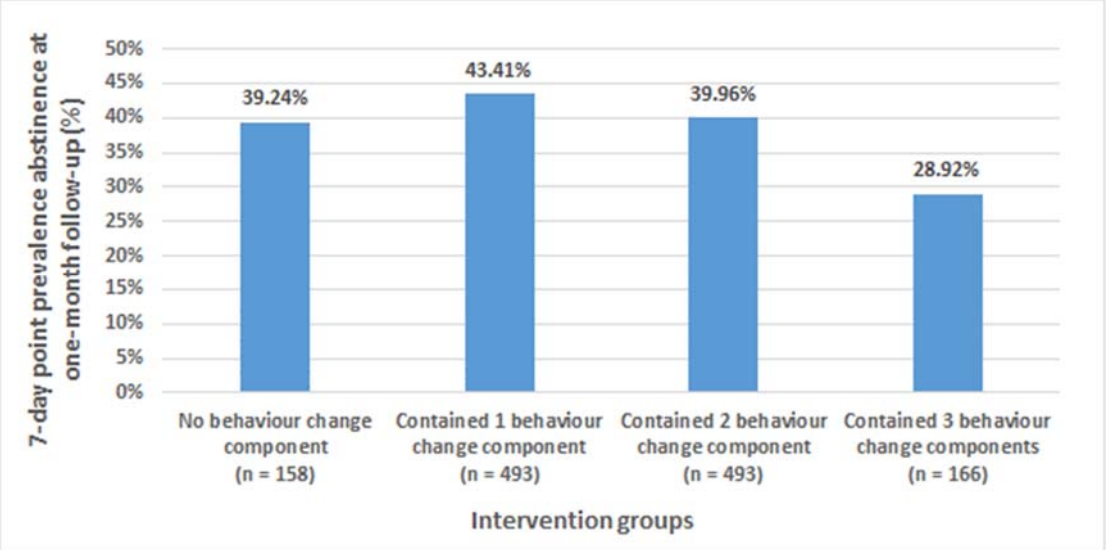


Figure 7.4 7-day point prevalence abstinence at 1-month follow-up based on the number of behaviour change components

Table 7.4 Outcome data summary at 1-month follow-up by experimental conditions

Outcome	Experimental condition							
	Placebo (n=198)	C (n=196)	O (n=197)	M (n=199)	CO (n=197)	CM (n=194)	OM (n=197)	COM (n=193)
Primary outcome, (%, n)								
Self-reported 7-day point prevalence abstinence	39.24%, 158	44.51%, 164	42.42%, 165	43.29%, 164	34.18%, 158	42.07%, 164	43.27%, 171	28.92%, 166
Quality of life, (mean (sd), n)								
EQ-5D-5L scores	0.96 (0.08), 140	0.98 (0.05), 144	0.97 (0.05), 154	0.98 (0.04), 155	0.96 (0.07), 142	0.97 (0.06), 153	0.96 (0.10), 154	0.97 (0.07), 145
Intended behaviour change, (mean (sd), n)								
Capability to quit smoking	17.87 (2.45), 142	18.07 (2.44), 145	18.23 (2.41), 154	18.40 (2.01), 155	17.75 (2.78), 144	18.20 (2.02), 152	18.25 (2.17), 154	17.93 (2.29), 147
Opportunity to support smoking cessation	17.55 (3.49), 142	18.39 (2.43), 145	17.93 (3.24), 154	18.06 (2.79), 155	17.66 (3.15), 144	18.02 (2.88), 151	18.04 (3.17), 154	17.79 (3.21), 146
Motivation to quit smoking	18.95 (2.08), 142	19.22 (1.80), 144	19.26 (2.15), 153	19.31 (1.53), 155	19.04 (2.24), 144	19.22 (1.86), 153	19.29 (1.82), 155	19.03 (1.94), 146
Smoking cessation self-efficacy scores	45.34 (15.09), 141	48.83 (11.96), 142	46.92 (13.60), 153	49.19 (11.43), 154	45.35 (13.93), 142	46.58 (13.76), 151	47.42 (13.26), 154	43.83 (13.74), 145
Intention-to-quit scores	8.37 (2.10), 142	8.72 (1.87), 145	8.62 (1.99), 156	8.74 (1.67), 155	8.34 (2.16), 144	8.59 (1.78), 152	8.85 (1.67), 155	8.27 (2.16), 148
Number of tobacco products used per day	4.54 (6.12), 158	3.43 (5.11), 164	3.24 (4.55), 165	3.41 (5.41), 164	4.54 (6.08), 158	4.24 (6.81), 164	3.47 (4.72), 171	4.68 (5.21), 166
Fagerstrom Test for Nicotine Dependence	1.33 (2.05), 141	0.99 (1.75), 150	0.97 (1.68), 153	1.08 (1.81), 154	1.51 (2.17), 147	1.16 (1.92), 153	0.94 (1.57), 158	1.39 (1.80), 153
AUDIT scores	4.65 (6.82), 141	4.55 (6.36), 143	3.63 (5.92), 154	4.09 (5.91), 153	3.70 (5.57), 141	3.52 (5.20), 149	4.25 (5.96), 155	4.63 (6.26), 147

7.5.2 Primary analysis of the primary outcome

A multivariate logistic regression model was used to estimate the effect of intervention components in BCT-enhanced text messages on self-reported 7-day point-prevalence abstinence at 1-month follow-up. Pre-specified covariates in the model included three main effects (one for each intervention component), interactions between each intervention component, and stratification factors (age group and baseline ITQ group). **Table 7.5** presents the results from two logistic regression models, one based on a complete case analysis, and one where missing values were imputed. In both models, there was no significant difference in smoking abstinence rate between providing BCT-enhanced text messages aimed at supporting smokers' capability to quit, smokers' opportunity to quit, or smokers' motivation to quit compared to BCT-enhanced text messages that did not contain the intervention component.

Smoking abstinence rates at 1-month follow-up did not differ among participant age groups but differed among participant baseline ITQ group. Participants who had a higher baseline ITQ were 3 times more likely to stop smoking (95% CI 2.10 to 4.25, $p<0.001$) than those who had a lower baseline ITQ. The results from the complete case analysis were similar to the one in which missing values were imputed (**Table 7.5**). The predicted probability of 7-day point prevalence abstinence at 1-month follow-up of the main effects and the stratification factors from the logistic regression model based on the complete case analysis is illustrated in **Figure 7.5.**

A further analysis assuming that 17% of the participants (n=261) who were lost follow-up were still smokers did not change the conclusion. There was no significant difference in the smoking abstinence rate between providing BCT-enhanced text messages aimed at supporting smokers' capability to quit, smokers' opportunity to quit, or smokers' motivation to quit compared to BCT-enhanced text messages that did not contain the intervention component (see **Appendix S**, **Table S2**).

Table 7.5 Logistic regression analysis for self-reported 7-day point prevalence abstinence, with pre-specified covariates (the primary analysis)

	Covariates	Odds Ratio	SE	z	P-value	95% CI	
						Lower	Upper
Multiple imputation (50 datasets)	**Stratification factors**						
	High ITQ	2.986	0.537	6.08	**<0.001**	2.099	4.250
	Age group: 31 - 40	0.866	0.130	-0.95	0.340	0.645	1.164
	Age group: above 40	0.867	0.114	-1.08	0.280	0.670	1.123
	Main effects						
	C	1.197	0.270	0.80	0.425	0.769	1.864
	O	1.051	0.239	0.22	0.829	0.672	1.643
	M	1.133	0.256	0.55	0.581	0.727	1.766
	Interactions						
	C and O	0.609	0.199	-1.52	0.129	0.321	1.155
	C and M	0.793	0.255	-0.72	0.471	0.422	1.490
	O and M	0.893	0.284	-0.36	0.723	0.479	1.666
	C, O, and M	0.998	0.452	0.00	0.997	0.410	2.428
	Constant	0.282	0.068	-5.26	**<0.001**	0.176	0.453
Complete case analysis (n = 1,310)	**Stratification factors**						
	High ITQ	2.994	0.536	6.12	**<0.001**	2.108	4.253
	Age group: 31 - 40	0.890	0.135	-0.77	0.440	0.661	1.197
	Age group: above 40	0.903	0.119	-0.77	0.441	0.698	1.169
	Main effects						
	C	1.233	0.284	0.91	0.363	0.785	1.938
	O	1.112	0.257	0.46	0.645	0.708	1.748
	M	1.156	0.267	0.63	0.529	0.736	1.817
	Interactions						
	C and O	0.567	0.186	-1.73	0.084	0.298	1.078
	C and M	0.764	0.247	-0.83	0.406	0.405	1.441
	O and M	0.875	0.282	-0.41	0.679	0.466	1.645
	C, O, and M	1.017	0.471	0.04	0.970	0.411	2.518
	Constant	0.275	0.065	-5.47	**<0.001**	0.173	0.437

Sample: Intention-to-treat sample

Note: Bold indicates $p < .05$; SE: standard error; CI: confidence interval.

C: received messages aimed at increasing smokers' capability to quit (C, CO, CM, and COM); **O:** received messages aimed at increasing opportunity to support smoking cessation (O, CO, OM, and COM); and **M:** received messages aimed at increasing motivation to quit (M, CM, OM, and COM); **High ITQ**: High intention-to-quit scores at baseline

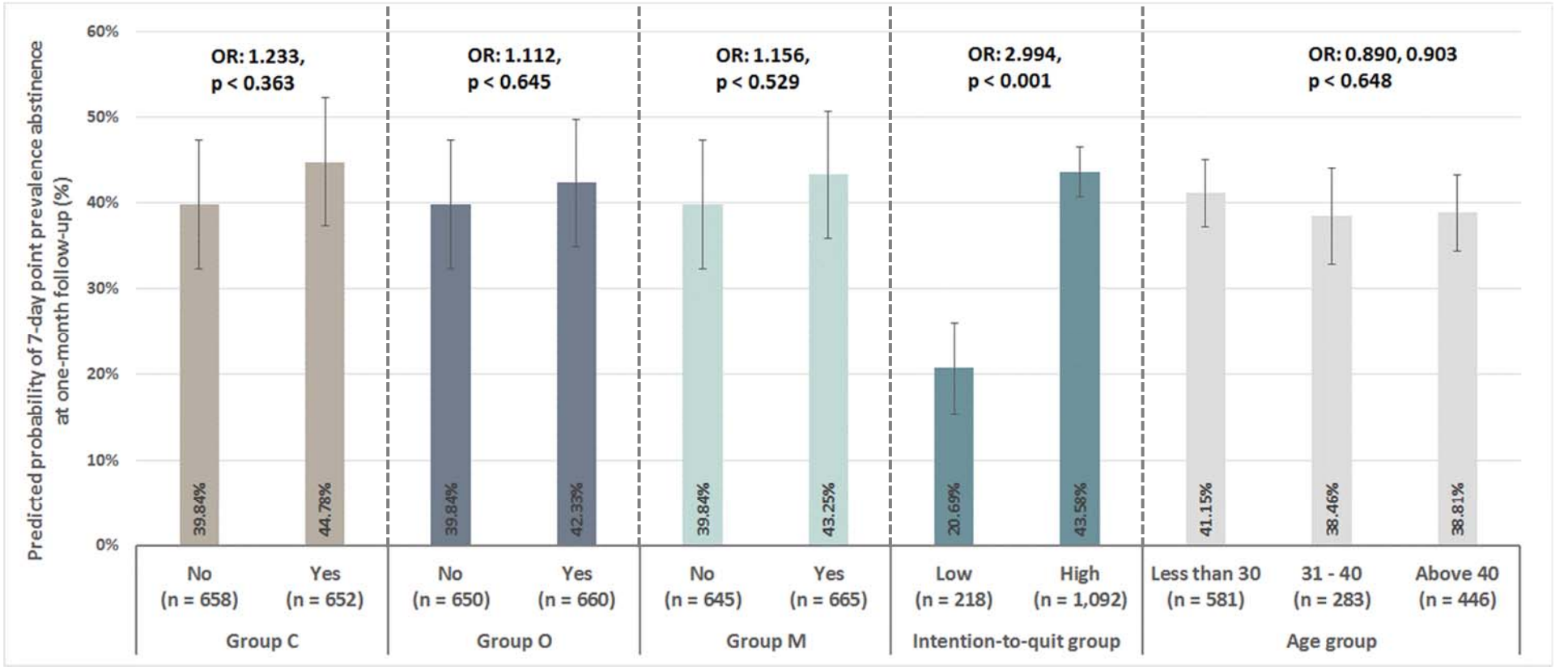


Figure 7.5 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by the main effect of text message groups and stratification factors (complete case analysis)

Overall, the addition of intervention components of two or more groups of BCT-enhanced text messages was associated with a decrease in the odds of quitting. **Figure 7.6** illustrates the 3-way interactions of the three behaviour change components. The plot on the left presents the experimental condition where there was no 'Motivation' component (Group M = No) and the plot on the right shows the condition where 'Motivation' component was provided (Group M = Yes). The blue lines represent the absence of 'Opportunity' component (Group O = No) whereas the red dotted lines denote the presence of 'Opportunity' component (Group O = Yes). These results suggest that there was a trend for an **antagonistic interaction**, where the effect of two intervention components was less than the sum of the effect of each component. However, it was not statistically significant (see interactions subsection in **Table 7.5**). The results showed that the predicted probability of smoking cessation for experimental group CO and COM were lower than the placebo group, both from complete case analysis and a multiply imputed dataset. **Figure 7.7** shows the predicted probability of 7-day point prevalence abstinence at 1-month follow-up for all experimental groups (more information in **Appendix S, Table S3**).

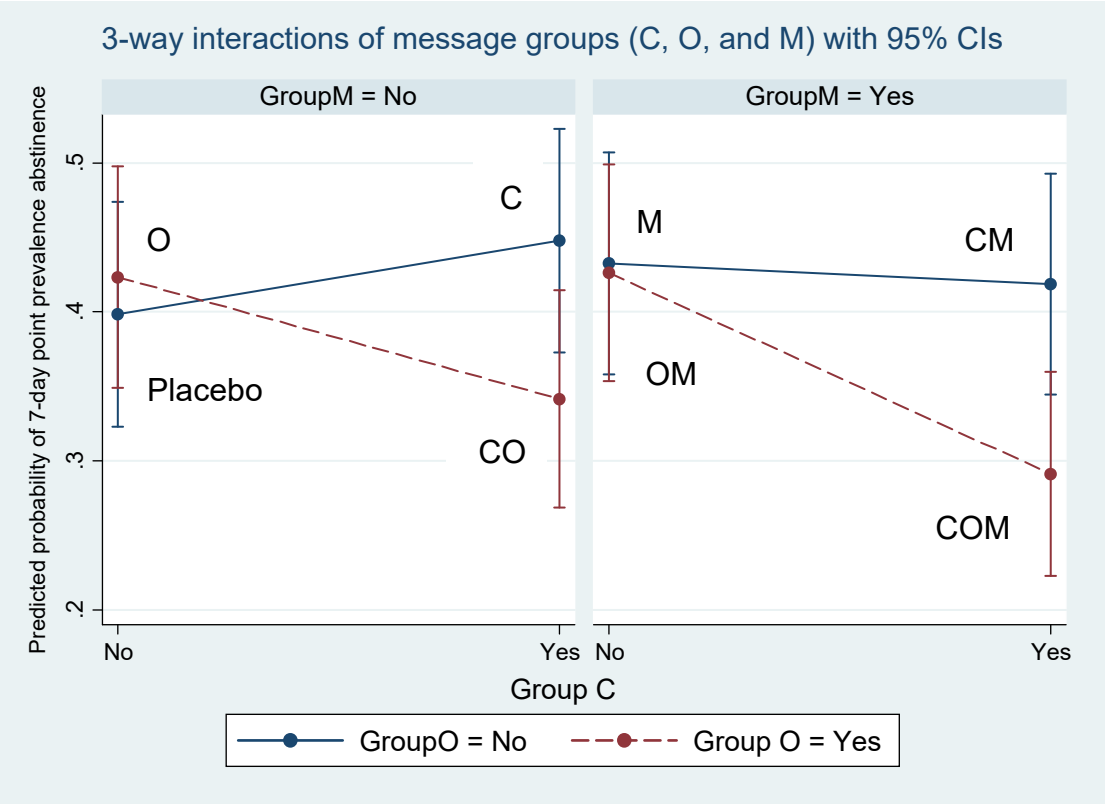


Figure 7.6 Three-way interactions of the intervention components: 'Capability', 'Opportunity', and 'Motivation'

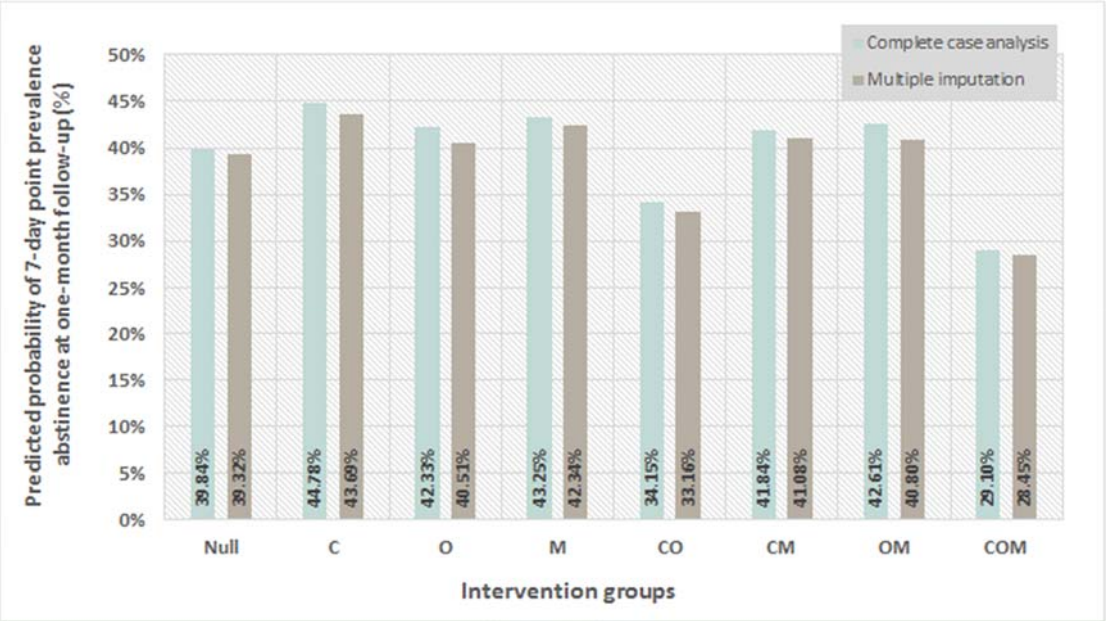


Figure 7.7 Predicted probability of the primary outcome from the logistic regression model: the primary analysis

7.5.3 Sensitivity analysis of the primary outcome

A logistic regression model was used to estimate the effect of intervention components in BCT-enhanced text messages on self-reported 7-day point-prevalence smoking abstinence at 1-month follow-up under 4 scenarios: 1) the participants receiving the intended 60 text messages, 2) the participants who reported that they received text messages, 3) the participants who reported that they read the text messages, and 4) adjusted for employment status, daily smoking status, number of tobacco products smoke, hazardous and harmful use of alcohol, and baseline self-efficacy. Providing BCT-enhanced text messages aimed at supporting smokers' capability to quit, smokers' opportunity to quit, or smokers' motivation to quit failed to significantly improve smoking abstinence rate compared to no intervention component. **Table 7.6** and **Figure 7.8** shows the predicted probability of 7-day point prevalence abstinence at 1-month follow-up for the eight experimental groups.

Table 7.6 Sensitivity analyses to assess self-reported 7-day point-prevalence smoking abstinence at 1-month follow-up

(a) multiple imputation analysis

		Intention-to-treat (n=1,571)		Per-protocol (n=1,260)		Text messages received (n=1,176)		Text messages read (n=1,099)		Adjusted for covariates (n=1,571)	
Multiple imputation (50 datasets)	**Covariates**	**OR**	**p-value**	**OR**	**p-value**	**OR**	**p-value**	**OR**	**p-value**	**OR**	**p-value**
	Stratification factors										
	High ITQ	2.986	**<0.001**	3.443	**<0.001**	2.781	**<0.001**	2.588	**<0.001**	2.180	**<0.001**
	Age group: 31 - 40	0.866	0.340	0.865	0.376	0.862	0.351	0.930	0.654	0.937	0.688
	Age group: above 40	0.867	0.280	0.933	0.627	0.873	0.326	0.921	0.565	0.784	0.092
	Main effects										
	C	1.197	0.425	0.995	0.983	1.136	0.602	1.044	0.867	1.186	0.478
	O	1.051	0.829	1.008	0.975	1.032	0.896	0.911	0.710	1.005	0.982
	M	1.133	0.581	0.926	0.754	1.135	0.599	0.978	0.930	1.034	0.890
	Interactions										
	C and O	0.609	0.129	0.687	0.288	0.598	0.137	0.637	0.208	0.664	0.237
	C and M	0.793	0.471	0.998	0.996	0.726	0.344	0.824	0.582	0.860	0.661
	O and M	0.893	0.723	0.995	0.989	0.878	0.699	1.075	0.836	1.087	0.805
	C, O, and M	0.998	0.997	0.859	0.757	1.090	0.860	1.002	0.998	0.767	0.582
	Constant	0.282	<0.001	0.270	<0.001	0.336	<0.001	0.390	<0.001	0.135	<0.001

C: received messages aimed at increasing smokers' capability to quit (C, CO, CM, and COM); **O:** received messages aimed at increasing opportunity to support smoking cessation (O, CO, OM, and COM); and **M:** received messages aimed at increasing motivation to quit (M, CM, OM, and COM); **High ITQ**: High intention-to-quit scores at the baseline; **OR**: odds ratio.

Adjusted for covariates: Employed group, status of daily smoke group, high number of cigarette smoke group, hazardous and harmful use of alcohol group, and baseline smoking cessation self-efficacy scores

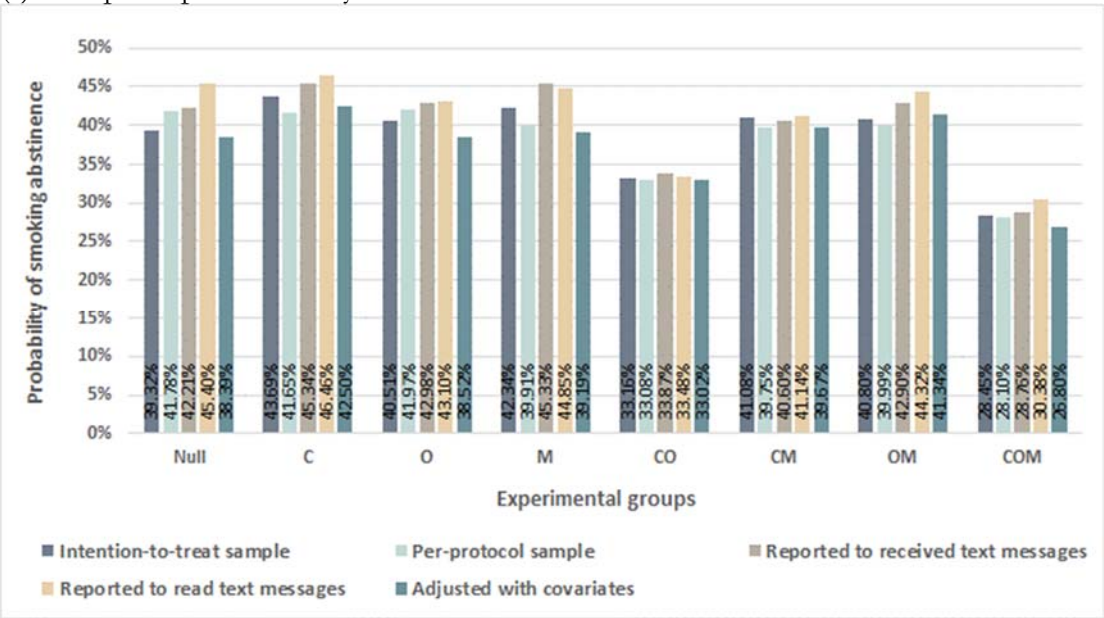
(b) complete case analysis

	Covariates	Intention-to-treat (n=1,310)		Per-protocol (n=1,117)		Text messages received (n=1,176)		Text messages read (n=1,099)		Adjusted for covariates (n=1,229)	
		OR	p-value	OR	p-value	OR	p-value	OR	p-value	OR	p-value
Complete case analysis	**Stratification factors**										
	High ITQ	2.994	**<0.001**	3.403	**<0.001**	2.781	**<0.001**	2.588	**<0.001**	2.336	**<0.001**
	Age group: 31 - 40	0.890	0.440	0.890	0.478	0.862	0.351	0.930	0.654	0.868	0.398
	Age group: above 40	0.903	0.441	0.964	0.799	0.873	0.326	0.921	0.565	0.746	0.050
	Main effects										
	C	1.233	0.363	0.993	0.978	1.136	0.602	1.044	0.867	1.083	0.756
	O	1.112	0.645	1.049	0.851	1.032	0.896	0.911	0.710	1.031	0.906
	M	1.156	0.529	0.935	0.790	1.135	0.599	0.978	0.930	0.982	0.943
	Interactions										
	C and O	0.567	0.084	0.657	0.239	0.598	0.137	0.637	0.208	0.687	0.307
	C and M	0.764	0.406	0.959	0.905	0.726	0.344	0.824	0.582	1.025	0.945
	O and M	0.875	0.679	0.947	0.878	0.878	0.699	1.075	0.836	1.106	0.777
	C, O, and M	1.017	0.970	0.912	0.854	1.090	0.860	1.002	0.998	0.709	0.497
	Constant	0.275	<0.001	0.275	<0.001	0.336	<0.001	0.390	<0.001	0.119	<0.001

C: received messages aimed at increasing smokers' capability to quit (C, CO, CM, and COM); **O:** received messages aimed at increasing opportunity to support smoking cessation (O, CO, OM, and COM); and **M:** received messages aimed at increasing motivation to quit (M, CM, OM, and COM); **High ITQ**: High intention-to-quit scores at the baseline; **OR**: odds ratio.

Adjusted for covariates: Employment status, smoking frequency, number of tobacco products smoked, alcohol use, and baseline smoking cessation self-efficacy scores

(a) multiple imputation analysis



(b) complete case analysis

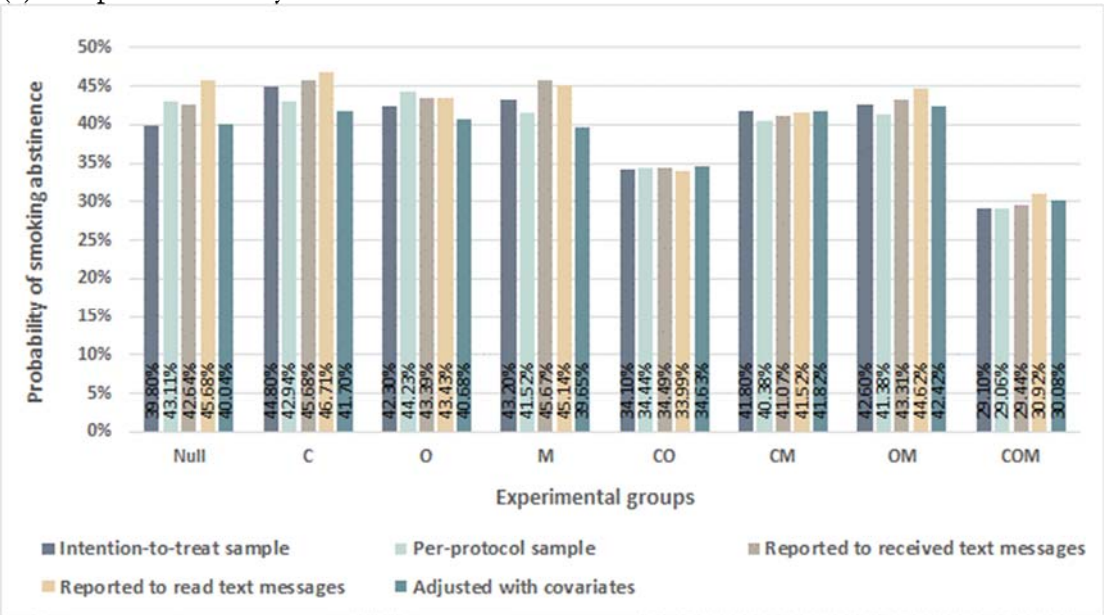


Figure 7.8 Predicted probability of the 7-day point prevalence abstinence at 1-month follow-up from the logistic regression model: the sensitivity analysis

7.5.4 Subgroup analysis of the primary outcome

Logistic regression models with pre-specified interaction terms between the intervention components and the following baseline variables: age group, ITQ group, gender, smoking dependence, light smoker, and alcohol dependence were conducted. The odds ratio for smoking cessation in participants who received BCT-enhanced text messages containing 'Capability' component (C, CO, CM, and COM) were found to differ between two subgroups: ITQ and alcohol dependence (**Table 7.7**). Providing BCT-enhanced text messages containing 'Capability' component increased the smoking cessation rate by 1.6-fold in smokers with low ITQ and 1.2-fold in smokers with alcohol dependence. The predicted probability of 7-day point prevalence abstinence at 1-month follow-up for each subgroup is illustrated from **Figure 7.9** to **Figure 7.14**.

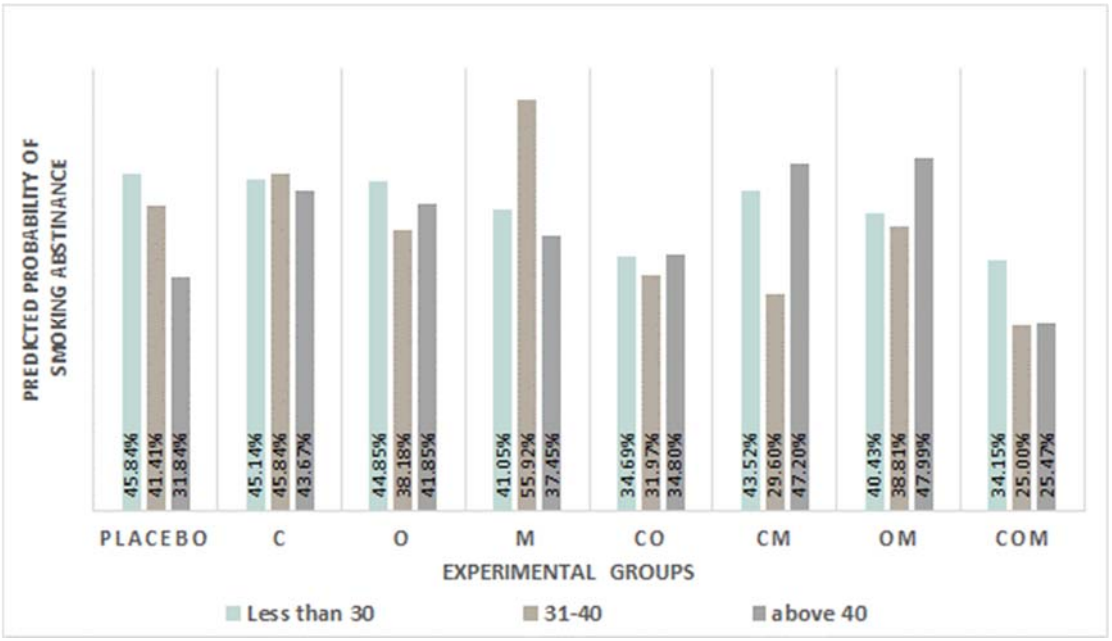


Figure 7.9 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by experimental groups and age group

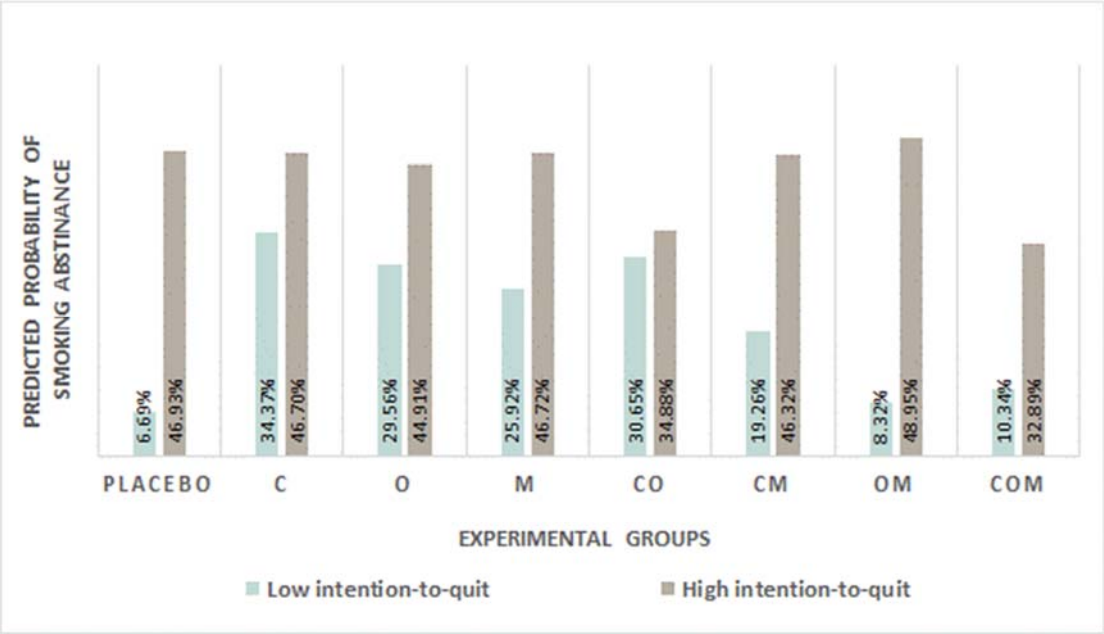


Figure 7.10 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by experimental groups and level of intention-to-quit

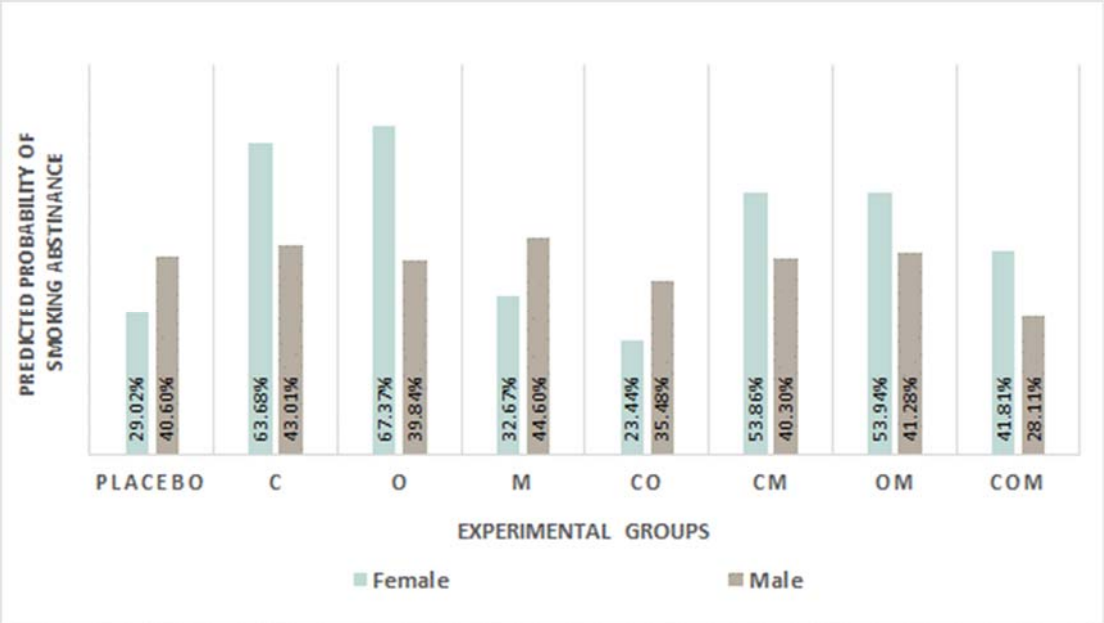


Figure 7.11 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by experimental groups and gender

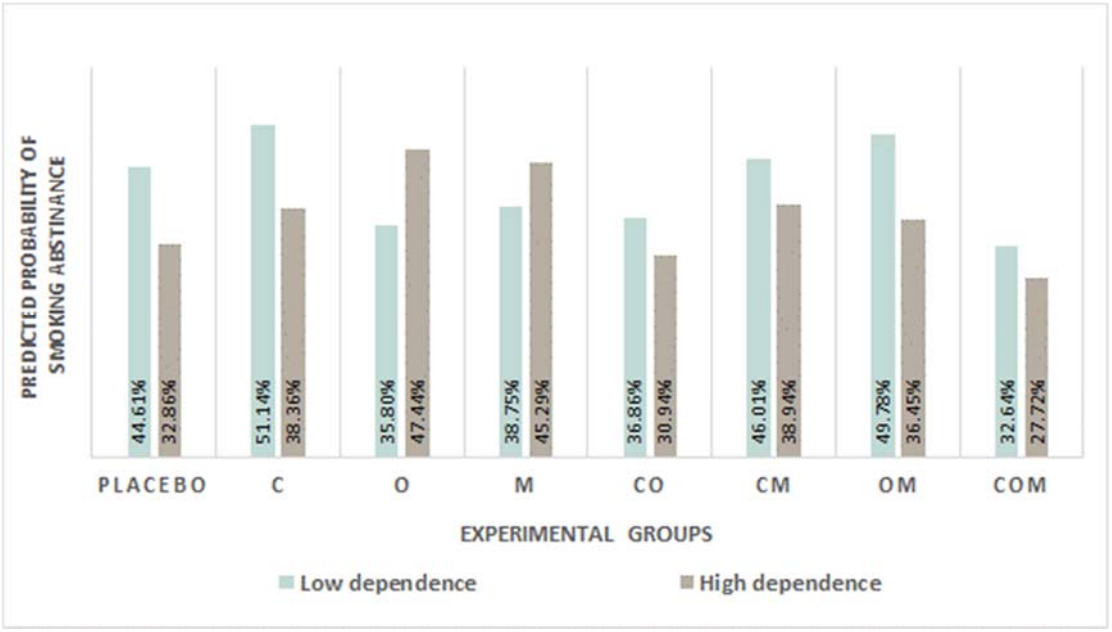


Figure 7.12 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by experimental groups and level of nicotine dependence

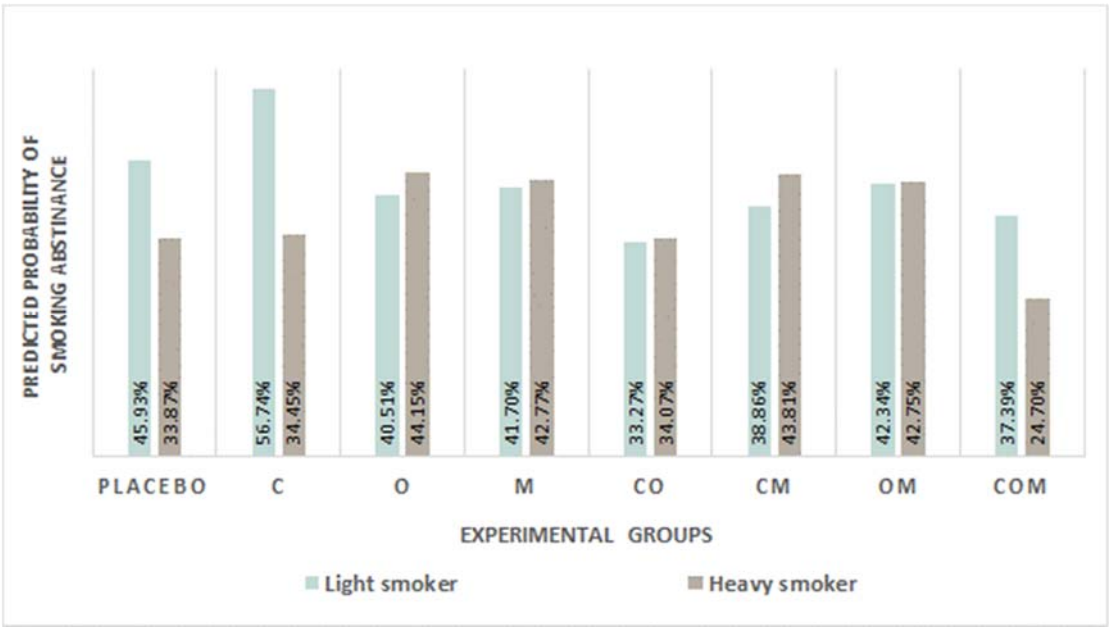


Figure 7.13 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by experimental groups and type of smoker

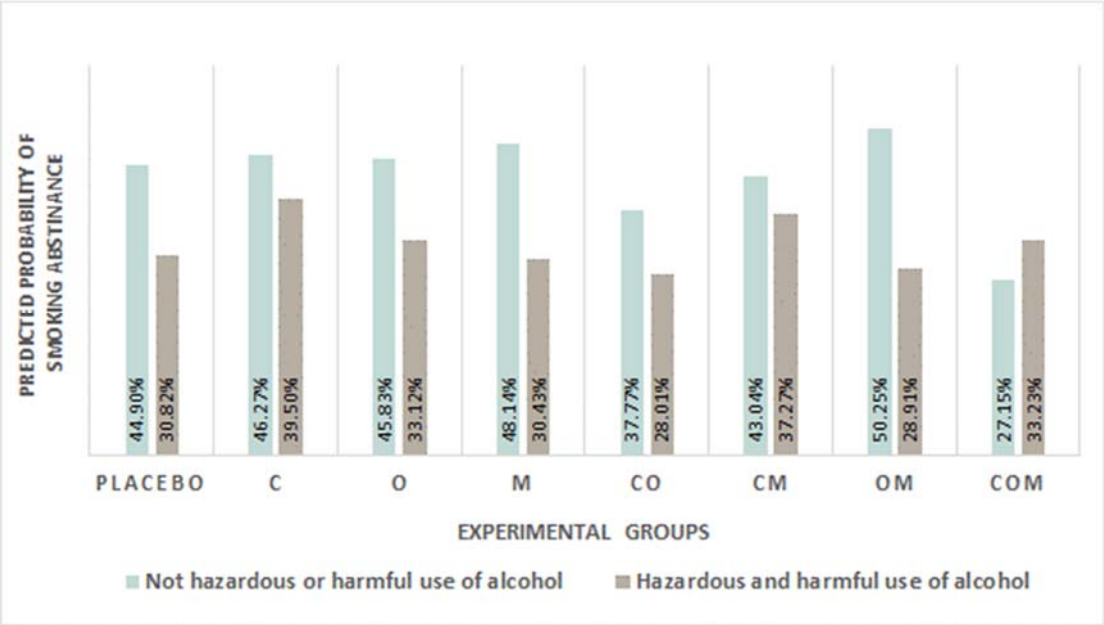


Figure 7.14 Predicted probability of 7-day point prevalence abstinence at 1-month follow-up, by experimental groups and alcohol use

Table 7.7 Subgroup analyses of self-reported 7-day point prevalence abstinence at 1-month follow-up

Subgroups	Group C		Group O		Group M	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
Age group (years)						
Less than 30	0.85 (0.61 – 1.19)	0.4740	0.79 (0.57 – 1.11)	0.5990	0.89 (0.63 – 1.24)	0.7551
31 – 40	0.62 (0.38 – 1.02)		0.65 (0.40 – 1.07)		0.89 (0.54 –1.47)	
Above 40	0.90 (0.61 – 1.33)		0.89 (0.60 – 1.31)		1.05 (0.71 –1.56)	
Baseline intention to quit level						
Low	1.60 (0.74 – 3.42)	**0.0368**	0.87 (0.41 – 1.87)	0.4911	0.59 (0.27 – 1.26)	0.1032
High	0.75 (0.59 – 0.96)		0.77 (0.61 – 0.98)		1.01 (0.80 – 1.29)	
Gender						
Female	0.98 (0.45 – 2.13)	0.5933	1.08 (0.50 – 2.34)	0.3764	1.00 (0.46 – 2.17)	0.9398
Male	0.80 (0.63 – 1.02)		0.77 (0.60 – 0.97)		0.94 (0.74 – 1.20)	
Baseline FTND score						
0-2 (low)	0.97 (0.68 – 1.37)	0.2775	0.76 (0.54 – 1.09)	0.5994	0.99 (0.70 – 1.41)	0.9459
3-10 (high)	0.75 (0.55 – 1.01)		0.86 (0.63 – 1.17)		0.98 (0.72 – 1.33)	
Baseline number of tobacco products used per day						
≤5 (light)	0.95 (0.67 – 1.34)	0.2995	0.73 (0.52 – 1.04)	0.3677	0.85 (0.60 – 1.20)	0.2808
>5 (moderate to heavy)	0.73 (0.54 – 1.00)		0.89 (0.65 – 1.20)		1.07 (0.79 – 1.45)	
AUDIT score:						
<8 (non hazardous or harmful use of alcohol)	0.68 (0.51 – 0.90)	**0.0231**	0.79 (0.59 – 1.04)	0.7626	0.92 (0.70 – 1.23)	0.8469
≥8 (hazardous and harmful use of alcohol)	1.18 (0.78 – 1.78)		0.84 (0.56 – 1.27)		0.98 (0.65 – 1.48)	

Sample: complete case analysis

7.5.5 Hypothesis generating: assessing the effect of baseline intention-to-quit smoking on smoking cessation at 1-month

In the previous section, logistic regression results for each additional interaction term between the subgroup covariates and intervention components showed similar results to the primary analysis except for the subgroup analysis of baseline ITQ. Therefore, the effects of baseline ITQ were further explored. **Figure 7.15** shows the proportion of participants with ITQ scores from 1 to 10 at baseline and 1-month follow-up. There was a higher proportion of participants with an ITQ score of 10 at 1-month follow-up and there was only a small proportion of participants with ITQ score from 1 to 4. Consequently, interaction terms between pre-specified ITQ groups (1-5 and 6-10) and the intervention components were added into the primary analysis model to explore the effect of intervention components in BCT-enhanced text messages.

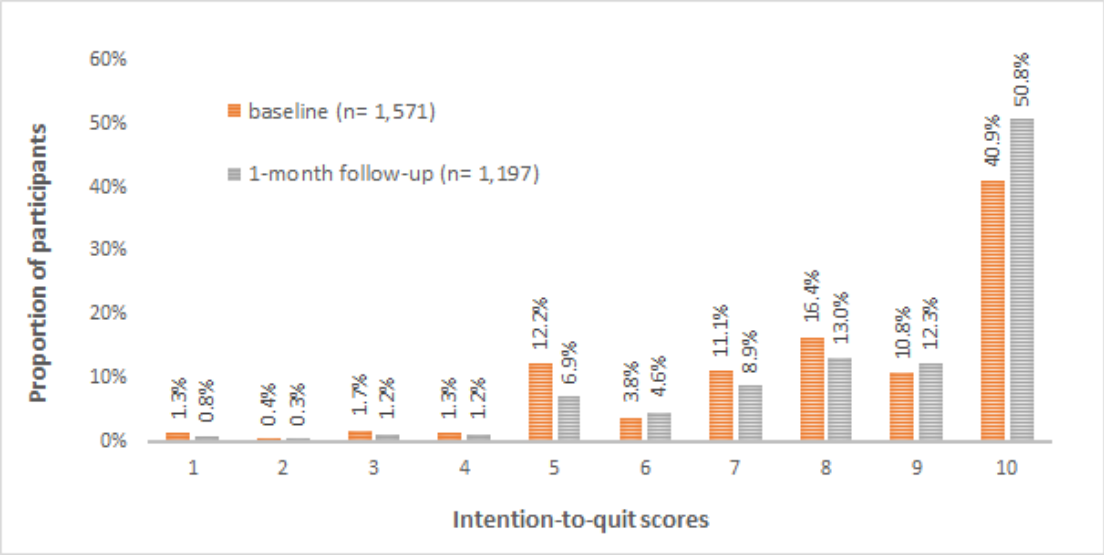


Figure 7.15 Proportion of participants who reported intention-to-quit smoking, before and after receiving text messages

Provision of BCT-enhanced text messages that contained 'capability' component (Group C vs no Group C: OR 7.31, 95% CI 1.44 to 37.17), 'opportunity' component (Group O vs no Group O: OR 5.85, 95% CI 1.12 to 30.66) significantly improved smoking cessation rates at 1-month follow-up. However, provision of BCT-enhanced text messages that contained 'motivation' component (Group M vs no Group M: OR 4.88, 95% CI 0.92 to

26.01) did not significantly improve smoking cessation rates at 1-month follow-up (see **Table 7.8**). In addition, there were significant antagonistic interaction effects when adding 'motivation' component with 'capability' component (CM), or with 'opportunity' component (OM). Similar results were observed with the multiply imputed dataset except that provision of messages aimed at increasing opportunity to support smoking cessation group O to high ITQ participants did not significantly decrease the smoking cessation rate. Predicted probabilities of smoking cessation for all treatment groups were higher than the placebo group when participants had lower ITQ scores (**Figure 7.10**).

Figure 7.16 illustrates the interactions between providing text messages aimed at different behaviour change components and participant's baseline ITQ group. For participants with a low intention-to-quit score at baseline, there was a higher smoking cessation rate in participants who received any intervention component compared to the placebo group. For participants who had a high baseline intention-to-quit score, there was a reduction in smoking cessation rate when they received BCT-enhanced text messages that contained 'capability' and 'opportunity' component (CO) or all components (COM) (**Appendix S, Table S4**).

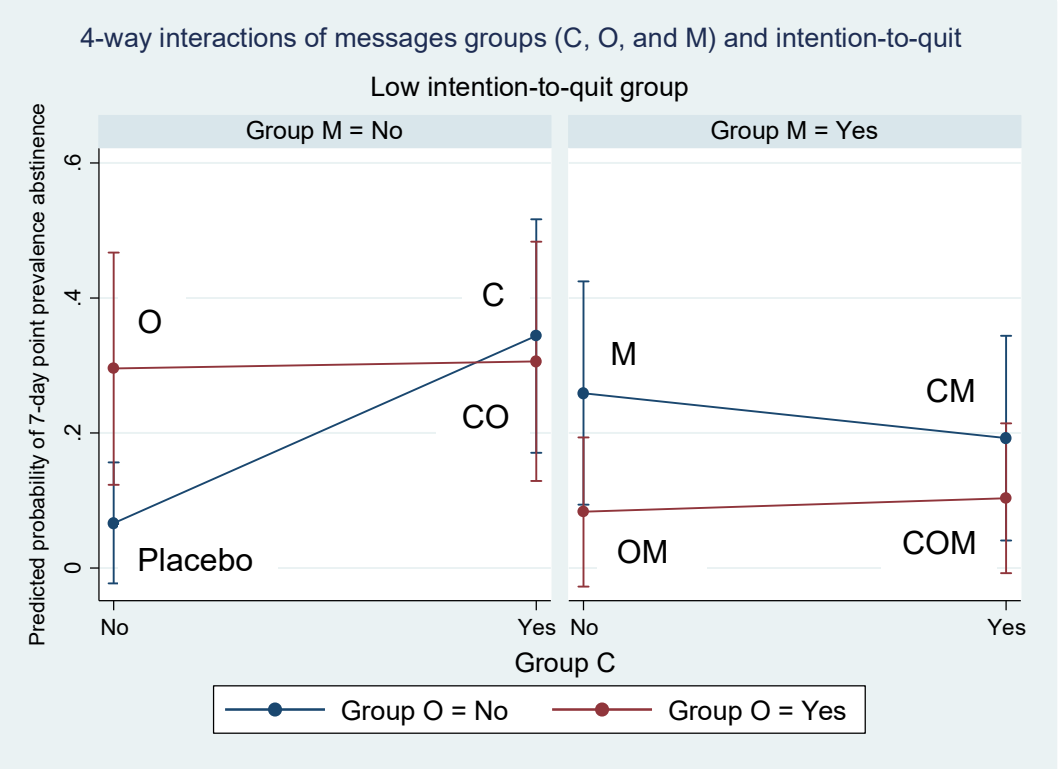
Table 7.8 Logistic regression analysis for self-reported 7-day point prevalence abstinence, with pre-specified covariates (hypothesis generating)

	Covariate	Odds Ratio	SE	z	P-value	95% CI	
						Lower	Upper
Complete case analysis (n = 1,310)	**Stratification factors**						
	High ITQ	12.343	9.296	3.340	**0.001**	2.821	54.012
	Age group: 31 - 40	0.895	0.136	-0.730	0.466	0.665	1.206
	Age group: above 40	0.909	0.120	-0.720	0.473	0.702	1.178
	Main effects						
	C	7.309	6.065	2.400	**0.017**	1.437	37.168
	O	5.854	4.946	2.090	**0.036**	1.118	30.660
	M	4.880	4.166	1.860	0.063	0.916	26.008
	Interactions						
	C and O	0.144	0.147	-1.890	0.058	0.019	1.071
	C and M	0.093	0.099	-2.230	**0.026**	0.012	0.749
	O and M	0.044	0.053	-2.590	**0.010**	0.004	0.470
	C and High ITQ	0.136	0.117	-2.310	**0.021**	0.025	0.740
	O and High ITQ	0.157	0.139	-2.100	**0.036**	0.028	0.883
	M and High ITQ	0.203	0.181	-1.790	0.073	0.036	1.159
	C, O, and M	12.934	20.059	1.650	0.099	0.619	270.278
	C, O, and High ITQ	4.599	4.977	1.410	0.158	0.552	38.347
	C, M, and High ITQ	10.643	11.896	2.120	**0.034**	1.190	95.158
	O, M, and High ITQ	26.796	33.568	2.620	**0.009**	2.300	312.167

	Covariate	Odds Ratio	SE	z	P-value	95% CI	
						Lower	Upper
	C, O, M, and High ITQ	0.061	0.099	-1.720	0.085	0.002	1.470
	Constant	0.076	0.056	-3.510	**<0.001**	0.018	0.320
Multiple imputation (50 datasets)	**Stratification factors**						
	High ITQ	8.946	6.290	3.12	**0.002**	2.252	35.528
	Age group: 31 - 40	0.866	0.131	-0.95	0.342	0.644	1.165
	Age group: above 40	0.867	0.115	-1.08	0.282	0.669	1.124
	Main effects						
	C	5.053	4.033	2.03	**0.043**	1.056	24.177
	O	4.111	3.325	1.75	0.081	0.841	20.094
	M	3.753	3.035	1.64	0.102	0.768	18.338
	Interactions						
	C and O	0.189	0.187	-1.68	0.093	0.027	1.322
	C and M	0.121	0.125	-2.05	**0.041**	0.016	0.915
	O and M	0.064	0.076	-2.31	**0.021**	0.006	0.664
	C and High ITQ	0.200	0.164	-1.96	**0.050**	0.040	0.999
	O and High ITQ	0.219	0.182	-1.83	0.067	0.043	1.114
	M and High ITQ	0.265	0.221	-1.60	0.111	0.052	1.355
	C, O, and M	11.469	17.304	1.62	0.106	0.595	221.140
	C, O, and High ITQ	3.679	3.825	1.25	0.210	0.479	28.255
	C, M, and High ITQ	8.234	8.833	1.97	**0.049**	1.005	67.484
	O, M, and High ITQ	18.663	22.797	2.40	**0.017**	1.699	205.063
	C, O, M, and High ITQ	0.066	0.104	-1.73	0.083	0.003	1.432
	Constant	0.104	0.073	-3.24	**0.001**	0.026	0.410

Note: C: received messages aimed at increasing smokers' capability to quit (C, CO, CM, and COM); **O:** received messages aimed at increasing opportunity to support smoking cessation (O, CO, OM, and COM); and **M:** received messages aimed at increasing motivation to quit (M, CM, OM, and COM); **High ITQ**: High intention-to-quit scores at baseline; SE: standard error; CI: confidence interval; Bold indicates $p < .05$.

(a) Low intention-to-quit group



(b) High intention-to-quit group

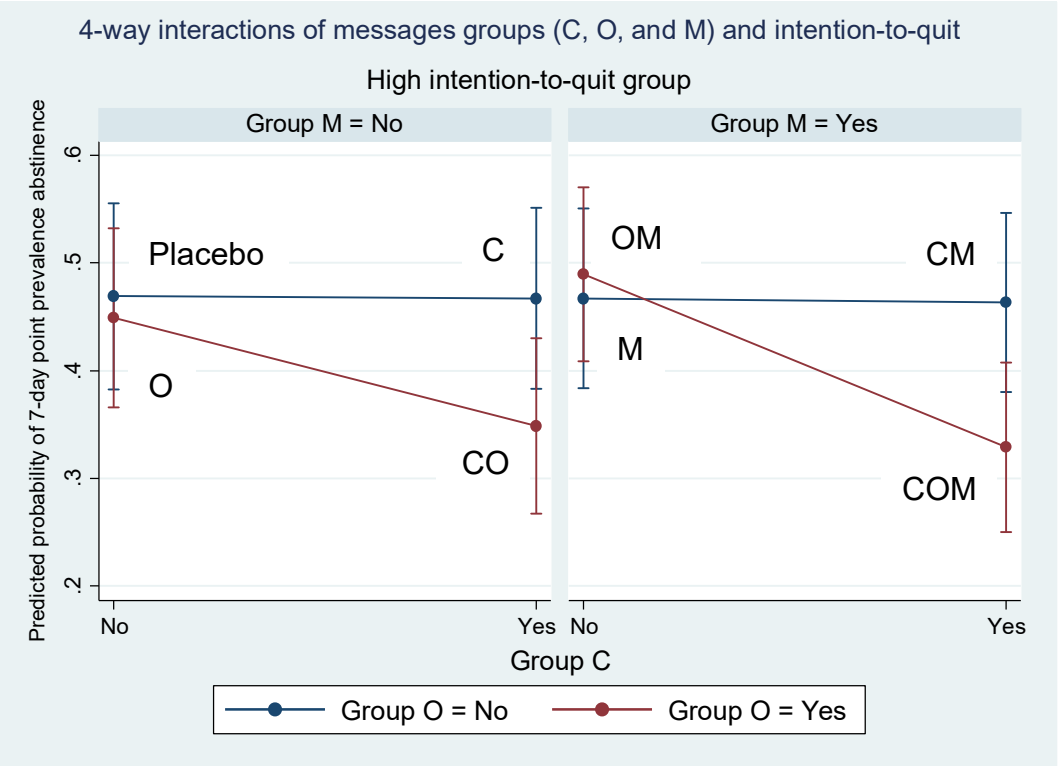


Figure 7.16 Four-way interactions of the intervention components ('Capability', 'Opportunity', and 'Motivation') and intention-to-quit group

7.6 Secondary outcome

7.6.1 Descriptive summary

On average, participants had a slightly higher mean EQ-5D-5L score at 1-month follow-up (0.97 ± 0.07 SD) compared to baseline (0.94 ±0.09 SD). Participants had higher intended behaviour change scores when comparing the scores at the baseline and 1-month follow-up, namely capability to quit score (16.84 ±3.23 SD versus 18.09 ±2.33 SD), opportunity to support smoking cessation score (16.86 ±3.83 SD versus 17.93 ±3.06 SD), motivation to quit score (18.89 ±2.64 SD versus 19.17 ±1.94 SD), smoking cessation self-efficacy scores (40.66 ±13.92 SD versus 46.71 ±13.44 SD), and ITQ score (8.12 ±2.13 SD versus 8.57 ±1.93 SD). Participants, on average, reported using lower numbers of tobacco products per day and had less dependence on tobacco at 1-month follow-up (3.94 ±5.55 SD and 1.17 ±1.85 SD, respectively) compared to baseline (9.75 ±8.44 and 3.23 ±2.35, respectively). Participants also had a lower mean AUDIT score, indicating lower use of alcohol from 6.21 ±7.87 at the baseline to 4.12 ±6.01 at 1-month follow-up.

Table 7.4 summarises the EQ-5D-5L utility scores and the intended behaviour change at 1-month follow-up by eight experimental conditions. The EQ-5D-5L utility scores of the participants were similar in all experimental conditions ranging from 0.96 to 0.98 at 1-month follow-up. The intended behaviour change scores were observed to be higher in participants who received BCT-enhanced text messages that contained any combinations of intervention components compared to the placebo group, except for capability to quit score in the CO group. Participants who were allocated to CO and COM conditions had a higher number of tobacco products used per day and the nicotine dependence scores and had a lower intention-to-quit score at 1-month follow-up.

7.6.2 Effect of BCT-enhanced text messages on other outcomes

Providing BCT-enhanced text messages aimed at any intervention component did not significantly improve the capability to quit score or motivation to quit score at 1-month follow-up. However, BCT-enhanced text messages containing 'capability' component improved participant's self-reported opportunity to quit score and self-efficacy score at 1-month follow-up. Moreover, provision of BCT-enhanced text messages containing 'motivation' component improved the self-efficacy score. The same antagonistic

interaction trend for providing an additional group of text messages was also present; however, it was not statistically significant for all intended behaviour change measurements. **Table 7.9** reports the censored Poisson regression results for intended behaviour change.

Table 7.10 reports the regression results for smoking behaviour, alcohol use behaviour, and quality of life. In summary, providing BCT-enhanced text messages aimed at any intervention component did not significantly improve smoking behaviour, alcohol use behaviour, or quality of life at 1-month follow-up.

Table 7.9 Censored Poisson regression for intended behaviour change and self-efficacy scores at 1-month follow-up

		Capability to quit scores (n = 1,186)		**Opportunity to quit scores (n = 1,184)**		**Motivation to quit scores (n = 1,180)**		**Smoking cessation self-efficacy (n = 1,162)**	
	Covariates	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value
Complete case analysis	**Stratification factors**								
	Intention-to-quit group: high	**0.041**	**0.043**	0.022	0.286	0.041	0.062	**0.080**	**<0.001**
	Age group: 31 - 40	-0.007	0.724	**-0.043**	**0.028**	-0.019	0.373	-0.015	0.196
	Age group: above 40	0.020	0.230	0.017	0.333	0.004	0.846	0.008	0.452
	Main effects								
	C	0.006	0.841	**0.066**	**0.031**	0.028	0.401	**0.064**	**<0.001**
	O	0.021	0.472	0.026	0.386	0.047	0.155	0.020	0.252
	M	0.036	0.221	0.030	0.320	0.043	0.186	**0.052**	**0.003**
	Interactions								
	C and O	-0.042	0.316	**-0.085**	**0.045**	-0.060	0.207	**-0.094**	**<0.001**
	C and M	-0.027	0.519	-0.069	0.105	-0.039	0.398	**-0.097**	**<0.001**
	O and M	-0.030	0.457	-0.016	0.707	-0.035	0.459	-0.045	0.068
	C, O, and M	0.036	0.538	0.065	0.278	0.017	0.798	0.060	0.088
	Baselines scores	**0.014**	**<0.001**	**0.020**	**<0.001**	**0.020**	**<0.001**	**0.009**	**<0.001**
	Constant	**2.684**	**<0.001**	**2.598**	**<0.001**	**2.685**	**<0.001**	**3.406**	**<0.001**

Table 7.10 Regression models for secondary outcomes at 1-month follow-up

		Number of tobacco products used per day (n = 1,296)*		Fagerstrom Test for Nicotine Dependence (n = 1,174)*		AUDIT scores (n = 1,156)*		EQ-5D-5L utility scores (n = 1,170)**	
	Covariates	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value
Complete case analysis	**Stratification factors**								
	Intention-to-quit group: high	**-0.440**	**<0.001**	**-0.510**	**<0.001**	0.033	0.830	0.002	0.742
	Age group: 31 - 40	0.209	0.063	0.258	0.062	-0.148	0.318	0.001	0.787
	Age group: above 40	**0.213**	**0.029**	**0.293**	**0.014**	**-0.399**	**0.002**	**-0.014**	**0.001**
	Main effects								
	C	-0.142	0.412	-0.233	0.276	-0.027	0.908	0.013	0.104
	O	-0.199	0.251	-0.138	0.516	-0.156	0.492	0.007	0.335
	M	-0.101	0.560	-0.146	0.488	-0.143	0.527	0.013	0.087
	Interactions								
	C and O	0.428	0.079	**0.653**	**0.028**	0.017	0.959	**-0.022**	**0.044**
	C and M	0.209	0.391	0.269	0.366	-0.036	0.910	-0.016	0.133
	O and M	0.184	0.447	0.088	0.766	0.250	0.427	**-0.023**	**0.034**
	C, O, and M	-0.248	0.467	-0.353	0.396	0.170	0.705	**0.030**	**0.046**
	Baselines value/scores	**0.043**	**<0.001**	**0.169**	**<0.001**	**0.086**	**<0.001**	**0.223**	**<0.001**
	Constant	**1.161**	**<0.001**	-0.189	0.364	**0.876**	**<0.001**	**0.758**	**<0.001**
	/lnalpha	0.717		0.761		1.190			
	alpha	2.049		2.140		3.286			

***Negative binomial regression model **Regression model**

7.7 Discussion

7.7.1 Main findings

This trial investigated the effectiveness of the combinations of three intervention components in BCT-enhanced text messages aimed at supporting Thai smokers to quit smoking. Providing BCT-enhanced text messages that contained 'capability', 'opportunity', or 'motivation' components failed to improve the smoking cessation rate at 1-month follow-up compared to text messages that did not contain the intervention component. The sensitivity analysis suggested that there was no change in the conclusion of the results when taking intervention fidelity into account or assuming that participants who were lost to follow-up continued to smoke.

There was a trend for an antagonistic interaction when adding more intervention components, especially for the CO and COM groups. Since this study did not calculate the sample size to be able to detect such interactions, it is still uncertain if the apparent antagonistic interaction was due to the two behaviour change components as alternative explanations are possible. For example, it could have resulted from a reduction in the dosage of some behaviour change components since participants in the CO, CM, and OM groups received 30 texts for each intervention component and participants in the COM group received 20 texts for each intervention component. Participants in the C, O, and M groups received 60 texts for each intervention component. Further research with carefully balanced dosages of each BCTs and behaviour change component should be conducted to confirm this theory.

Alternatively, though the intended behaviour change scores were higher in participants who received BCT-enhanced text messages that contained any intervention components compared to the placebo group, it was observed that participants in the experimental conditions CO and COM had lower intention-to-quit scores, smoked more, and depended more on nicotine compared to other experimental groups at the 1-month follow-up. Therefore, it is unknown whether the decreasing effect of the CO and COM group and the observed antagonistic interaction were from the ability to change the intended behaviour (as the moderating factor) or from the interactions of intervention components

which conflicts with the COM-B model of synergistic interactions between the behaviour change components.

The descriptive results also suggested that participants preferred text messages that contain 'motivation' or 'capability' components since text messages that contain 'opportunity' component received the lowest technology engagement scores. This may be due to text messages about the TNQ such as "Support at your fingertips. Call 1600 Quitline for free" forming the content of around one-quarter of the texts received by this group. Participants may have been familiar with the TNQ and may not have found this extra information useful.

A pre-defined subgroup analysis suggested that BCT-enhanced text messages for tobacco cessation were more beneficial in participants with a low intention-to-quit level compared to participants with a high intention-to-quit level, especially text messages that contained either 'capability' or 'opportunity' components. Since participants who have higher intention-to-quit already plan to stop smoking, the text messages may have added only a small benefit to this group compared to those with low intention-to-quit or even acted as a source of annoyance if they had already quit. However, this result should be regarded as a hypothesis to be confirmed since this was a post-hoc analysis. Careful consideration of this result should be noted since hypothesis testing from multiple subgroup analyses increases the probability of false positive findings (multiplicity); therefore, the significance level to reject the null hypothesis should be reduced to a value much less than 0.05.

When considering the mechanism of behaviour change, there was no significant difference in the two intended behaviour change scores, the capability to quit scores and motivation to quit scores. There was a main effect of 'Capability' text messages which showed an increase in opportunity to quit scores. Also, the 'Capability' text messages and 'Motivation' text messages improved smoking cessation self-efficacy. From this mechanism of change, it might be because the BCT-enhanced text messages did not change the intended target component of behaviour change. Additional intervention for smokers could improve other mechanisms of change, in this case the opportunity to quit scores. Alternatively, it might be that the questionnaire to measure intended behaviour change scores was not sensitive to capture the changes; whereas, the changes was found with smoking cessation self-efficacy (a validated questionnaire). Therefore, the use of this questionnaire for future assessment should involve tests for its reliability and validity.

7.7.2 Comparison with other studies

Providing text messages for smoking cessation has been found to be effective in many studies from developed countries (97, 101, 103, 108, 126, 245). These studies were RCTs with parallel designs and the participant inclusion criterion was willing to quit smoking in 15 to 30 days or willing to set a quit date prior to entering the trial. Moreover, in most studies, the text messages were designed to promote two-way communication, which might be more engaging to smokers. Similar factorial trials with four design features (message tone, navigation autonomy, email reminders, and inclusion of testimonials) for the content of internet-based smoking cessation interventions did not improve outcomes; however, that study reported low intervention engagement where one-third of the participants did not look at the intervention (246). Text messages were provided as standard care for a telephone quitline in the United Kingdom but additional interventions (smoking cessation medicine and intensive counselling) were not found to significantly improve smoking cessation rate over standard care (247).

There were only three participants who contacted the TNQ to stop receiving text messages. The discontinuation rate of text messages was very low in this study (n=3, 0.2%). This might be because the burden on participants to contact the research team via text messages or telephone calls (participants shoulder the cost of texts or calls) may have been too high. The discontinuation rate for this study is lower than in other studies, perhaps because discontinuation of the intervention may have been less of a burden for participants. For example, Naughton *et al.* reported a discontinuation rate of 9% (118) and 19% (117) from SMS interventions that allowed participants to send free text 'STOP' to the research team to stop receiving future SMS messages.

7.7.3 Strengths and limitations of the study

To my knowledge, this is the first study to conduct a randomised controlled trial using a full factorial design to test the content of behaviour change texts for tobacco cessation. This study was conducted in Thailand, a middle-income country where mHealth research is scarce. The study was implemented in a pragmatic setting as an additional intervention to support the TNQ service. The participants included in this trial can be generalised to those in the real world where smokers who can benefit from the intervention are from both the TNQ and online channel (representing other smokers that sought smoking

cessation support from public health campaigns). Participants in this trial were not limited to those who set a quit date, but were a mixed group with different levels of intention to quit smoking. Participants were from both genders and all age groups, with a mixed range of educational backgrounds and socioeconomic status. However, the majority tended to be younger than the general population since younger people are more likely to engage in mobile phone technology.

This study used a randomised design; therefore, selection bias and assessment bias were unlikely to occur and confounding factors were expected to be low. Stratified permuted block randomisation was used to ensure the balance of important prognostic factors for smoking cessation between experimental groups. Text messages were sent to participants automatically; and intervention fidelity was high (80%). The results were analysed using both a complete case analysis and multiple imputations using chained equations as a method to deal with missing data and improved the precision of the estimation by not ignoring cases lost to follow-up.

The overall smoking cessation rate was high, with around 40% of the sample stopping smoking at 1-month follow-up. This study measured self-reported smoking cessation rates, a subjective outcome which is subject to social approval bias. However, the trial is being continued to measure a longer duration for cessation rate and an objective measurement of smoking status using the carbon monoxide breath test. The results from these two follow-up measurements will be used to report to the funders and the TNQ.

The smoking cessation rate for the participants receiving placebo texts (40%) was high compared to the expected 16% of smokers used in the sample size calculation. This high rate might be due to the participant inclusion criteria changes in this study to include smokers with or without a quit date which resulted in participants being recruited at an early stage. The high rate could also be due to the nationwide 'World No Tobacco' campaign, thus smokers who were more motivated were recruited. It is also possible that additional text messages for smokers who had higher intention-to-quit added little benefit compared to those that had lower intention-to-quit, as shown in the subgroup analysis of the intention-to-quit group. Lastly, the placebo text that contained information about diet, exercise and stress reduction could provide an unintentional effect on smoking behaviour or could act as reminder even if there was no cue to smoking or smoking cessation.

Dichotomising continuous data (grouping continuous data into binary variables) such as ITQ is not generally recommended in post-hoc analyses as it discards information and may underestimate variation in outcomes (248, 249). However, this is more relevant to a study that intends to fit a prediction model, which was not the objective of this study. Grouping smokers by ITQ scores into two groups was pre-specified as a stratification factor. It is suggested in the literature that the number of stratification factors should be kept to a minimum as adjusted models may lead to a high type I error rate (169). Therefore, ITQ score was treated as a binary variable rather than a continuous variable in the primary analysis model.

The sample size calculation for this trial assumed that there would be no interaction between treatment arms and a simple calculation of the difference between the two groups (with or without each behaviour change component) was made. However, the results of this study suggested an interaction between groups of text messages; therefore, a larger sample size is required in order to capture the magnitude between the main effect and interaction effects (149).

7.7.4 Challenges conducting this research

The trial was designed to collect data using a self-administered online or paper questionnaire. However, it was shown that depending on these two methods alone was not feasible given the low response rate at the beginning of the trial. There were some complaints to recruiters about the lengthy questionnaire (30 minutes) and some praticipants were not familiar with the online questionnaire despite the fact that 87% of the participants used smartphones and 74% of them used mobile applications. Allowing for telephone interviews was shown to be more feasible for data collection. For 1-month follow-up interview, participants were asked to report their smoking status and the number of tobacco products used when they were not free at the time of the call to minimise loss to follow up resulting from not be able to contact them. Therefore, follow-up retention rates were high, with 17% loss to follow-up at 1-month for the primary outcome. The loss to follow-up rate at 1-month for other outcome variables was 24%.

There are no published Equator guidelines specific for reporting a factorial study. The recommendation that is currently available in the literature only highlights the reporting of the 2×2 factorial design (4 experimental groups) where there is only one 2-way interaction. For a more complex design, there is no standard way of reporting such results. Reporting

the results in terms of the main effect and interaction effects is challenging for a factorial trial that contains more than two experimental factors. The results of this thesis were presented in tables and accompanying figures to provide more information for readers and help them easily interpret the predicted probability of smoking cessation and interactions resulting from the regression model.

7.7.5 Implications for practice and further research

The results from this thesis will be disseminated to the TNQ, and recommendations will include 1) provision of BCT-enhanced text messages to support smoking cessation did not differ between groups, and 2) if resources to provide text messages are limited, priority should be given to those with lower intention-to-quit scores (scores from 1 to 5).

Further research from this study should include measuring the long-term benefit of text messages at 6-month follow-up, and confirming participant's smoking status using the carbon monoxide breath test. Economic evaluation of text messages for TNQ routine practices will be conducted to understand whether text messages can provide value for money for all smokers or only in selected subgroups, such as the lower intention-to-quit group. If the TNQ has a budget constraint, prioritisation of the benefit of providing text messages would help maximise the benefits generated by the limited budget.

7.8 Chapter summary

This trial investigated the effectiveness of three behavioural change components alone and in combination in text messages aimed at supporting Thai smokers to stop smoking. The results of this study did not show a significant impact of these behaviour change components in text messages. However, providing messages aimed at increasing smokers' capability to quit and opportunity to support smoking cessation improved the smoking cessation rates in smokers with low baseline intention-to-quit scores.

Chapter 8: Thesis discussion

8.1 Chapter overview

This chapter summarises the key findings of this thesis and reflects on the overall strengths, limitations, and challenges of the development and evaluation of mobile health (mHealth) behaviour change interventions. It also outlines the implications for theory and practices and provides directions for future research. It concludes with a reflection on the PhD, outputs from this thesis, and some brief closing remarks.

8.2 Interpretation of empirical findings from this thesis

The overall aim of this thesis was to improve smoking cessation rates among Thai smokers by understanding the effective components of mHealth behaviour change interventions associated with improvements in smoking cessation. The objectives were to identify, develop, and test mHealth behaviour change interventions aimed at supporting smoking cessation for Thai smokers. The thesis involved three stages highlighted in **Chapters 3** to **7**.

First, a systematic review and meta-regression were conducted to systematically identify the effective components of mHealth behaviour change interventions associated with improvements in smoking cessation (**Chapter 3**). A meta-regression, which takes into account the characteristics of control groups was proposed over the traditional method which ignores the different nature of control groups in complex interventions. Predictors that were significantly associated with improved smoking cessation rate were mHealth interventions that applied theory for intervention design, and contained behaviour change techniques (BCTs) mapping into COM-B behaviour change components ('capability', 'opportunity', and 'motivation'). These results provoke a need to conduct further research to test each COM-B component separately and in combination.

Second, text messages were designed and developed based on BCTs that were mapped into COM-B behaviour change components. The messages were validated by a BCT expert from the United Kingdom and a panel of Thai experts in tobacco control research, including the future implementers (**Chapter 4**). Of 39 evidence-based BCTs identified from the initial step, 32 were rated acceptable among the panel and were included in the final set of text messages. A total of 240 text messages were developed comprising 60 texts for each group (placebo, 'Capability', 'Opportunity', and 'Motivation').

Third, to simultaneously test the effectiveness of 'Capability', 'Opportunity', and 'Motivation' in text messages for smoking cessation in Thailand, a factorial randomised control trial was conducted (**Chapter 5** for the methods and analysis plan, **Chapter 6** for the trial recruitment and **Chapter 7** for the results). Of 1,571 participants enrolled and randomised to receive BCT-enhanced text messages, providing text messages that contained 'capability', 'opportunity', or 'motivation' components did not significantly improve smoking cessation rates at 1-month follow-up compared to text messages that did not contain any intervention component. Additional components of BCT-enhanced text messages showed a non-significant trend of a decreased odds of smoking cessation, suggesting an antagonistic interaction effect. From a post-hoc analysis, the separate effect of 'capability', 'opportunity', and 'motivation' was found in smokers with low baseline intention-to-quit smoking; however, this result should be regarded as hypothesis generating rather than hypothesis testing.

8.3 Comparison to existing evidence

The development of an mHealth behaviour change intervention in this PhD involved a process of identifying (**Chapter 3**) and selecting (**Chapter 4**) BCTs that act as active ingredients for behaviour change interventions. Methods to determine BCTs in recent publications include focus group discussion (145, 250) and through selection using the behaviour change wheel and APEASE criteria as a guide (250, 251). Baker and colleagues have commented on the subjectivity of the selection of BCTs and offered the possibility to improve the selection process based on systematic review and preparatory qualitative work, where information is available (251), which is similar to this PhD.

The Multiphase Optimisation Strategy (MOST) is another approach that has been used to screen effective components for behaviour change interventions (151). It has been used to

identify effective components for smoking cessation interventions instead of confirming its effectiveness (152-154). The MOST approach was feasible in identifying promising components for phase-based smoking cessation (155, 252); however, this approach required more resources by conducting three separate fractional factorial clinical experiments of intervention components for the preparation (motivation) (152), cessation (154), and maintenance (153) phase. This approach might not be applicable to low- or middle-income countries where limited budgets for research are available.

Two previous RCTs that used a factorial experiment design were conducted to understand the individual and combined effects of mHealth behaviour change intervention components for smoking cessation. Borland *et al.* (2013) tested the provision of internet-based and SMS-based interventions (4 experimental groups) among 3,530 smokers and recent quitters (100). The provision of SMS alone improved the short-term smoking cessation rate, and the addition of an internet-based intervention decreased the effect size, suggesting an antagonistic effect. The author suggested that such effects may result from low engagement of the internet-based interventions (34% of the participants used the intervention). This contradicted a study by Fraser *et al* which examined the 'on' and 'off' effects of five components (website, quitline counselling, messaging, brochures, and cessation medication) in 1,034 smokers (107). The messaging conditions decreased the smoking cessation rate at 7-month follow-up. The results also suggested that there was an antagonistic effect that messaging condition discourages the website use. Though the cause of such association was unknown to the authors, they suggested that it may be because the user had already received push information through messaging and ignore the use of the website which was perceived to be more of a burden.

8.4 Strengths and limitations of the development and evaluation of a mobile health behaviour change intervention

This thesis considered the smallest components of behaviour change interventions into the consideration at the design stage of intervention development. This is the first study to identify behaviour change techniques from a systematic review and meta-regression as the initial step of intervention development since the behaviour change technique taxonomy (BCTTv1) became available in 2013 (30). Coding the active components in the control

groups of complex intervention evaluation allows an understanding of different characteristics of controls. The use of meta-regression that take different types of controls into the data synthesis is more informative compared to the traditional meta-analysis. However, this approach is challenging for a complex intervention that contained multiple behaviours, such as diet and active lifestyle, to serve the desired outcomes where BCTs need to be identified based on specific behaviour. Often, researchers do not map their intervention to the behaviour change techniques (111). However, there is an increasing trend to utilise the BCTTv1 in identifying ingredient components, and therefore warranting future research in the identification of BCTs for future systematic reviews rather than using judgement from the authors (**Chapter 3**). Also, the level of details reporting for the development of the intervention in this thesis allows other researchers to accumulate knowledge or replicate this intervention, unlike typical 'black box' behaviour change interventions.

This thesis attempted to create the intervention from the smallest unit of behaviour change techniques and to link the BCTs to COM-B theory constructs—Capability, Opportunity and Motivation—and used a factorial design to understand the main effect of each theory construct or behaviour change component. Though a factorial design was used as a screening tool for the MOST and SMART type of studies without sample size calculations, this study was conducted with the goal of identifying the components in the text messages that would benefit Thai smokers. This is because the plan for providing text messages within the TNQ in Thailand had already been decided upon. Therefore, a confirmation style of a trial was needed. However, this randomised controlled trial did not have sufficient power to detect significant interaction effects between the behaviour change components. There was a decreasing trend in the effect of increasing number of BCT-enhanced text messages. Therefore, the factorial design should be used as a screening tool rather than to confirm the effectiveness of the set of interventions because it requires a higher sample size. This study would be beneficial to other trialists who would like to conduct a factorial design for different sets of behaviour change techniques.

From the meta-regression results in **Chapter 3**, evidence from well-resourced contexts suggested that advanced features of mHealth interventions are associated with a higher smoking cessation rate. The odds ratio of smoking cessation rate increased by a factor of 1.6 (95% CI 1.26 to 1.94) when the intervention was tailored based on user's needs such as craving for cigarettes. Also, a usability test of the text messages content at the development

stage (**Chapter 4**) among a group of smokers and those who stopped smoking may improve the acceptability of the text message contents (105). However, the development of an automated system for text messages requires a test and a back-and-forward communication approach with the programmer. The feature of text messages programme that allows tailoring functionality are resource intensive and requires advanced programming expertise. Due to the limited resources available for this PhD, the automated text message-based intervention in this study was developed to be a one-way fixed intervention that can be delivered at scale feasibly. This means that text messages were only sent by the provider and there was no function to allow for participants to reply to the provider or chief investigator, Pritaporn Kingkaew (PK).

There is also a lack of questionnaires to identify and measure the theory constructs of the COM-B (Capability, Opportunity, and Motivation: COM) as a proxy. To my knowledge, there is no existing questionnaire to measure the behaviour change components for smoking cessation at the time of the questionnaire design. One recent survey developed a 10-item questionnaire containing three items for 'Capability', two items for 'Opportunity', and five items for 'Motivation' using 5 and 7 Likert scales; it was developed to observe the short-term effects on alcohol consumption within drinking guidelines (253). The questionnaire in this thesis was developed to represent a theoretical construct of COM using a 10-scale 2-question for each component measure. Face validity, content validity, construct validity and reliability of the questionnaire prior to its use is ideal; however, the process required additional resources and served its right for a separate study. Therefore, this is another limitation of using this questionnaire.

8.5 Challenges of the development and evaluation of mobile health behaviour change intervention

Alhough the COM-B framework is relatively straightforward in terms of explaining mechanisms of behaviour change, there is a lack of a systemic and validated coding that maps the BCTs onto the COM-B framework. The mapping in this thesis was based on prior coding reported in studies by Cane *et al.* (2012, 2015) (80, 83), one of the developers of BCTTv1 taxonomy. However, some BCTs were not mapped, and the author's (PK) judgement was made. However, the development of the intervention (**Chapter 4**) involved steps to improve the reliability of BCT coding. The removal of *BCT Reduce negative emotion*

from BCT-enhanced texts were due to perception from the Thai stakeholders that this BCT could fall into both the 'Capability' and the 'Motivation' group. One another note, Fulton *et al.* (2016) attempted to map the BCTs into the COM-B and TDF framework (254). There was a discrepancy in BCT mapping between Fulton's study and this thesis. For example, Fulton mapped *BCT Material incentive* into both the 'Motivation' and 'Capability' groups whereas PK mapped this BCT into the 'Motivation' group only. The coding could be improved by conducting a discriminant validity study in future.

Although the 'Opportunity' component of the COM-B framework is defined as all the factors that lie outside the individual that makes the behaviour possible or which prompts it, there are no BCTs related to the contextual change that could be underlining factors of behaviour change. The use of the COM-B framework to design behaviour change interventions may be too broad for behaviours that involve contextual factors. External factors such as public media campaigns and the rise of the tobacco tax can affect smoker's decision to quit smoking (255). This study did not collect external factors that could affect one's decision; however, the experimental groups were expected to be well-balanced for both known and unknown factors given the randomisation of intervention groups (168). Moreover, the participants were recruited over a period of one year, and this should have averaged out any seasonal effects that might have occurred such as from the nationwide 'World No Tobacco' campaign.

The BCTTv1 taxonomy was developed with the aim to gain an international consensus of terminology used for behaviour change techniques, allowing for cumulative knowledge. However, the development of BCT involve respondents mainly from the US and Europe (256). Therefore, it will be challenging to apply BCTTv1 taxonomy when behaviour change interventions are developed in a context where English is not the official language or when the interventions are not individual-based interventions and involves local cultures and beliefs. Confirmation for the generalisability of the BCTTv1 to Asian countries or other low-middle income countries may be useful in the future for wider application of BCTs.

The challenges of implementing a randomised controlled trial were the trial recruitment (**Chapter 6**) and the data collection methods. Telephone interviews were used as the primary method to collect data, allowing for a greater data-completion rate. Although technology has advanced greatly and a high proportion of people used smartphones in this trial (87%), Thai people were not familiar with the online questionnaire, suggesting a certain lack of competence or confidence in digital literacy skills. A shorter version of the online

questionnaire, or a form of a screening test for digital literacy skills, could help improve clinical trials that are conducted online.

8.6 Implications for theory and practice

This PhD thesis highlights the use of meta-regression as a method for selecting effect moderators to be tested in a clinical trial as an alternative approach to multiple factorial studies in the optimising phase of the MOST approach (151). With the speed of technology advancement, meta-regression studies (with coded control groups) can help to accelerate the process of the component selection process. Moreover, when feasible, individual data of studies included in the meta-regression analysis could advance the limitation of using aggregate data at the study level, providing more precise estimates.

Theory-based interventions that employ a single theory may not apply to complex behaviour change interventions, and the tendency to use only one theory may not necessarily advance research (257). Results from this RCT highlighted the possibility of moderators and mediators of behaviour change by suggesting different effectiveness by subgroups such as in smokers with different levels of intention-to-quit (see **Figure 8.1**). This finding suggested that there is a possible pathway of behavioural moderators (e.g. intention-to-quit smoking or smoking cessation self-efficacy) that is related to performing the behaviour (smoking cessation). An example of theory that contained behavioural intention to determine behaviour includes the Theory of Planned Behaviour (TPB) proposed by Ajzen (186). An addition of possible moderators/mediators can advance behaviour change research and provide the surrogate endpoint for intervention users for potential implementation in routine practice (252).

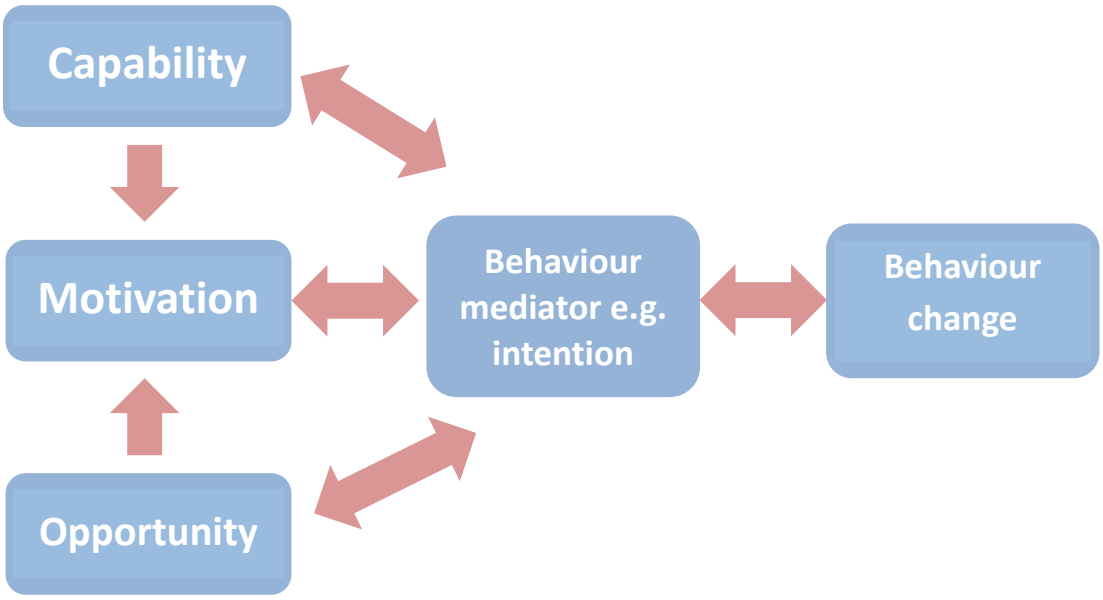


Figure 8.1 Proposed addition of mediators of behaviour change to the COM-B framework

Text messages with specific behaviour change components provide benefits to smokers who have lower intention-to-quit. The results from this thesis will be used to inform the practice in the Thai National Quitline. Priority can be given to those with lower intention-to-quit scores to maximise the resources used. Further analyses are planned at the 6-month follow-up period to confirm the long-term effects of text messages on smoking cessation rates. Economic evaluation of text messages for TNQ routine practices will be conducted to see whether text messages would provide value for money for all smokers who use the service from the TNQ or only in selected subgroups such as smokers with a low intention-to-quit. Since there is a resource constraint in the budget provided to the TNQ, prioritisation of the benefit of providing text messages would maximise the limited budget of the organisation with planning for monitoring and evaluation after implementation.

8.7 Directions for future research

The RCT results (**Chapter 7**) suggest that baseline intention-to-quit group is a potential moderator of the treatment effect since the intervention was more beneficial among smokers with a low intention-to-quit. The results shine some light on the use of intention-to-quit smoking as tailoring variables for future adaptive interventions for smoking cessation. Adaptive interventions, also known as tailored interventions, have been in the research field for many years; they can be used as a decision rule to determine appropriate intervention pathways for interventions (e.g. contents and dosage) as discussed in Collins

et al. 2004 (65). Such tailoring variables can be based on the analysis of moderator and mediator variables from the RCT (258-260); examples of this application can be found in Strecher's study about a web-based smoking cessation programme (261) and Piper's study using data from a factorial experiment design (252). Future research is needed to explore the moderators and mediators of 1) the behaviour change techniques, 2) the mechanism of behaviour change, and 3) the effective engagement (183) with digital health interventions in a systemic manner. This approach would advance the knowledge of public health interventions provided via a digital platform.

8.8 Reflection on the PhD

As a pharmacist and a health economist with previous work experience on health technology assessment, mainly in pharmaceutical products, the behaviour change field is not within my comfort zone. A lack of expertise in the evaluation of a complex intervention for health promotion and disease prevention in Thailand was the initial driver for pursuing a PhD in this field. To conduct a PhD project with the ability to fill the scientific knowledge gap and to improve health policy practice in Thailand drove and motivated me to conduct an experimental research with primary data. This so-called 'ambitious project' (shouted at me by others that I have encountered during the period of this PhD) warranted many hardships. However, this PhD provided me with an opportunity to develop not only the subject knowledge but also research skills in the following ways:

- the ability to identify training needs and training resources, ranging from the BCT taxonomy self-training course to Stata commands for meta-regression analysis, stratified permuted block randomisation, multiple imputations for missing data and data analysis for factorial design;
- the realisation of the importance of theory and framework to guide research and the application of the development of theory-based interventions and data collection;
- the ability to apply for and secure research funding, and to be the chief investigator, the trial manager, an interviewer, a recruiter and trainer for trial interviewers, a data cleaner, and a statistical analyst for a randomised controlled trial;
- the ability to embrace unexpected events and find possible and eventual solutions consisting of the SMS blacklist, trial recruitment, and managing a team to conduct telephone interviews;

- the ability to communicate research to different audiences through international conferences and the institute symposium; and finally
- the ability to persevere with this PhD by adopting some BCTs—such as goal setting, graded task, self-reward—myself.

Towards the end of this PhD, I became more critical when assessing published papers, especially clinical trials. This PhD provided me with an understanding of the pathway of designing and evaluating health promotion and disease prevention interventions, how complicated a trial can become over time, and how best to manage it. To sum up, I would say that this PhD journey has fulfilled my need in becoming a better scholar comparing to myself three and a half years ago.

8.9 Presentations, publication and publication plan

Poster presentations:

- The 1st CBC Conference, London, UK, 23-24 February 2015: "A systematic review of the behaviour change methods used in mobile health interventions"

Oral presentations:

- Faculty of Medicine & Health Postgraduate research conference, Leeds, UK, 13 June 2018: "Testing the combination of behaviour change techniques in text messages for smoking cessation: A factorial randomised trial in Thailand"
- The 4th International Conference on Public Health 2018, 19-21 July 2018: "Testing the combination of behaviour change techniques in text messages for smoking cessation: A factorial randomised trial in Thailand"

Publication: Kingkaew P, Glidewell L, Walwyn R, Fraser H, Wyatt JC. Identifying effective components for mobile health behaviour change interventions for smoking cessation and service uptake: protocol of a systematic review and planned meta-analysis. Systematic reviews. 2017;6(1):193.

Publication plan:

1. A systematic review and meta-analysis of effective components for mobile health behaviour change interventions for smoking cessation and service uptake
   Target journal: Journal of Medical Internet Research (JMIR)
   Expected submission: November 2018
2. A randomised factorial trial to test the effectiveness of behavioural change components in text messages for smoking cessation in Thailand
   Target journal: BMJ Open
   Expected submission: January 2019
3. The use of the COM-B framework to develop mobile health behaviour change interventions: challenges and experiences
   Target journal: Annals of Behavioral Medicine
   Expected submission: March 2019
4. Recruitment to a randomised factorial trial: challenges and strategies to increase trial participants
   Target journal: Implementation Science
   Expected submission: March 2019

8.10 Concluding remarks

This PhD showcases the design and evaluation of a mHealth behaviour change intervention in a resource-limited country with emerging mobile technology. The intervention—text messages—was designed to provide support for Thai smokers aimed at theory-based behaviour change components and was supported by current literature and accepted by relevant stakeholders and future users. Although an evidence synthesis suggested a promising effect of combinations of BCT-enhanced mHealth interventions, it failed to provide a significant improvement in cessation rates in a trial that was carried out in a pragmatic setting. Understanding the effect of these behaviour change components by looking inside the intervention 'black box' would advance the cumulative knowledge in this field of research.

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Appendix

Appendix A: Scoping review search strategy for mobile health interventions for smoking cessation

Database: Ovid MEDLINE(R) <1996 to 2015, latest update: September Week 2 2015>

Search Strategy:

1 exp Cell Phones/ (6247)
2 (cell$ adj3 phone$).tw. (1776)
3 (cell$ adj3 telephone$).tw. (355)
4 (mobile adj3 phone$).tw. (3124)
5 (mobile adj3 telephone$).tw. (387)
6 smartphone$.tw. (1176)
7 smart-phone$.tw. (235)
8 exp text messaging/ (920)
9 SMS.tw. (2038)
10 (short adj messag$).tw. (409)
11 (text adj messag$).tw. (1119)
12 texting.tw. (242)
13 exp mobile application/ (577)
14 (mobile adj3 app?).tw. (175)
15 (mobile adj3 application?).tw. (584)
16 (phone$ adj3 app?).tw. (43)
17 (phone$ adj3 application?).tw. (147)
18 (smartphone$ adj3 app?).tw. (159)
19 (smartphone$ adj3 application?).tw. (306)
20 (smart-phone$ adj3 app?).tw. (8)
21 (smart-phone$ adj3 application?).tw. (34)
22 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 (10984)
23 exp Smoking Cessation/ (20575)
24 exp "tobacco use"/ or exp smoking/ (84202)
25 (smoking adj1 cessation).tw. (14169)
26 smoking.tw. (119966)
27 tobacco.tw. (51695)
28 23 or 24 or 25 or 26 or 27 (174340)
29 (systematic adj1 review).tw. (51023)
30 meta-analysis.tw. (56334)
31 29 or 30 (91128)
32 22 and 28 and 31 (21)

Appendix B: Ethical approval letters and amendments

1) Institute for the Development of Human Research Protections (IHRP)

Ethics Committee

Institute for the Development of Human Research Protections (IHRP)

Building 8 Floor 7 Room 702 Department of Medical Science Ministry Public Health Nonthaburi Thailand 11000

Certificate of Approval

Title of Project: Testing the combination of mobile health interventions for smoking cessation servives uptake and smoking cessation. (Thai summary Version 2, Dated 22/09/2016, English Protocol Version 0.4, 24 July 2016)

Principal Investigator: Miss Pritaporn Kingkaew

Responsible Organization: 1. Health Intervention and Technology Assessment Program, Ministry of Public Health.
2. University of Leeds

The Ethics Committee of Institute for the Development of Human Research Protections (IHRP) had reviewed the research proposal. Concerning on scientific, ICH-GCP and ethical issues, the committee has approved for the implementation of the research study mentioned above.

(Dr.Vichai Chokevivat)	(Dr.Pramote Stienrut)
Chairman	Committee and Secretary

Date of First Meeting: September 21, 2016

Date of Approval: September 27, 2016

Ethics Committee

Institute for the Development of Human Research Protections (IHRP)

Building 8 Floor 7 Room 702 Department of Medical Science Ministry Public Health Nonthaburi Thailand 11000

Certificate of Approval

Title of Project: Testing the combination of mobile health interventions for smoking cessation servives uptake and smoking cessation. (Thai summary Version 2, Dated 22/09/2016, English Protocol Version 0.4, 24 July 2016)

Principal Investigator: Miss Pritaporn Kingkaew

Responsible Organization: 1. Health Intervention and Technology Assessment Program, Ministry of Public Health.
2. University of Leeds

Document Reviewed:

1. Participant information sheet Questionnaire Version 3 Dated 14/03/2017 -Thai
2. Consent form Questionnaire Version 3 Dated 14/03/2017 –Thai
3. Advertisement Dated 14/03/2017

The Ethics Committee of Institute for the Development of Human Research Protections (IHRP) had reviewed the research proposal. Concerning on scientific, ICH-GCP and ethical issues, the committee has approved for the implementation of the research study mentioned above.

(Dr.Vichai Chokevivat)
Chairman

(Dr.Pramote Stienrut)
Committee and Secretary

Date of Approval: March 27, 2017

Ethics Committee

Institute for the Development of Human Research Protections (IHRP)

Building 8 Floor 7 Room 702 Department of Medical Science Ministry Public Health Nonthaburi Thailand 11000

Certificate of Approval

Title of Project: Testing the combination of mobile health interventions for smoking cessation servives uptake and smoking cessation. (Thai summary Version 2, Dated 22/09/2016, English Protocol Version 0.4, 24 July 2016)

Principal Investigator: Miss Pritaporn Kingkaew

Responsible Organization: 1. Health Intervention and Technology Assessment Program, Ministry of Public Health.
2. University of Leeds

Document Reviewed:

1. Summary Protocol Version 4 Dated 23/05/2017 –Thai

The Ethics Committee of Institute for the Development of Human Research Protections (IHRP) had reviewed the research proposal. Concerning on scientific, ICH-GCP and ethical issues, the committee has approved for the implementation of the research study mentioned above.

(Dr.Vichai Chokevivat)	(Dr.Pramote Stienrut)
Chairman	Committee and Secretary

Date of Approval: May 29, 2017

2) School of Medicine Research Ethics Committee (SoMREC)

UNIVERSITY OF LEEDS

Faculty of Medicine and Health Research Office
School of Medicine Research Ethics Committee (SoMREC)

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31 October 2016

Pritaporn Kingkaew
Leeds Institute of Health Sciences
Medicines and Health
Leeds Institute of Health Sciences
Room G.02 Charles Thackrah Building
101 Clarendon Road
LEEDS LS2 9LJ

Dear Pritaporn

Ref no: **MREC16-001**

Title: **Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand**

Your research application has been reviewed by the School of Medicine Ethics Committee (SoMREC) and we can confirm that ethics approval is granted based on the following documentation received from you.

Document	*Version*	*Date Submitted*
New_ethical_review_form-v2-8Sep16	2.0	08/09/2016
Participant information sheets-Quali-v4-12Oct16	4.0	12/10/2016
Participant information sheets-v4-12Oct16	4.0	12/10/2016
Consent form-Quali-v4-12Oct16	4.0	12/10/2016
Consent form-v4-12Oct16	4.0	12/10/2016
In Country Approval from Thailand IHRP_approval letter	3.0	30/09/2016
Questionnaire 1-v2	2.0	08/09/2016
Questionnaire 2-v1	1.0	08/08/2016
Questionnaire 3-v1	1.0	08/08/2016
RCT-protocol-v1-05Aug16	1.0	08/08/2016
Fieldwork_Assessment_Form_high_risk_final_protected_nov_15-Pritaporn	1.0	08/08/2016
Recruitment material-v1	1.0	08/08/2016
Data management plan-v1	1.0	05/08/2016

Please notify the committee if you intend to make any amendments to the original research ethics application or documentation. All changes must receive ethics approval prior to implementation. Please contact the Faculty Research Ethics Administrator for further information (fmhuniethics@leeds.ac.uk)

Ethics approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation,

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11 January 2017

Pritaporn Kingkaew
Leeds Institute of Health Sciences
Medicines and Health
Leeds Institute of Health Sciences
Room G.02 Charles Thackrah Building
101 Clarendon Road
LEEDS LS2 9LJ

Dear Pritaporn

Ref no: **MREC16-001**

Title: **Amendment 1 - Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand**

We are pleased to inform you that your amendment to your research ethics application has been reviewed by the School of Medicine Research Ethics Committee (SoMREC) and we can confirm that ethics approval is granted based on the following documents received from you:

Document	*Version*	*Date submitted*
UoL Amendment_form_MREC16-001	1.0	02/12/2016
Questionnaire 1-v3	3.0	02/12/2016
Questionnaire 2-v2	2.0	02/12/2016
Questionnaire 3-v2	2.0	02/12/2016

Please notify the committee if you intend to make any further amendments to the original research as submitted and approved to date. This includes recruitment methodology; all changes must receive ethical approval prior to implementation. Please contact the Faculty Research Ethics Administrator for further information (fmhuniethics@leeds.ac.uk)

Ethics approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The committee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

We wish you continued success with the project.

Yours sincerely

Dr Naomi Quinton

Co-Chair, SoMREC, University of Leeds

(Approval granted by Dr Naomi Quinton on behalf of SoMREC Co-Chairs)

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14 March 2017

Pritaporn Kingkaew
Leeds Institute of Health Sciences
Room 10.38
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The University of Leeds
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Dear Pritaporn

Ref no: **MREC16-001**

Title: **Amendment 2 - Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand**

We are pleased to inform you that your amendment to your research ethics application has been reviewed by the School of Medicine Research Ethics Committee (SoMREC) and we can confirm that ethics approval is granted based on the following documents received from you:

Document	*Version*	*Date submitted*
New_ethical_review_form-v3-9Mar17	3.0	10/03/2017
UoL Amendment 2_form_MREC16-001_9Mar17	1.0	10/03/2017
Participant information sheets-v5-24Feb17	5.0	10/03/2017
Consent form-v5-24Feb17	5.0	10/03/2017
Recruitment material-v2	2.0	10/03/2017

Please notify the committee if you intend to make any further amendments to the original research as submitted and approved to date. This includes recruitment methodology; all changes must receive ethical approval prior to implementation. Please contact the Faculty Research Ethics Administrator for further information (fmhuniethics@leeds.ac.uk)

Ethics approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The committee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

We wish you continued success with the project.

Yours sincerely

Dr Naomi Quinton

Co-Chair, SoMREC, University of Leeds

(Approval granted by Dr Naomi Quinton on behalf of SoMREC Co-Chairs)

UNIVERSITY OF LEEDS

Faculty of Medicine and Health Research Office
School of Medicine Research Ethics Committee (SoMREC)

Room 9.29, Level 9
Worsley Building
Clarendon Way
Leeds, LS2 9NL
United Kingdom

✆ +44 (0) 113 343 1642

08 June 2017

Pritaporn Kingkaew
Leeds Institute of Health Sciences
Room 10.38
Level 10, Worsley Building
The University of Leeds
LEEDS LS2 9JT

Dear Pritaporn

Ref no: **MREC16-001**

Title: **Amendment 3 - Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand**

We are pleased to inform you that your amendment to your research ethics application has been reviewed by the School of Medicine Research Ethics Committee (SoMREC) and we can confirm that ethics approval is granted based on the following documents received from you:

Document	*Version*	*Date submitted*
UoL Amendment_form_MREC16-001_22May17	1.0	23/05/2017
New_ethical_review_form-v4-22May17	4.0	23/05/2017

Please notify the committee if you intend to make any further amendments to the original research as submitted and approved to date. This includes recruitment methodology; all changes must receive ethical approval prior to implementation. Please contact the Faculty Research Ethics Administrator for further information (fmhuniethics@leeds.ac.uk)

Ethics approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The committee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

We wish you continued success with the project.

Yours sincerely

Roger Parslow

Dr Roger Parslow
Co-Chair, SoMREC, University of Leeds

(Approval granted by Dr Roger Parslow on behalf of SoMREC Co-Chairs)

Table B1 Summary of protocol amendments, reasons for modifications, and approval date

No.	Reasons for modifications	Approval date
1	1. Questionnaire modification 1.1 Items added - Added participant mobile phone number to serve as research identification numbers - Added religion as a parameter to determine participants' beliefs - Added household income as a parameter to determine participants' socioeconomic status to ensure that the baseline characteristic for participants' socioeconomic status was available in the case where there were a number of missing information within the household asset question 1.2 Items modification - Household asset was modified to match the assets listed under the current national household survey - Alcohol consumption behaviour was replaced with the AUDIT, a validated questionnaire recommended by the WHO - Reason for smoking modified from free-form answers to multiple choice instead	11/01/17
2	1. Updated contact details 2. Proposed to allow telephone interviews as another method to collect data 3. Added a series of advertisement materials 4. Proposed to modify the participant information sheet and consent form for the online questionnaire 5. Proposed to provide incentives for participants who completed the trial	14/03/17
3	1. Modified the inclusion criteria "(1) Thai smokers who received a single brief counselling session for smoking cessation from the TNQ and (2) did not set a quit date within one month" to "(1) Thai smokers who want to quit smoking" 2. Dropped the secondary outcomes (self-reported of setting quit date at 1-month and 6-month follow-ups) as a result of modifying the inclusion criteria	08/06/17

Appendix C: Funding approval letter

Health Promotion Economic Evaluation
Collaborative Center - Thailand
Department of Preventive & Social Medicine,
Faculty of Medicine, Chulalongkorn University,
Rama 4 Rd, Pathumwan, Bangkok 10330 Thailand

15th August 2016

To whom it may concern,

This letter is to certify that the Project "Development and evaluation of mobile health behavior change intervention to support tobacco cessation in Thailand" proposed by Ms.Pritaporn Kingkaew was selected as one of the projects to be financially supported by the Health Promotion Economic Evaluation Collaborative Center using the budget from ThaiHealth (Grant no. 58-00-0385). The amount of funding for this project will not exceed 1,595,000.00 Bath and the financial support will start from 15th August 2016 through 10th April 2018.

Sincerely,

Piya Hanvoravongchai, MD ScD

Head
Health Promotion Economic Evaluation
Collaborative Center, Thailand

Appendix D: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2009 checklist

Section and topic	Item No	Checklist item	Page
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	25
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	-
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	25-26
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	27
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	27-28
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	29
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	238, Appendix E
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	29-30
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in	30

Section and topic	Item No	Checklist item	Page
		duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	31 - 36
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	36
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	36
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	36-38
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	37
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	38
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	38-39
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	40-51
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	51-53
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	55-59
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	54-55
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	54
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	59-62

Section and topic	Item No	Checklist item	Page
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	62-63
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	63-64
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	64-65
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Appendix E: Electronic search strategies for systematic review

Database: Ovid MEDLINE(R) <1996 to October Week 1 2015>

Search Strategy (search results)

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1 exp Cell Phones/ (6383)
2 (cell$ adj3 phone$).tw. (1793)
3 (cell$ adj3 telephone$).tw. (358)
4 (mobile adj3 phone$).tw. (3170)
5 (mobile adj3 telephone$).tw. (389)
6 smartphone$.tw. (1242)
7 smart-phone$.tw. (241)
8 exp text messaging/ (947)
9 SMS.tw. (2062)
10 (short adj messag$).tw. (419)
11 (text adj messag$).tw. (1138)
12 texting.tw. (249)
13 (multimedia adj messag$).tw. (47)
14 (messag$ adj service$).tw. (456)
15 interactive voice response.tw. (569)
16 (interactive adj voice).tw. (635)
17 (voice adj response).tw. (606)
18 exp Electronic Mail/ (2076)
19 email.tw. (2279)
20 e-mail.tw. (4184)
21 (electronic adj mail).tw. (468)
22 exp Internet/ (57263)
23 internet-based.tw. (4657)
24 exp Web Browser/ (159)
25 web-based.tw. (15047)
26 exp Social Media/ (2040)
27 (social adj media).tw. (1614)
28 (digital adj media).tw. (162)
29 exp mobile application/ (618)
30 (mobile adj3 app?).tw. (183)
31 (mobile adj3 application?).tw. (608)
32 (phone$ adj3 app?).tw. (44)
33 (phone$ adj3 application?).tw. (154)
34 (smartphone$ adj3 app?).tw. (167)
35 (smartphone$ adj3 application?).tw. (326)
36 (smart-phone$ adj3 app?).tw. (8)
37 (smart-phone$ adj3 application?).tw. (34)
38 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 (81687)
39 exp Smoking Cessation/ (20778)
40 exp "tobacco use"/ (84928)
41 exp smoking/ (84685)
42 exp "Tobacco Use Disorder"/ (8118)
43 (smok$ adj1 cessation$).tw. (14369)
44 (tobacco adj1 cessation$).tw. (1199)
45 (smok$ adj1 behavio$).tw. (4774)
46 smoking.tw. (121089)
47 tobacco.tw. (52102)
48 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 (176683)
49 randomized controlled trials as topic/ (95323)
50 randomized controlled trial/ (318671)
51 (controlled adj trial$).tw. (114073)
52 (random$ adj trial$).tw. (53520)
53 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. (88505)
54 (allocated adj2 random$).tw. (15133)
55 49 or 50 or 51 or 52 or 53 or 54 (474738)
56 case report.tw. (130402)
57 letter/ (620202)
58 historical article/ (155792)
59 animals/ not (human/ and animals/) (1999802)
60 56 or 57 or 58 or 59 (2870715)
61 55 not 60 (450113)
62 38 and 48 and 61 (381)

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <October 08, 2015>

Search Strategy (search results)

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1 (cell$ adj3 phone$).tw. (276)
2 (cell$ adj3 telephone$).tw. (20)
3 (mobile adj3 phone$).tw. (805)
4 (mobile adj3 telephone$).tw. (41)
5 smartphone$.tw. (755)
6 smart-phone$.tw. (132)
7 SMS.tw. (481)
8 (short adj messag$).tw. (135)
9 (text adj messag$).tw. (377)
10 texting.tw. (82)
11 (multimedia adj messag$).tw. (4)
12 (messag$ adj service$).tw. (141)
13 interactive voice response.tw. (55)
14 (interactive adj voice).tw. (65)
15 (voice adj response).tw. (58)
16 email.tw. (539)
17 e-mail.tw. (626)
18 (electronic adj mail).tw. (47)
19 internet-based.tw. (722)
20 web-based.tw. (2632)
21 (social adj media).tw. (734)
22 (digital adj media).tw. (29)
23 (mobile adj3 app?).tw. (206)
24 (mobile adj3 application?).tw. (349)
25 (phone$ adj3 app?).tw. (44)
26 (phone$ adj3 application?).tw. (77)
27 (smartphone$ adj3 app?).tw. (122)
28 (smartphone$ adj3 application?).tw. (178)
29 (smart-phone$ adj3 app?).tw. (2)
30 (smart-phone$ adj3 application?).tw. (19)
31 (smok$ adj1 cessation$).tw. (1536)
32 (tobacco adj1 cessation$).tw. (174)
33 (smok$ adj1 behavio$).tw. (466)
34 smoking.tw. (12366)
35 tobacco.tw. (7088)
36 randomized controlled trial/ (353)
37 (controlled adj trial$).tw. (15542)
38 (random$ adj trial$).tw. (4770)
39 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. (8353)
40 (allocated adj2 random$).tw. (2304)
41 case report.tw. (30120)
42 letter/ (28234)
43 or/1-30 (7593)
44 or/31-35 (17339)
45 or/36-40 (26970)
46 41 or 42 (58012)
47 45 not 46 (26815)
48 43 and 44 and 47 (43)

Database: Embase <1996 to 2015 Week 40>

Search Strategy (search results)

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1 *mobile phone/ (5122)
2 (cell$ adj3 phone$).tw. (2798)
3 (cell$ adj3 telephone$).tw. (455)
4 (mobile adj3 phone$).tw. (5067)
5 (mobile adj3 telephone$).tw. (556)
6 smartphone$.tw. (2701)
7 smart-phone$.tw. (743)
8 *text messaging/ (803)
9 SMS.tw. (3570)
10 (short adj messag$).tw. (640)
11 (text adj messag$).tw. (1948)
12 texting.tw. (471)
13 (multimedia adj messag$).tw. (65)
14 (messag$ adj service$).tw. (684)
15 interactive voice response.tw. (736)
16 (interactive adj voice).tw. (846)
17 (voice adj response).tw. (782)
18 *e-mail/ (1150)
19 email.tw. (7133)
20 e-mail.tw. (8141)
21 (electronic adj mail).tw. (625)
22 *Internet/ (27440)
23 internet-based.tw. (7251)
24 *web browser/ (953)
25 web-based.tw. (24151)
26 *social media/ (2067)
27 (social adj media).tw. (3188)
28 (digital adj media).tw. (279)
29 *mobile application/ (751)
30 (mobile adj3 app?).tw. (445)
31 (mobile adj3 application?).tw. (1173)
32 (phone$ adj3 app?).tw. (131)
33 (phone$ adj3 application?).tw. (371)
34 (smartphone$ adj3 app?).tw. (413)
35 (smartphone$ adj3 application?).tw. (683)
36 (smart-phone$ adj3 app?).tw. (54)
37 (smart-phone$ adj3 application?).tw. (129)
38 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 (86179)
39 *smoking cessation/ (15153)
40 *smoking cessation program/ (962)
41 *"tobacco use"/ (453)
42 *smoking/ (33274)
43 *tobacco dependence/ (6799)
44 (smok$ adj1 cessation$).tw. (19955)
45 (tobacco adj1 cessation$).tw. (1679)
46 (smok$ adj1 behavio$).tw. (5842)
47 smoking.tw. (182051)
48 tobacco.tw. (68550)
49 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 (228302)
50 randomized controlled trials as topic/ (66030)
51 randomized controlled trial/ (339642)
52 (controlled adj trial$).tw. (163202)
53 (random$ adj trial$).tw. (75982)
54 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. (129213)
55 (allocated adj2 random$).tw. (21434)
56 50 or 51 or 52 or 53 or 54 or 55 (558014)
57 case report.tw. (222904)
58 case study/ (31401)
59 abstract report/ (431)
60 letter/ (598783)
61 animals/ not (human/ and animals/) (458442)
62 57 or 58 or 59 or 60 or 61 (1300730)
63 56 not 62 (541432)
64 38 and 49 and 63 (360)

Database: PsycINFO <2002 to October Week 1 2015>

Search Strategy (search results)

---

1 exp Cellular Phones/ (2573)
2 (cell$ adj3 phone$).tw. (1391)
3 (cell$ adj3 telephone$).tw. (107)
4 (mobile adj3 phone$).tw. (2075)
5 (mobile adj3 telephone$).tw. (171)
6 smartphone$.tw. (844)
7 smart-phone$.tw. (236)
8 SMS.tw. (777)
9 (short adj messag$).tw. (320)
10 (text adj messag$).tw. (1120)
11 texting.tw. (414)
12 (multimedia adj messag$).tw. (52)
13 (messag$ adj service$).tw. (324)
14 interactive voice response.tw. (240)
15 (interactive adj voice).tw. (261)
16 (voice adj response).tw. (256)
17 exp Electronic Communication/ (11530)
18 email.tw. (2503)
19 e-mail.tw. (2692)
20 (electronic adj mail).tw. (288)
21 exp internet/ (23078)
22 internet-based.tw. (3463)
23 exp Websites/ (3560)
24 web-based.tw. (8732)
25 exp Social Media/ (5613)
26 (social adj media).tw. (3338)
27 (digital adj media).tw. (801)
28 (mobile adj3 app?).tw. (153)
29 (mobile adj3 application?).tw. (484)
30 (phone$ adj3 app?).tw. (46)
31 (phone$ adj3 application?).tw. (127)
32 (smartphone$ adj3 app?).tw. (89)
33 (smartphone$ adj3 application?).tw. (158)
34 (smart-phone$ adj3 app?).tw. (17)
35 (smart-phone$ adj3 application?).tw. (23)
36 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 (49177)
37 exp Smoking Cessation/ (7963)
38 exp Tobacco Smoking/ (17691)
39 (smok$ adj1 cessation$).tw. (7116)
40 (tobacco adj1 cessation$).tw. (631)
41 (smok$ adj1 behavio$).tw. (2996)
42 smoking.tw. (27515)
43 tobacco.tw. (13855)
44 37 or 38 or 39 or 40 or 41 or 42 or 43 (33575)
45 clinical trials/ (8734)
46 (controlled adj trial$).tw. (22819)
47 (random$ adj trial$).tw. (5785)
48 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. (13348)
49 (allocated adj2 random$).tw. (1921)
50 45 or 46 or 47 or 48 or 49 (42935)
51 case report.tw. (10326)
52 letter/ (1080)
53 animals/ (1645)
54 51 or 52 or 53 (13047)
55 50 not 54 (42816)
56 36 and 44 and 55 (148)

Database: CINAHL (EbscoHOST) <1981 to 9 October 2015>

Search Strategy (search results)

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1 (MH "Wireless Communications")
2 TI (cell* n3 phone*) OR AB (cell* n3 phone*)
3 TI (cell* n3 telephone*) OR AB (cell* n3 telephone*)
4 TI (mobile n3 phone*) OR AB (mobile n3 phone*)
5 TI (mobile n3 telephone*) OR AB (mobile n3 telephone*)
6 TI ("smart phone") OR TI ("smart phones") OR AB ("smart phone") OR AB ("smart phones")
7 TI (smart-phone*) OR AB (smart-phone*)
8 TI (smartphone*) OR AB (smartphone*)
9 (MH "Text messaging")
10 TI (SMS) OR AB (SMS)
11 TI (short w1 messag*) OR AB (short w1 messag*)
12 TI (text w1 messag*) OR AB (text w1 messag*)
13 TI (texting) OR AB (texting)
14 TI (multimedia w1 messag*) OR AB (multimedia w1 messag*)
15 TI (messag* w1 service*) OR AB (messag* w1 service*)
16 TI ("interactive voice response") OR AB ("interactive voice response")
17 TI (interactive w1 voice) OR AB (interactive w1 voice)
18 TI (voice w1 response) OR AB (voice w1 response)
19 (MH "Electronic Mail")
20 TI (email) OR AB (email)
21 TI (e-mail) OR AB (e-mail)
22 TI (electronic w1 mail) OR AB (electronic w1 mail)
23 (MH "Internet")
24 TI (internet-based) OR AB (internet-based)
25 TI (web-based) OR AB (web-based)
26 (MH "Social Media")
27 TI (social w1 media) OR AB (social w1 media)
28 TI (digital w1 media) OR AB (digital w1 media)
29 TI (mobile n3 app#) OR AB (mobile n3 app#)
30 TI (mobile n3 application#) OR AB (mobile n3 application#)
31 TI (phone* n3 app#) OR AB (phone* n3 app#)
32 TI (phone* n3 application#) OR AB (phone* n3 application#)
33 TI (smartphone* n3 app#) OR AB (smartphone* n3 app#)
34 TI (smartphone* n3 application#) OR AB (smartphone* n3 application#)
35 TI (smart-phone* n3 app#) OR AB (smart-phone* n3 app#)
36 TI (smart-phone* n3 application#) OR AB (smart-phone* n3 application#)
37 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36
38 (MH"Smoking Cessation")
39 (MH"Smoking Cessation Programs")
40 (MH"Smoking")
41 TI (smok* n1 cessation*) OR AB (smok* n1 cessation*)
42 TI (tobacco n1 cessation*) OR AB (tobacco n1 cessation*)
43 TI (smok* n1 behavio*) OR AB (smok* n1 behavio*)
44 TI (smoking) OR AB (smoking)
45 TI (tobacco) OR AB (tobacco)
46 S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45
47 (MH "Clinical Trials")
48 (MH "Randomized Controlled Trials")
49 TI (controlled w1 trial*) OR AB (controlled w1 trial*)

50 TI (random* w1 trial*) OR AB (random* w1 trial*)
51 TI ((singl* or doubl* or treb* or tripl*) w1 (blind* or mask*)) OR AB ((singl* or doubl* or treb* or tripl*) w1 (blind* or mask*))
52 TI (allocated n2 random*) OR AB (allocated n2 random*)
53 S47 OR S48 OR S49 OR S50 OR S51 OR S52
54 (MH "Case Studies")
55 TI ("case report") OR AB ("case report")
56 (MH "Animal Studies")
57 S54 OR S55 OR S56
58 S53 NOT S57
59 S37 AND S46 AND S58

Database: Web of Science <9 October 2015>

Search Strategy (search results)

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1 TS= (cell* NEAR/3 phone*)
2 TS= (cell* NEAR/3 telephone*)
3 TS= (mobile NEAR/3 phone*)
4 TS= (mobile NEAR/3 telephone*)
5 TS= (smartphone*)
6 TS= (smart-phone*)
7 TS= (smart NEAR/1 phone*)
8 TS= ("SMS" OR "texting")
9 TS= (short NEAR/1 messag*)
10 TS= (text NEAR/1 messag*)
11 TS= (multimedia NEAR/1 messag*)
12 TS= (messag* NEAR/1 service*)
13 TS= ("interactive voice response")
14 TS= (interactive NEAR/1 voice)
15 TS= (voice NEAR/1 response)
16 TS= ("email" OR "e-mail")
17 TS (electronic NEAR/1 mail)
18 TS= (internet-based)
19 TS= (web-based)
20 TS= (social NEAR/1 media)
21 TS= (digital NEAR/1 media)
22 TS= (mobile NEAR/3 app$)
23 TS= (mobile NEAR/3 application$)
24 TS= (phone* NEAR/3 app$)
25 TS= (phone* NEAR/3 application$)
26 TS= (smartphone* NEAR/3 app$)
27 TS= (smartphone* NEAR/3 application$)
28 TS= (smart-phone* NEAR/3 app$)
29 TS= (smart-phone* NEAR/3 application$)
30 #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
31 TS= (smok* NEAR/1 cessation*)
32 TS= (tobacco NEAR/1 cessation*)
33 TS= (smok* NEAR/1 behavio*)
34 TS= (smoking)
35 TS= (tobacco)
36 #35 OR #34 OR #33 OR #32 OR #31
37 TS= (controlled NEAR/1 trial$)
38 TS= (random* NEAR/1 trial$)
39 TS= (allocated NEAR/2 random*)
40 #39 OR #38 OR #37
41 TS= ("case report")
42 TS= (animals)
43 #42 OR #41
44 #40 NOT #43
45 #44 AND #36 AND #30

Appendix F: Systematic review study eligibility form

Study characteristics	Review inclusion criteria	Yes	Un clear	No	Location in text
Type of study	Is the study described as a randomised controlled trial (RCT)?	☐	☐	☐	
Participants	Did studies include smokers regardless of their intention to quit from any sources or settings?	☐	☐	☐	
Types of intervention	Were interventions delivered through mobile phones? The delivery mode includes text messaging, mobile apps, interactive voice responses, email, internet, web browser, and social media.	☐	☐	☐	
	Were interventions aimed at increasing smoking cessation uptake or smoking cessation rates?	☐	☐	☐	
	Were comparators include no interventions or usual care or alternative mHealth interventions?	☐	☐	☐	
Types of outcome measures	Did study report any smoking-related outcomes, including abstinence rates or average number of cigarettes smoked per day or percentage of smokers who self-report setting quit dates or self-reporting intention to quit smoking?	☐	☐	☐	
INCLUDE ☐ EXCLUDE ☐					
Reason for exclusion					
Notes:					

Appendix G: Systematic review data collection form

Review title
Identifying effective components for mobile health behaviour change interventions for smoking cessation and service uptake: protocol of a systematic review and planned meta-analysis

Study ID
e.g. Abroms 2014

Report IDs of other reports of this study

Notes:

General Information

Date form completed	
Name/ID of person extracting data	
Report title	
Report ID	
Reference details	
Report author contact details	
Publication type	
Study funding source	
Possible conflicts of interest	
Notes:	

Population and setting

	Description		**Location in text**
Population description			
Setting			
Inclusion criteria			
Exclusion criteria			
Methods of recruitment of participants			
Informed consent obtained	☐ Yes ☐ No ☐ Unclear		
Notes:			

Methods

	Descriptions as stated in report/paper		Location in text
Aim of study			
Design			
Unit of allocation			
Start date			
End date			
Duration of participation			
Ethical approval needed/ obtained for study	☐ Yes ☐ No ☐ Unclear		
Notes:			

Risk of Bias assessment

Domain	Risk of bias			Support for judgement	Location in text
	Low risk	High risk	Unclear		
Random sequence generation	☐	☐	☐		
Allocation concealment	☐	☐	☐		
Blinding of participants	☐	☐	☐		
Blinding of personnel	☐	☐	☐		
Blinding of outcome assessment	☐	☐	☐		
Incomplete outcome data	☐	☐	☐		
Selective outcome reporting?	☐	☐	☐		
Other bias	☐	☐	☐		
Notes:					

Participants

	Description as stated in report/paper	Location in text
Total no. randomised		
Clusters		
Baseline imbalances		
Withdrawals and exclusions		
Age		
Sex *(Percentage of male)*		

Average cigarettes per day		
Addiction score *(e.g. Nicotine dependence)*		
Other treatment received *(additional to study intervention)*		
Notes:		

Intervention group

	Description as stated in report/paper	**Location in text**
Group name		
No. randomised to group		
Theoretical basis		
Description		
Duration of treatment period		
Timing		
Delivery		
Providers		
Co-interventions		
Resource requirements to replicate intervention		
Modification during the course of study		
Tailored design		
☐ No tailored design		
☐ Tailor based on user characteristics		
☐ Tailor based on user need		
☐ Both characteristics and need		
Notes:		

Behaviour change technique categories	**Behaviour change techniques**	**Description as stated in report/paper**	**Location in text**
☐ no BCT			
☐ Goals and planning			
☐ Feedback and monitoring			
☐ Social support			
☐ Shaping knowledge			
☐ Natural consequences			
☐ Comparison of behaviour			
☐ Associations			

Behaviour change technique categories	Behaviour change techniques	Description as stated in report/paper	Location in text
☐ Repetition and substitution			
☐ Comparison of outcomes			
☐ Reward and threat			
☐ Regulation			
☐ Antecedents			
☐ Identity			
☐ Schedule consequences			
☐ Self-belief			
☐ Covert learning			

Control group

	Description as stated in report/paper	Location in text
Group name		
No. randomised to group		
Theoretical basis		
Description		
Duration of treatment period		
Timing		
Delivery		
Providers		
Co-interventions		
Resource requirements to replicate intervention		
Modification during the course of study		
Tailored design		
☐ No tailored design		
☐ Tailor based on user characteristics		
☐ Tailor based on user need		
☐ Both characteristics and need		
Notes:		

Behaviour change technique categories	Behaviour change techniques	Description as stated in report/paper	Location in text
☐ no BCT			
☐ Goals and planning			
☐ Feedback and monitoring			
☐ Social support			
☐ Shaping knowledge			

Behaviour change technique categories	Behaviour change techniques	Description as stated in report/paper	Location in text
☐ Natural consequences			
☐ Comparison of behaviour			
☐ Associations			
☐ Repetition and substitution			
☐ Comparison of outcomes			
☐ Reward and threat			
☐ Regulation			
☐ Antecedents			
☐ Identity			
☐ Schedule consequences			
☐ Self-belief			
☐ Covert learning			

Results

	Description as stated in report/paper				Location in text
Comparison					
Outcome 1 *(e.g. 7-day point prevalence abstinence at 1-month follow-up)*	**Intervention**		**Control**		
	Event	Total	Event	Total	
Outcome 2					
Outcome 3					
Any other results reported					

Perceived barrier and theory coding scheme

	Description as stated in report/paper	Location in text
Perceived barriers		
Theory coding scheme		
☐ Theory used to inform interventions		
☐ Theory used to classify participants		
☐ Theory used to tailor interventions according to participants		
☐ Theory used to measure outcome changes		
☐ Theory used in discussion of study		

Notes:

Technology engagement

	Description as stated in report/paper	Location in text
Reported technology engagement		
Measurement		
Notes:		

Other information

	Description as stated in report/paper	Location in text
Technology related difficulties		
Methodological limitations regarding the design of the study		
References to other relevant studies		
Correspondence required for further study information		
Notes:		

Appendix H: Template for Intervention Description and Replication (TIDieR) checklist

Item		Locations (Chapter and page no.)
	BRIEF NAME	
1.	Provide the name or a phrase that describes the intervention.	Ch4, p.67
	WHY	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Ch.4, p.67-69
	WHAT	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Ch.5, p.92-95 and Appendix M
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Ch.5, p.94-95 and Appendix N
	WHO PROVIDED	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Ch.5, p.96-98
	HOW	
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Ch.5, p.92
	WHERE	
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Ch.5, p.94
	WHEN and HOW MUCH	
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Ch.5, p.93
	TAILORING	
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A
	MODIFICATIONS	
10.	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A
	HOW WELL	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Ch.5, p.104-105
12.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Ch.7, p.158-159

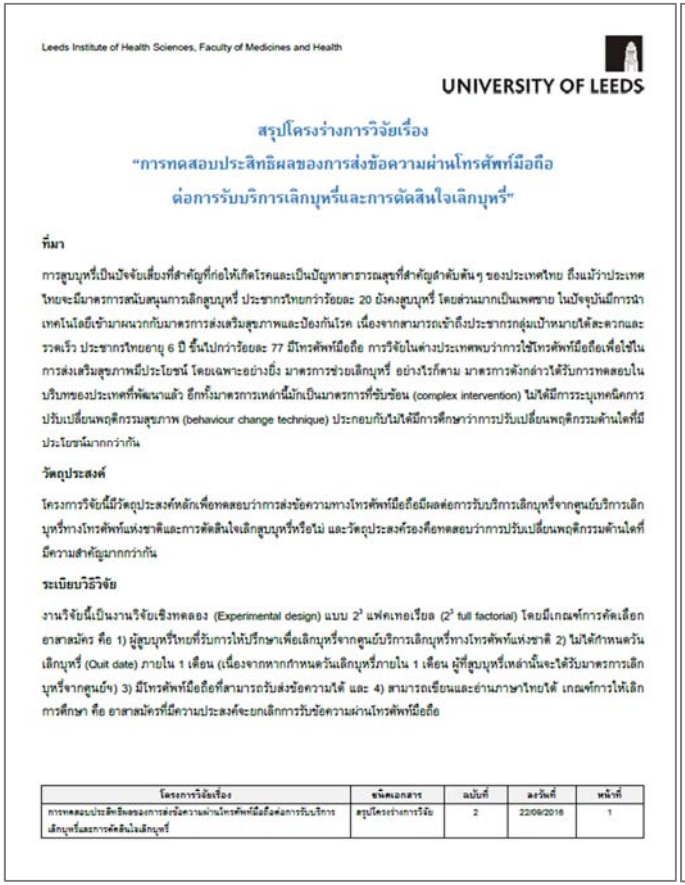
Appendix I: Consolidated criteria for Reporting Qualitative research (COREQ) checklist

No. Item	Guide questions/description	Information/page
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Pritaporn Kingkaew
2. Credentials	What were the researcher's credentials? e.g. PhD, MD	Pritaporn Kingkaew, B.Pharm, MSc Health Economics, PhD candidate
3. Occupation	What was their occupation at the time of the study?	PhD candidate
4. Gender	Was the researcher male or female?	Female
5. Experience and training	What experience or training did the researcher have?	Had experience on moderating focus group discussion
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Ch.4, p.73
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	N/A
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Ch.4, p.71-72
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Ch.4, p.72
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Ch.4, p.72
12. Sample size	How many participants were in the study?	Ch.4, p.79
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Ch.4, p.80
Setting		

No. Item	Guide questions/description	Information/page
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Ch.4, p.73
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Ch.4, p.79-80
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Ch.4, p.79-80
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Ch.4, p.73-74 and Appendix J
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Ch.4, p.74
20. Field notes	Were field notes made during and/or after the interview or focus group?	Ch.4, p.74
21. Duration	What was the duration of the interviews or focus group?	Ch.4, p.73
22. Data saturation	Was data saturation discussed?	N/A
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Ch.4, p.74
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Ch.4, p.74
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data?	Ch.4, p.74
27. Software	What software, if applicable, was used to manage the data?	N/A
28. Participant checking	Did participants provide feedback on the findings?	Ch.4, p.74
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	N/A
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Ch.4, p.79-83
31. Clarity of major themes	Were major themes clearly presented in the findings?	Ch.4, p.79-83
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	N/A

Appendix J: Materials for focus group discussion

1) Two-page trial summary



Leeds Institute of Health Sciences, Faculty of Medicines and Health

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สรุปโครงร่างการวิจัยเรื่อง

"การทดสอบประสิทธิผลของการส่งข้อความผ่านโทรศัพท์มือถือ

ต่อการรับบริการเลิกบุหรี่และการตัดสินใจเลิกบุหรี่"

ที่มา

การสูบบุหรี่เป็นปัจจัยเสี่ยงที่สำคัญที่ก่อให้เกิดโรคและเป็นปัญหาสาธารณสุขที่สำคัญลำดับต้นๆ ของประเทศไทย ถึงแม้ว่าประเทศไทยจะมีมาตรการสนับสนุนการเลิกสูบบุหรี่ ประชากรไทยกว่าร้อยละ 20 ยังคงสูบบุหรี่ โดยส่วนมากเป็นเพศชาย ในปัจจุบันมีการนำเทคโนโลยีเข้ามาผนวกกับมาตรการส่งเสริมสุขภาพและป้องกันโรค เนื่องจากสามารถเข้าถึงประชากรกลุ่มเป้าหมายได้สะดวกและรวดเร็ว ประชากรไทยอายุ 6 ปี ขึ้นไปกว่าร้อยละ 77 มีโทรศัพท์มือถือ การวิจัยในต่างประเทศพบว่าการใช้โทรศัพท์มือถือเพื่อใช้ในการส่งเสริมสุขภาพมีประโยชน์ โดยเฉพาะอย่างยิ่ง มาตรการช่วยเลิกบุหรี่ อย่างไรก็ตาม มาตรการดังกล่าวได้รับการทดสอบในบริบทของประเทศที่พัฒนาแล้ว อีกทั้งมาตรการเหล่านี้มักเป็นมาตรการที่ซับซ้อน (complex intervention) ไม่ได้มีการระบุเทคนิคการปรับเปลี่ยนพฤติกรรมสุขภาพ (behaviour change technique) ประกอบกับไม่ได้มีการศึกษาว่าการปรับเปลี่ยนพฤติกรรมด้านใดที่มีประโยชน์มากกว่ากัน

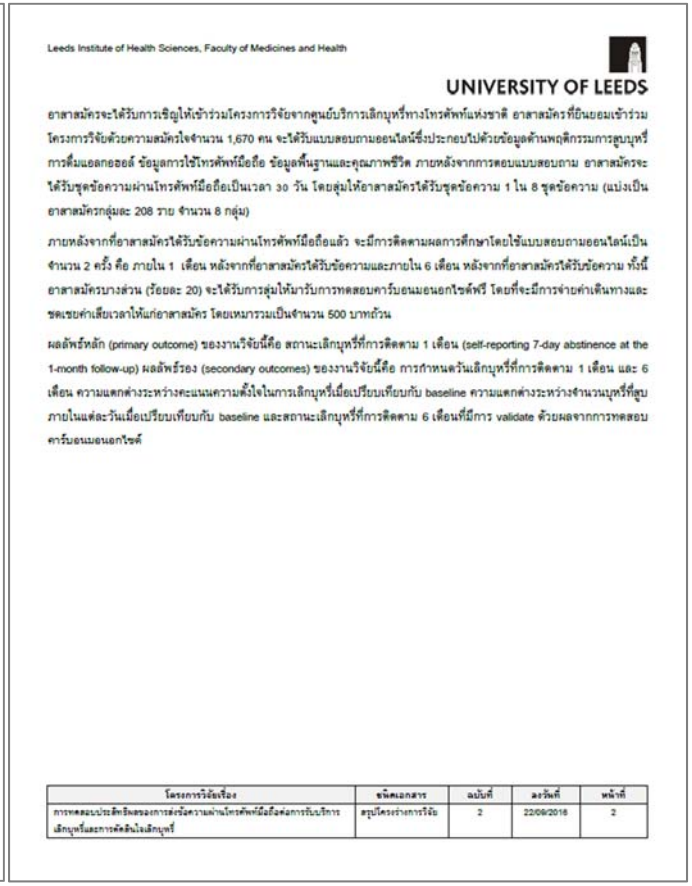
วัตถุประสงค์

โครงการวิจัยนี้มีวัตถุประสงค์หลักเพื่อทดสอบว่าการส่งข้อความทางโทรศัพท์มือถือมีผลต่อการรับบริการเลิกบุหรี่จากศูนย์บริการเลิกบุหรี่ทางโทรศัพท์แห่งชาติและการตัดสินใจเลิกสูบบุหรี่หรือไม่ และวัตถุประสงค์รองคือทดสอบว่าการปรับเปลี่ยนพฤติกรรมด้านใดที่มีความสำคัญมากกว่ากัน

ระเบียบวิธีวิจัย

งานวิจัยนี้เป็นงานวิจัยเชิงทดลอง (Experimental design) แบบ 2^3 แฟคเทอเรียล (2^3 full factorial) โดยมีเกณฑ์การคัดเลือกอาสาสมัคร คือ 1) ผู้สูบบุหรี่ไทยที่รับการให้ปรึกษาเพื่อเลิกบุหรี่จากศูนย์บริการเลิกบุหรี่ทางโทรศัพท์แห่งชาติ 2) ไม่ได้กำหนดวันเลิกบุหรี่ (Quit date) ภายใน 1 เดือน (เนื่องจากหากกำหนดวันเลิกบุหรี่ภายใน 1 เดือน ผู้ที่สูบบุหรี่เหล่านี้จะได้รับมาตรการเลิกบุหรี่จากศูนย์ฯ) 3) มีโทรศัพท์มือถือที่สามารถรับส่งข้อความได้ และ 4) สามารถเขียนและอ่านภาษาไทยได้ เกณฑ์การให้เลิกการศึกษา คือ อาสาสมัครที่มีความประสงค์จะยกเลิกการรับข้อความผ่านโทรศัพท์มือถือ

โครงการวิจัยเรื่อง	ชนิดเอกสาร	ฉบับที่	ลงวันที่	หน้าที่
การทดสอบประสิทธิผลของการส่งข้อความผ่านโทรศัพท์มือถือต่อการรับบริการเลิกบุหรี่และการตัดสินใจเลิกบุหรี่	สรุปโครงร่างการวิจัย	2	22/09/2016	1



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อาสาสมัครจะได้รับการเชิญให้เข้าร่วมโครงการวิจัยจากศูนย์บริการเลิกบุหรี่ทางโทรศัพท์แห่งชาติ อาสาสมัครที่ยินยอมเข้าร่วมโครงการวิจัยด้วยความสมัครใจจำนวน 1,670 คน จะได้รับแบบสอบถามออนไลน์ซึ่งประกอบไปด้วยข้อมูลด้านพฤติกรรมการสูบบุหรี่ การดื่มแอลกอฮอล์ ข้อมูลการใช้โทรศัพท์มือถือ ข้อมูลพื้นฐานและคุณภาพชีวิต ภายหลังจากการตอบแบบสอบถาม อาสาสมัครจะได้รับชุดข้อความผ่านโทรศัพท์มือถือเป็นเวลา 30 วัน โดยสุ่มให้อาสาสมัครได้รับชุดข้อความ 1 ใน 8 ชุดข้อความ (แบ่งเป็นอาสาสมัครกลุ่มละ 208 ราย จำนวน 8 กลุ่ม)

ภายหลังจากที่อาสาสมัครได้รับข้อความผ่านโทรศัพท์มือถือแล้ว จะมีการติดตามผลการศึกษาโดยใช้แบบสอบถามออนไลน์เป็นจำนวน 2 ครั้ง คือ ภายใน 1 เดือน หลังจากที่อาสาสมัครได้รับข้อความและภายใน 6 เดือน หลังจากที่อาสาสมัครได้รับข้อความ ทั้งนี้อาสาสมัครบางส่วน (ร้อยละ 20) จะได้รับการสุ่มให้มารับการทดสอบคาร์บอนมอนอกไซด์ฟรี โดยที่จะมีการจ่ายค่าเดินทางและชดเชยค่าเสียเวลาให้แก่อาสาสมัคร โดยเหมารวมเป็นจำนวน 500 บาทถ้วน

ผลลัพธ์หลัก (primary outcome) ของงานวิจัยนี้คือ สถานะเลิกบุหรี่ที่การติดตาม 1 เดือน (self-reporting 7-day abstinence at the 1-month follow-up) ผลลัพธ์รอง (secondary outcomes) ของงานวิจัยนี้คือ การกำหนดวันเลิกบุหรี่ที่การติดตาม 1 เดือน และ 6 เดือน ความแตกต่างระหว่างคะแนนความตั้งใจในการเลิกบุหรี่เมื่อเปรียบเทียบกับ baseline ความแตกต่างระหว่างจำนวนบุหรี่ที่สูบภายในแต่ละวันเมื่อเปรียบเทียบกับ baseline และสถานะเลิกบุหรี่ที่การติดตาม 6 เดือนที่มีการ validate ด้วยผลจากการทดสอบคาร์บอนมอนอกไซด์

โครงการวิจัยเรื่อง	ชนิดเอกสาร	ฉบับที่	ลงวันที่	หน้าที่
การทดสอบประสิทธิผลของการส่งข้อความผ่านโทรศัพท์มือถือต่อการรับบริการเลิกบุหรี่และการตัดสินใจเลิกบุหรี่	สรุปโครงร่างการวิจัย	2	22/09/2016	2

2) Meeting agenda

กำหนดการประชุมผู้เชี่ยวชาญ

เพื่อให้ข้อคิดเห็นเกี่ยวกับการส่งข้อความผ่านโทรศัพท์มือถือ
เพื่อสนับสนุนการลดการบริโภคยาสูบ

วันศุกร์ที่ 4 พฤศจิกายน พ.ศ. 2559 เวลา 13:30 – 16:30 น.
ณ ห้องประชุม โครงการประเมินเทคโนโลยีและนโยบายด้านสุขภาพ 3
กรมอนามัย กระทรวงสาธารณสุข

เวลา	วัตถุประสงค์
13:30 – 14:00	กล่าวชี้แจงวัตถุประสงค์ของการประชุมและนำเสนอโครงร่างการวิจัย โดย ภญ.ปฤษฐพร กิ่งแก้ว
การสนทนากลุ่มเพื่ออภิปรายเนื้อหาข้อความ	
14:00 – 14:30	ข้อความที่ออกแบบเพื่อเพิ่มความสามารถในการเลิกบุหรี่ (smokers' capability to quit smoking)
14:30 – 15:00	ข้อความที่ออกแบบเพื่อเพิ่มปัจจัยที่สนับสนุนให้เลิกบุหรี่ (opportunity to support smoking cessation)
15:00 – 15:30	ข้อความที่ออกแบบเพื่อเพิ่มกำลังใจในการเลิกบุหรี่ (motivation to quit smoking)
15:30 – 16:00	ข้อความที่ไม่เกี่ยวข้องกับการบริโภคยาสูบ
16:00 – 16:30	สรุปผลการประชุมและการร่วมงานกับเครือข่ายในอนาคต

3) Participant information sheet

Leeds Institute of Health Sciences, Faculty of Medicines and Health

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Participant information sheet

Research title: "Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

Can text messages help improve the Thailand National Quitline service uptake and smoking cessation rates?

You are invited to participate in this group discussion. Please take your time to understand the following information. If you are unclear about any of the information below, please do not hesitate to ask the researcher using the contact information listed below.

Purpose of this research

This group discussion aims to investigate whether text messages to support smoking cessation is acceptable and to explore the feasibility of text message programme to support the Thailand National Quitline service.

Do you have to take part?

Participating in this research should be on a voluntary basis only. If you decide to join the group discussion, you will be asked to provide written consent. Please be informed that you can decline to participate or withdraw from the group discussion without giving any reason and without any negative consequences. However, the responses or quotations that you have already given to members of the research team will be used for the research unless you withdraw within 48 hours. This is because the researcher will start to analyse the information that has been given and will no longer take your response out from the report.

What will your participation involve?

You will be asked to attend two meetings after you have provided consent. The first meeting will be focusing on whether text messages are acceptable. The second meeting will be focusing on the feasibility of implementation of text message programme in the Thailand National Quitline. Each meeting will take around 3 hours of your time. For the research purposes, we will take written notes during the group discussion and audio recordings of your responses. Compensation will be provided for your time along with transportation.

How many people will be involved?

There will be 10 people who participate in this group discussion.

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Participant information sheet - Qualitative	4	12/10/2016

What are the possible benefits of taking part?

There is no direct benefit from participating in this group discussion but the information that you provide will help shape this research and improve policy recommendation for an implementation of text message programme in the future.

What are the possible disadvantages of taking part?

The group discussion should take around 3 hours of your time for each meeting. You may feel uncomfortable discussing some issues. If so, please feel free to leave those issues or leave the meeting. If you are experiencing distress from being involved in this group discussion, the Mental Health hotline (1667) may be able to support you.

All responses will be confidential

Your personal information, such as name and contact details, will not be linked with your response, quotations or any research materials. Your responses will be kept strictly confidential. Members of the research team and individuals from the University of Leeds will have access to your anonymised responses. For the use of this research in the future, other genuine researchers will be able to access to your anonymised responses or use your anonymised responses only if they agree to preserve the confidentiality of the information. Any personal information that could identify you will be removed before files are shared with other researchers.

How will your information be used?

All information collected from this group discussion will be kept confidential. The data will be stored electronically in an anonymised form for 5 years and may be used for future relevant research. All publications from this group discussion will not contain your name or any information that can identify you.

Who is organizing and funding this research?

This is a part of PhD research project conducted by Pritaporn Kingkaew, a PhD candidate from University of Leeds, United Kingdom and a researcher from Health Intervention and Technology Assessment Program, Thailand. This PhD research project is supervised by Liz Glidewell and Rebecca Walwyn from the University of Leeds and Jeremy C. Wyatt from the University of Southampton, United Kingdom. This research is funded by Network coordinator for economic evaluation of health promotion interventions and Health Intervention and Technology Assessment Program.

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If you have any questions or concerns regarding the research project, please contact

Pritaporn Kingkaew

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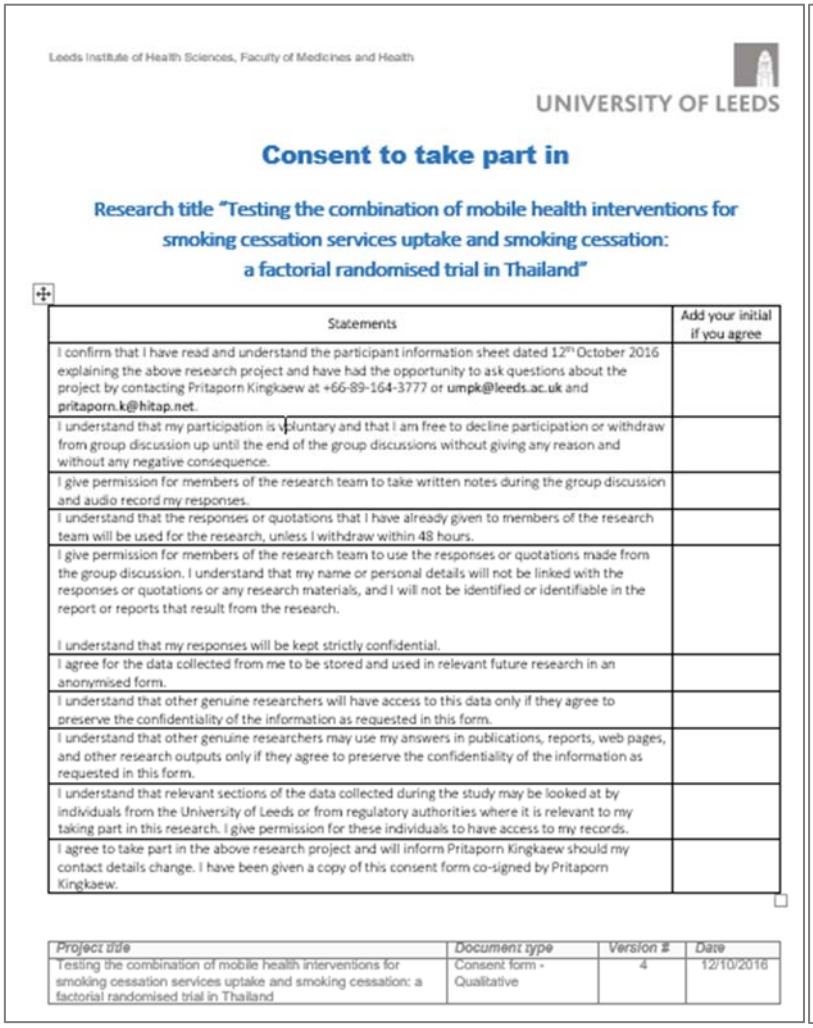
Tel: +44-74-6621-5703

This study has been reviewed by the School of Medicine Research Ethics Committee, University of Leeds (MREC16-001) and the Institute for the Development of Human Research Protections, Thailand.

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Participant information sheet - Qualitative	4	12/10/2016

4) Consent form



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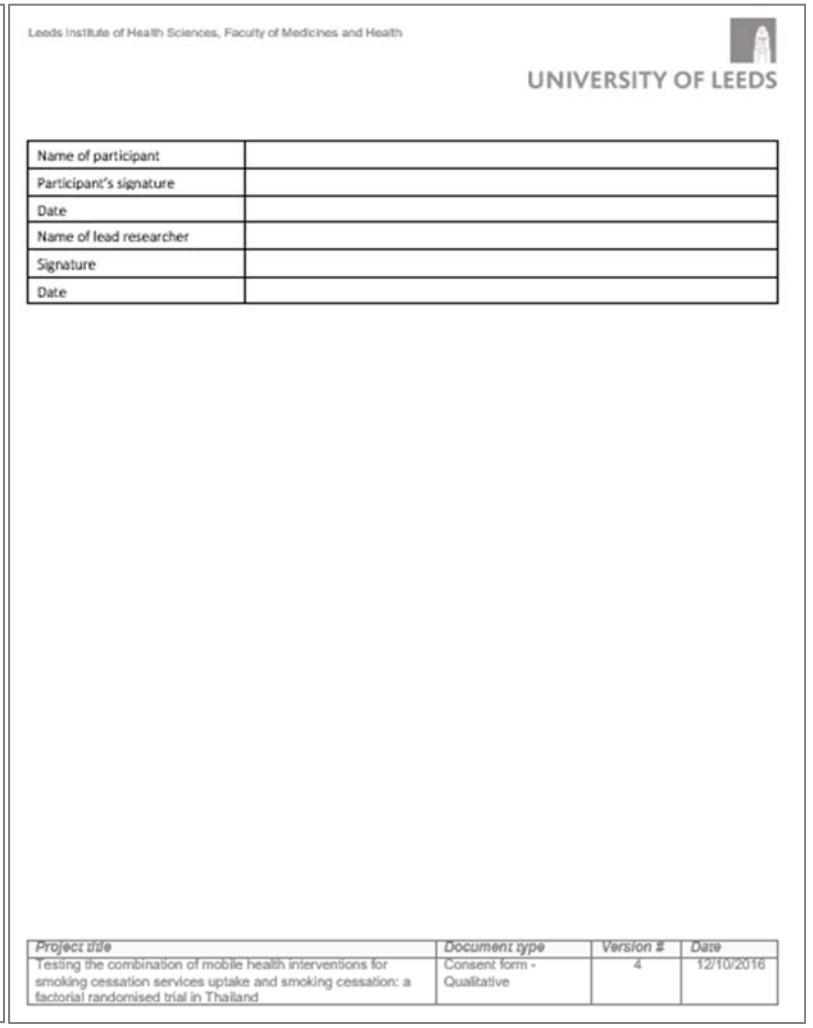
Consent to take part in

Research title "Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

Statements	Add your initial if you agree
I confirm that I have read and understand the participant information sheet dated 12th October 2016 explaining the above research project and have had the opportunity to ask questions about the project by contacting Pritaporn Kingkaew at +66-89-164-3777 or umpk@leeds.ac.uk and pritaporn.k@hitap.net.	
I understand that my participation is voluntary and that I am free to decline participation or withdraw from group discussion up until the end of the group discussions without giving any reason and without any negative consequence.	
I give permission for members of the research team to take written notes during the group discussion and audio record my responses.	
I understand that the responses or quotations that I have already given to members of the research team will be used for the research, unless I withdraw within 48 hours.	
I give permission for members of the research team to use the responses or quotations made from the group discussion. I understand that my name or personal details will not be linked with the responses or quotations or any research materials, and I will not be identified or identifiable in the report or reports that result from the research. I understand that my responses will be kept strictly confidential.	
I agree for the data collected from me to be stored and used in relevant future research in an anonymised form.	
I understand that other genuine researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.	
I understand that other genuine researchers may use my answers in publications, reports, web pages, and other research outputs only if they agree to preserve the confidentiality of the information as requested in this form.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from the University of Leeds or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I agree to take part in the above research project and will inform Pritaporn Kingkaew should my contact details change. I have been given a copy of this consent form co-signed by Pritaporn Kingkaew.	

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Consent form - Qualitative	4	12/10/2016



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Name of participant	
Participant's signature	
Date	
Name of lead researcher	
Signature	
Date	

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Consent form - Qualitative	4	12/10/2016

Appendix K: Excluded behaviour change techniques, status and rationale for exclusion

Behaviour change techniques (n*)	Status	Rationale to be excluded
CAPABILITY		
2. Feedback and monitoring		
2.1 Monitoring of behaviour by others without feedback	Not selected	Not supported by the systematic review findings
2.2 Feedback on behaviour (n=6)	Not applicable	Not feasible to deliver within the delivery mechanism
2.5 Monitoring of outcome(s) of behaviour without feedback (n=1)		
2.6 Biofeedback (n=1)		
2.7 Feedback on outcome(s) of behaviour (n=3)		
4. Shaping knowledge		
4.3 Re-attribution	Not selected	Not supported by the systematic review findings
4.4 Behavioural experiments	Not applicable	Not feasible to deliver within the delivery mechanism
8. Repetition and substitution		
8.3 Habit formation	Not applicable	Not feasible to deliver within the delivery mechanism
8.4 Habit reversal	Not applicable	Not feasible to deliver within the delivery mechanism
8.5 Overcorrection	Not selected	Not supported by the systematic review findings
11. Comparison of outcomes		
11.3 Conserving mental resources (n=3)	Not applicable	Not feasible to deliver within the delivery mechanism
12. Antecedents		
12.6 Body changes	Not applicable	Not relevant to the topic
OPPORTUNITY		
6. Comparison of behaviour		
6.1 Demonstration of the behaviour (n=2)	Not applicable	Not feasible to deliver within the delivery mechanism
6.3 Information about others' approval (n=7)	Not applicable	Not feasible to deliver within the delivery mechanism
7. Associations		
7.2 Cue signalling reward	Not selected	Not supported by the systematic review findings
7.3 Reduce prompts/cues (n=1)	Not applicable	Not feasible to deliver within the delivery mechanism
7.4 Remove access to the reward		
7.5 Remove aversive stimulus (n=1)		

Behaviour change techniques (n*)	Status	Rationale to be excluded
7.6 Satiation		
7.7 Exposure		
12. Antecedents		
12.5 Adding objects to the environment*	Not applicable	Not feasible to deliver within the delivery mechanism
13. Identity		
13.3 Incompatible beliefs	Not selected	Not supported by the systematic review findings
13.4 Valued self-identify	Not selected	Not supported by the systematic review findings
MOTIVATION		
1. Goals and planning		
1.4 Action planning (n=8)	Not applicable	Not feasible to deliver within the delivery mechanism
1.6 Discrepancy between current behaviour and goal (n=1)	Not applicable	Not feasible to deliver within the delivery mechanism
5. Natural consequences		
5.2 Salience of consequences	Not applicable	Not feasible to deliver within the delivery mechanism
5.4 Monitoring of emotional consequences (n=2)	Not selected	Not feasible to deliver within the delivery mechanism
5.5 Anticipated regret	Not selected	Avoid a negative reinforcement statement
5.6 Information about emotional consequences (n=1)	Not selected	Use BCT 5.3 Information about social and environmental consequences as an alternative
5.7 Information about consequences (unspecified) (n=12)	Not selected	Use BCT 5.3 Information about social and environmental consequences as an alternative
7. Associations		
7.8 Associative learning*	Not applicable	Not feasible to arrange within the delivery mechanism
9. Comparison of outcomes		
9.1 Credible source	Not selected	Not supported by the systematic review findings
9.3 Comparative imagining of future outcomes		
10. Reward and threat		
10.1 Material incentive (behaviour)	Not selected	Not supported by the systematic review findings
10.2 Material reward (behaviour)	Not applicable	Not feasible to arrange within the delivery mechanism
10.3 Non-specific reward (n=5)	Not applicable	Not feasible to arrange within the delivery mechanism

Behaviour change techniques (n*)	Status	Rationale to be excluded
10.4 Social reward (n=2)	Not applicable	Not feasible to arrange within the delivery mechanism
10.7 Self-incentive	Not selected	Not supported by the systematic review findings
10.8 Incentive (outcome)	Not selected	Not supported by the systematic review findings
10.10 Reward (outcome)	Not applicable	Not feasible to arrange within the delivery mechanism
10.11 Future punishment	Not selected	Not supported by the systematic review findings
11. Regulation		
11.4 Paradoxical instructions	Not selected	Not supported by the systematic review findings
14. Scheduled consequences		
14.1 Behaviour cost	Not applicable	Not feasible to arrange within the delivery mechanism
14.2 Punishment		
14.3 Remove reward		
14.4 Reward approximation		
14.5 Rewarding completion		
14.6 Situation-specific reward		
14.7 Reward incompatible behaviour		
14.8 Reward alternative behaviour		
14.9 Reduce reward frequency		
14.10 Remove punishment (n=3)		
15. Self-belief		
15.3 Focus on past success (n=4)	Not selected	Use BCT 15.2 Mental rehearsal of successful performance as an alternative
16. Covert learning		
16.1 Imaginary punishment (n=2)	Not selected	Avoid a negative reinforcement statement
16.3 Vicarious consequences	Not selected	Not supported by the systematic review findings

*Number of studies reported to contain the select BCTs in their intervention group

Appendix L: Results from two independent coders

No.	Text messages	Intended BCTs coded by PK	BCTs coded by FL
11	Set your goal. How many cigarettes will you reduce within a week?	1.3 Goal setting (outcome)	**1.1 Goal setting (behaviour)**
33	All you need is a commitment to abstinence. It is a good example to those around you.	13.1 Identification of self as role model	**1.9 Commitment**; 13.1 Identification of self as a role model
55	Tobacco use is associated with 1 in 6 deaths of Thai people.	5.1 Information about health consequences	5.1 Information about health consequences
12	You can do it. Just tell yourself that you can quit smoking.	15.1 Verbal persuasion about capability; 15.4 Self talk	15.1 Verbal persuasion about capability; 15.4 Self talk
37	Prepare to quit by trying to abstain from smoking at home like when you have to abstain at your work place or school.	8.6 Generalisation of target behaviour	**1.4 Action planning**; 8.6 Generalisation of target behaviour
43	Stop smoking for 6 months and you can see that coughing will have decreased.	5.1 Information about health consequences	5.1 Information about health consequences; **9.3 comparative imagining of future outcomes**
45	The beginning of your smoking abstinence is difficult. Try to avoid parties.	12.3 Avoidance/ reducing exposure to cues for the behaviour	12.3 Avoidance/ reducing exposure to cues for the behaviour
7	Stop smoking now and it will make your heart healthy and younger by 5 years.	5.1 Information about health consequences	5.1 Information about health consequences; **9.3 comparative imagining of future outcomes**
9	List down the reason why you would like to quit, and then place it around your house.	7.1 Prompts/cues	**9.2 Pros and cons**; 7.1 Prompts/cues
34	Write messages to encourage your abstinence, then stick them around home.	7.1 Prompts/cues	**15.4 Self-talk**; 7.1 Prompts/cues
56	Prepare to quit by trying to reduce one cigarette a day until your quit date.	8.7 Graded tasks	8.7 Graded tasks; **1.4 Action planning**
13	If need to smoke cigarettes within half an hour after waking up, you are addicted to nicotine.	5.1 Information about health consequences	5.1 Information about health consequences

No.	Text messages	Intended BCTs coded by PK	BCTs coded by FL
46	Avoiding your smoker friends for a while will help your quitting journey become easier.	12.2 Restructuring the social environment	**12.3 Avoidance/reducing exposure to cues for the behaviour**
47	Many people do not like smokers because they feel that they have been hurt indirectly.	5.3 Information about social and environmental consequences	**6.3 Information about others' approval**; 5.3 Information about social and environmental consequences
15	Nicotine replacement therapy can help you with the nicotine withdrawal symptoms. Consult a pharmacy near you.	11.1 Pharmacological support	11.1 Pharmacological support
20	Try to stop smoking as much as you can, and then record how long you were able to stop.	2.3 Self-monitoring of behaviour	**4.4 behavioural experiments**
27	Nicotine replacement therapy can assist you in quitting smoking by up to 2 times compared to abruptly quitting.	11.1 Pharmacological support	11.1 Pharmacological support
58	Have you thrown away your cigarettes and ash tray today?	12.1 Restructuring the physical environment	**12.3 Avoidance/reducing exposure to cues for the behaviour**; 12.1 Restructuring the physical environment
23	Tell your friends that you are a person who wants to quit smoking.	13.5 Identity associated with changed behaviour	13.5 Identity associated with changed behaviour; **3.1 Social support (unspecified)**
26	If smoking helps you to relax, try to find new ways to make you relaxed.	8.2 Behaviour substitution	**11.3 Conserving mental resources**

PK: Pritaporn Kingkaew; **FL:** Fabiana Lorencatto

Appendix M: Text messages and target behaviour change techniques to be evaluated in the trial

1) Containing 'Capability' behaviour change component

Text messages	Behaviour change techniques	C	CO	CM	COM
It's hard to quit smoking because of nicotine and habits formed by smoking.	5.1 Information about health consequences	/	/	/	/
If you can get addicted to smoking, you can also quit. Try and go cold-turkey.	4.1 Instruction on how to perform the behaviour	/	/	/	/
Quitting smoking from today onwards will make your heart stronger and reduce your heart's age by 5 years.	5.1 Information about health consequences	/			
Go cold-turkey. Plan and counteract your smoking desires.	1.2 Problem solving	/	/	/	/
If smoking is the first thing that comes to your mind when you wake up, it means you are addicted to nicotine.	5.1 Information about health consequences	/	/	/	/
Drinking lots of water can help reduce your desire to smoke and make it easier to quit.	1.2 Problem solving	/	/	/	/
You are easily tired and have shortness of breath because smoking prevents your lungs from working at maximum capacity.	5.1 Information about health consequences	/	/	/	/
When you want to smoke, try to take slow and deep breaths for 5 minutes.	1.2 Problem solving/ 12.4 Distraction	/	/	/	/
When you feel like smoking, write down the situation so you can find a way to cope it.	4.2 Information about antecedents	/	/	/	/
If you need to put cigarette in your mouth after eating, find an alternative to smoking.	8.2 Behaviour substitution	/	/	/	/
If you can refrain from smoking in non-smoking areas, you can do it in other areas too.	8.6 Generalisation of target behaviour	/	/	/	/
Try not to smoke after a meal by eating sour fruits instead.	8.2 Behaviour substitution	/	/	/	
What to do if you want to smoke? Play games on your mobile phone for 10 minutes.	1.2 Problem solving/ 12.4 Distraction	/	/	/	/

Text messages	Behaviour change techniques	C	CO	CM	COM
Playing games on your mobile phone for 10 minutes can help distract you from an urge to smoke.	12.4 Distraction	/			
The urge to smoke only lasts for 5 minutes. Engage in something you like other than smoking.	1.2 Problem solving/ 8.2 Behaviour substitution	/	/	/	/
Quit smoking for 1 month. Your lungs and blood circulation will improve.	5.1 Information about health consequences	/	/	/	
Kill time by doing something that you like instead of smoking.	8.2 Behaviour substitution	/	/	/	/
If you smoke to relax, try changing your habits and breathe in and out instead.	8.2 Behaviour substitution	/	/	/	
1 in 6 deaths among Thai people are associated with smoking.	5.1 Information about health consequences	/	/	/	/
Quitting smoking is like fighting with yourself. Try to abstain as long as possible and write it down.	2.3 Self-monitoring of behaviour	/	/	/	/
The familiarity of having cigarettes in your mouth is one reason why you are addicted to smoking.	5.1 Information about health consequences	/			
If you can get addicted to smoking, you can also quit. Be brave. Go cold-turkey.	4.1 Instruction on how to perform the behaviour	/			
Quitting smoking today to avoid heart disease.	5.1 Information about health consequences	/			
You can quit smoking by figure out how to get around the urge to smoke.	1.2 Problem solving	/			
You are addicted to nicotine if you need to smoke 30 minutes after waking up.	5.1 Information about health consequences	/			
The desire to smoking in the initial stages of quitting can be reduced by drinking lots of water.	1.2 Problem solving	/			
Are you impotent? Smoking is a cause for erectile dysfunction.	5.1 Information about health consequences	/	/	/	
Whenever you want to smoke, try playing games on your mobile phone for 10 minutes.	12.4 Distraction	/			
Prepare to quit smoking, write down what situations make you want to smoke.	4.2 Information about antecedents	/			

Text messages	Behaviour change techniques	C	CO	CM	COM
Mouthwash should be used after a meal instead of after smoking a cigarette.	8.2 Behaviour substitution	/			
If you can refrain from smoking in the office or at school, you can also do it at home.	8.6 Generalisation of target behaviour	/			
Try to not smoke during your office breaks by chatting with your friends instead.	12.4 Distraction	/	/	/	/
What should you do if you want to smoke? Talk to a friend who quit smoking.	1.2 Problem solving/ 12.4 Distraction	/			
Talking with a friend who quit smoking can help deviate your attention from wanting to smoke.	12.4 Distraction	/	/	/	/
Whenever you want to smoke, find something you like to do for only the first 5 minutes and your urge will dissipate by itself.	1.2 Problem solving/ 8.2 Behaviour substitution	/			
If you quit smoking for 6 months, you will notice that you cough less.	5.1 Information about health consequences	/	/	/	/
Set rules for yourself. Don't let yourself become too free during the initial stages of quitting.	8.2 Behaviour substitution	/			
If you smoke to relieve stress, try to meditate instead.	8.2 Behaviour substitution	/	/	/	
Smoking is the leading cause of death in Thai people.	5.1 Information about health consequences	/			
Quit smoking intentionally. Being with writing down how long you are able to go without smoking.	2.3 Self-monitoring of behaviour	/			
The desire to smoke comes from nicotine in the cigarette. The more you smoke, the more you want to smoke.	5.1 Information about health consequences	/			
If you can get addicted to smoking, you can also quit. Try harder, go cold-turkey.	4.1 Instruction on how to perform the behaviour	/	/	/	
The age of your heart will decrease by 5 years if you quit smoking starting from today.	5.1 Information about health consequences	/	/	/	/
It's not hard to go cold-turkey. Just devise a method to counteract your smoking desires.	1.2 Problem solving	/			
If the first cigarette of the day is hard to quit, you are addicted to nicotine.	5.1 Information about health consequences	/			

Text messages	Behaviour change techniques	C	CO	CM	COM
During quitting, try to drink 8-10 glasses of water a day. It can help reduce the desire to smoke.	1.2 Problem solving	/			
Black lips, black gums, and smelly odours are only a small fraction of the harms of smoking.	5.1 Information about health consequences	/	/	/	
Whenever you want to smoke, try calling a friend who quit smoking.	1.2 Problem solving/ 12.4 Distraction	/			
Prepare yourself for quitting by writing down situations which make you want to smoke.	4.2 Information about antecedents	/			
Whenever you want to put cigarettes in your mouth, take sugar-free candy. It will help make quitting easier.	8.2 Behaviour substitution	/	/	/	
If you can refrain from smoking at home, try to do so in other areas too.	8.6 Generalisation of target behaviour	/			
Try to refrain from smoking when you use the bathroom by playing games on your mobile phone instead.	8.2 Behaviour substitution	/	/	/	
Whenever you want to smoke, take deep breaths in and out for 5 minutes.	1.2 Problem solving/ 12.4 Distraction	/			
Take slow and deep breaths for 5 minutes. It can help reduce your interest in smoking.	12.4 Distraction	/			
You can remedy your urge to smoke by doing something you like for the first 5 minutes when you want to smoke.	1.2 Problem solving/ 8.2 Behaviour substitution	/			
Quit smoking for 1 year and you reduce the risk of heart diseases by half.	5.1 Information about health consequences	/	/	/	
During the beginning of quitting, try to keep yourself busy instead of smoking.	8.2 Behaviour substitution	/			
If you smoke to control your weight, try exercising and diet control instead.	1.2 Problem solving/ 8.2 Behaviour substitution	/	/	/	/
More than 70,000 people die from smoking every year. Do you want to become one of them?	5.1 Information about health consequences	/			
Don't forget to write down the amount of time that you are able to go without smoking.	2.3 Self-monitoring of behaviour	/			

2) Containing 'Opportunity' behaviour change component

Text messages	Behaviour change techniques	O	CO	OM	COM
In each year, many people are able to quit smoking. If they can do it, so can you.	6.2 Social comparison	/	/	/	
If you want to quit smoking, call 1600 free of charge on all mobile networks.	3.2 Social support (practical) & 3.3 Social support (emotional)	/	/	/	/
Take the first step to quit smoking. Start by throw away your cigarettes and lighter.	12.1 Restructuring the physical environment	/	/	/	/
Encouraging messages from loved ones can help you successfully quit.	3.3 Social support (emotional)	/	/	/	/
1600 Quit Smoking hotline. Call free on all mobile networks.	3.2 Social support (practical) & 3.3 Social support (emotional)	/	/	/	/
Smoking medication can help reduce withdrawal symptoms. Ask your local pharmacist today.	11.1 Pharmacological support	/	/	/	/
Quitting is not as hard as you think. Just don't get close to other smokers.	12.2 Restructuring the social environment	/	/	/	/
Avoid places which urge you to smoke.	12.3. Avoidance/reducing exposure to cues for the behaviour	/	/	/	/
Going cold-turkey works. To know more, call 1600 now free of charge.	3.2 Social support (practical) & 3.3 Social support (emotional)	/	/	/	/
Remind yourself constantly whenever you want to smoke with a note to yourself.	7.1 Prompts/cues	/	/	/	/
Quitting today set a good example for those around you.	13.1. Identification of self as role model	/	/	/	/
Smoking cessation medication can help you successfully quit smoking.	11.1 Pharmacological support	/	/	/	/
Quitline 1600 is ready to encourage you during times of suffering.	3.3 Social support (emotional)	/	/	/	/
Read this message every time you are suffering for encouragement. Remind yourself that you can quit.	7.1 Prompts/cues	/	/	/	/
Quitting is hard during the beginning. Try changing your environment and avoid smoking area.	12.3. Avoidance/reducing exposure to cues for the behaviour	/	/	/	/
Fight against the urge to smoke by being around friends who don't smoke.	12.2 Restructuring the social environment	/	/	/	/

Text messages	Behaviour change techniques	O	CO	OM	COM
Support from your loved ones can help encourage you to quit smoking.	3.3 Social support (emotional)	/	/	/	/
Your friends can help. Have friends who have successfully quit smoking recommend what to do when you want to smoke.	3.1 Social support (unspecific)	/	/	/	/
If you can't quit smoking this time, it doesn't mean you've failed. Try again. There is always another chance.	13.2. Framing/reframing	/	/	/	/
Encouragement at your fingertips. Dial 1600 for motivation during your struggles.	3.3 Social support (emotional)	/	/	/	/
Many Thais are able to quit smoking. If they can do it, so can you.	6.2 Social comparison	/			
Consultations at your fingertips. Dial 1600 for the smoking cessation Quitline.	3.2 Social support (practical) & 3.3 Social support (emotional)	/			
The first step to quitting is to throw away your cigarettes and lighter.	12.1 Restructuring the physical environment	/			
To successfully quit smoking, you need support from your loved ones.	3.3 Social support (emotional)	/			
If you want to quit smoking, call 1600 on all mobile networks.	3.2 Social support (practical) & (emotional)	/			
Withdrawal symptoms can be reduced by smoking cessation medication. Consult your local pharmacist.	11.1 Pharmacological support	/			
Distancing yourself temporarily from friends who smoke will make it easier to quit.	12.2 Restructuring the social environment	/			
When you first start to quit, you should avoid places which remind you want to smoke.	12.3. Avoidance/reducing exposure to cues for the behaviour	/			
Steel your resolve. Go cold-turkey. Call 1600 free of charge.	3.2 Social support (practical) & 3.3 Social support (emotional)	/			
Why did you decide to quit smoking? Write it down and post it all around as a reminder.	7.1 Prompts/cues	/			
Being committed can help you quit smoking and set a good example to those around you.	13.1. Identification of self as role model	/	/	/	

Text messages	Behaviour change techniques	O	CO	OM	COM
Assistance near your home. Receive recommendations about smoking cessation medication from your local pharmacist.	11.1 Pharmacological support	/			
If you need encouragement, call 1600 Quitline where help is always available.	3.3 Social support (emotional)	/			
Note why you want to quit smoking in your mobile phone and read it whenever you feel the urge to smoke.	7.1 Prompts/cues	/	/	/	
To quit smoking, you must not give in to your desires. Avoid locations where there are lots of smokers.	12.3. Avoidance/reducing exposure to cues for the behaviour	/	/	/	
Quit smoking is only difficult at first. Just be around friends who don't smoke.	12.2 Restructuring the social environment	/			
Encouraging messages from loved ones can help you successfully quit smoking.	3.3 Social support (emotional)	/			
Experiences from friends who have quit smoking can make it easier for you to quit.	3.1 Social support (unspecific)	/			
Don't be discouraged if you can't quit smoking. Keep on trying.	13.2. Framing/reframing	/			
Support at your fingertips. Call 1600 Quitline for free.	3.3 Social support (emotional)	/			
Quitting is not as hard as you think. If others can do it, you can too.	6.2 Social comparison	/	/	/	/
Call 1600 now. Quitline can help you.	3.2 Social support (practical) & 3.3 Social support (emotional)	/			
Have you thrown away your cigarettes and lighter already today?	12.1 Restructuring the physical environment	/	/	/	
Don't forget to ask for encouragement from your loved ones during your days of suffering.	3.3 Social support (emotional)	/	/	/	
You can also go cold-turkey. To learn more, call 1600 free of charge.	3.2 Social support (practical) & 3.3 Social support (emotional)	/			
What to do if you want to smoke? Ask about smoking cessation medication from your local pharmacist.	11.1 Pharmacological support	/			
Second-hand smoke can make you feel like smoking. Stay away to steel your resolve.	12.2 Restructuring the social environment	/	/	/	
Try to stay away from places where you usually smoke during the initial stages of quitting.	12.3. Avoidance/reducing exposure to cues for the behaviour	/	/	/	

Text messages	Behaviour change techniques	O	CO	OM	COM
Consultants at your fingertips. If you want to quit, call 1600 free.	3.2 Social support (practical) & 3.3 Social support (emotional)	/			
What is your reason to quit smoking? Write it down and place it everywhere to remind yourself constantly.	7.1 Prompts/cues	/	/	/	
Just being committed to quitting is already a good example to those around you.	13.1. Identification of self as role model	/			
Ask for recommendations on smoking cessation medication from your local pharmacy.	11.1 Pharmacological support	/			
Quitline 1600 is ready to take the next step with you during your suffering.	3.3 Social support (emotional)	/			
Writing down encouraging messages in your mobile phone as a reminder can help you successfully quit smoking.	7.1 Prompts/cues	/			
Avoid places which make you feel like smoking during the initial stages of quitting.	12.3. Avoidance/reducing exposure to cues for the behaviour	/			
Hang out with friends who don't smoke for a while to steel your resolve in going cold-turkey.	12.2 Restructuring the social environment	/			
One important factor for quitting is support from those you care about.	3.3 Social support (emotional)	/			
Ask those who have successfully quit how they managed to navigate the difficulties.	3.1 Social support (unspecific)	/			
Don't give up if you can't quit smoking this time. You can try to quit again.	13.2. Framing/reframing	/	/	/	
Support at your fingertips. 1600 can help you.	3.3 Social support (emotional)	/			

3) Containing 'Motivation' behaviour change component

Text messages	Behaviour change techniques	M	CM	OM	COM
Close your eyes and think: If you can successfully quit, it will be a great feeling.	15.2. Mental rehearsal of successful performance/ 16.2 Imaginary reward (Covert conditioning)	/	/	/	/
An important motivator is clearly defining the day you will quit smoking.	1.1 Goal setting (behaviour)	/	/	/	/
Let's decide to quit smoking within these 7 days.	1.1 Goal setting (behaviour)	/	/	/	/
Tell yourself often every morning that you can quit smoking.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/	/	/	/
There are more positive outcomes from quitting smoking than to smoke. Throw away your cigarettes today.	9.2 Pros and cons	/	/	/	/
Ready to quit smoking? Don't forget to make a promise to your loved ones that you will surely quit.	1.9 Commitment	/			
Let your friends know that you are about to quit smoking!	13.5 Identity associated with changed behaviour	/	/	/	/
If you can make time to smoke, you can also make time to quit. Let's designate the day you will quit today.	1.1 Goal setting (behaviour)	/	/	/	/
Promise your loved ones that you will quit smoking. Their support will help you keep moving forward.	1.9 Commitment	/	/	/	/
Tell others about your experiences in quitting smoking. You will receive numerous support from your friends.	10.5 Social incentive	/	/	/	/
Have you stopped smoking according to your target this week?	1.5 Review behaviour goal(s)	/			
Put money in the piggybank with money saved from not smoking.	10.9 Self-reward	/	/	/	/
Don't hurt those close to you with cigarette smoke.	5.3 Information about social and environmental consequences	/	/	/	/
You can do it. Just tell yourself loudly that you can stop smoking.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/	/	/	/
The nearest people receiving second-hand smoke are your loved ones.	5.3 Information about social and environmental consequences	/	/	/	/

Text messages	Behaviour change techniques	M	CM	OM	COM
You can quit. We are here to support you in your fight to quit smoking.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/	/	/	/
Targets are meant to be reached. Were you able to achieve your target to quit smoking already?	1.5 Review behaviour goal(s)	/	/	/	
Quit smoking today. You will have up to 20,000 baht extra to use.	5.3 Information about social and environmental consequences	/	/	/	/
You will be able to stay with your loved ones up to 10 years longer if you quit smoking today.	10.6 Non-specific incentive	/			
Telling yourself, you are someone who wants to quit smoking!	13.5 Identity associated with changed behaviour	/			
If you can successfully quit smoking one day, imagine how proud you will feel.	15.2. Mental rehearsal of successful performance/ 16.2 Imaginary reward (Covert conditioning)	/			
Setting a quit date on an important day is one motivation to successfully quit.	1.1 Goal setting (behaviour)	/	/	/	
Choose a day that you like this month and start to quit immediately.	1.1 Goal setting (behaviour)	/			
Tell yourself loudly that you can quit!	15.1 Verbal persuasion about capability/ 15.4 Self talk	/	/	/	
Compare the pros and cons of quitting smoking and ask yourself whether you should quit?	9.2 Pros and cons	/			
Quitting smoking begins with making promises to your loved ones.	1.9 Commitment	/	/	/	/
Tell your friends that you are about to quit smoking and you don't want to smoke ever again.	13.5 Identity associated with changed behaviour	/			
The faster you set a quit date, the closer your target will become.	1.1 Goal setting (behaviour)	/	/	/	
A good motivator is a promise to your loved ones that you will quit.	1.9 Commitment	/			
Social media can be a place that can give you emotional support. Try sharing your experiences on quitting with others.	10.5 Social incentive	/	/	/	
Two weeks have passed. Have you already set a quit date?	1.5 Review behaviour goal(s)	/	/	/	/
Treat yourself to a prize so you can increase your resolve to quit smoking successfully.	10.9 Self-reward	/			

Text messages	Behaviour change techniques	M	CM	OM	COM
Don't be complacent. You are hurting those close to you with your smoking.	5.3 Information about social and environmental consequences	/			
You can do it. Just keep telling yourself that you must quit.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/			
Don't let your loved ones close to you suffer from your second-hand smoke.	5.3 Information about social and environmental consequences	/	/	/	
You can quit. Your loved ones are motivation to keep fighting to quit smoking.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/			
Review your target today: were you able to quit?	1.5 Review behaviour goal(s)	/			
You can save up to 2000 baht a month by quitting today.	5.3 Information about social and environmental consequences	/			
Quit smoking today; you will gain 10 years to spend with your loved ones.	10.6 Non-specific incentive	/	/	/	/
Define your status, you are trying to quit smoking.	13.5 Identity associated with changed behaviour	/			
Close your eyes and think: I could quit, everyone will be so proud of me.	15.2. Mental rehearsal of successful performance/ 16.2 Imaginary reward (Covert conditioning)	/	/	/	
Set a quit date. Motivate yourself to quit smoking successfully.	1.1 Goal setting (behaviour)	/			
Decide on a precise quit date and get started on that day.	1.1 Goal setting (behaviour)	/			
Try telling yourself constantly that you can quit smoking.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/			
The cons of smoking are greater than the pros. Have you quit smoking yet?	9.2 Pros and cons	/			
Don't forget your promise to your loved ones that you will quit smoking.	1.9 Commitment	/			
Change yourself. If anyone asks, tell them that you are quitting smoking.	13.5 Identity associated with changed behaviour	/			
Quitting smoking begins with deciding on a quit date as soon as possible.	1.1 Goal setting (behaviour)	/			

Text messages	Behaviour change techniques	M	CM	OM	COM
Your promise to your loved ones is your motivation to successfully quit smoking.	1.9 Commitment	/			
If you need support, try posting your status on Facebook that "I am about to quit smoking".	10.5 Social incentive/ 13.5 Identity associated with changed behaviour	/			
Try to review: have you been able to stop smoking today yet?	1.5 Review behaviour goal(s)	/			
If you can quit smoking today, don't forget to give yourself a prize.	10.9 Self-reward	/			
Smoke from cigarettes harms those around you constantly.	5.3 Information about social and environmental consequences	/			
You can do it. Keep telling yourself every morning that you can quit.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/			
Second-hand smoke is harming those that you love.	5.3 Information about social and environmental consequences	/			
You can quit. Everyone is supporting you, keep on fighting to quit smoking.	15.1 Verbal persuasion about capability/ 15.4 Self talk	/	/	/	
It's nearly been a month. Let's see if you could quit according to your target.	1.5 Review behaviour goal(s)	/	/	/	/
Quit smoking for 1 year and you can save money more than 20,000 baht.	5.3 Information about social and environmental consequences	/	/	/	
Choose to be with your loved ones for a long time. Quit smoking today.	10.6 Non-specific incentive	/	/	/	
Tell yourself that you are not a smoker anymore, you are quitting smoking.	13.5 Identity associated with changed behaviour	/	/	/	/

4) Placebo text

Text messages
Each year, around 20,000 Thai people die from obesity.
Each year, around 50,000 Thai people die from heart disease.
More than three million people in Thailand suffer from diabetes.
Our behaviour is the causes of most chronic diseases. Let's change behaviour to fight the diseases.
Good health start from a healthy diet and regular exercise.
Write down what you eat each meal.
Have you done at least 30 minutes of exercise a day?
Maintain a good mood will help overcome many chronic diseases.
Drink at least 8-10 glasses of water a day helps flush out the waste in your body.
You should walk around 2.5-3.5 kilometres or 10,000 steps per day.
Stress can harm you, think positive and have adequate rest.
Stress-free, just practise meditation for 10 minutes a day.
Reduce salt and sugar added to your meal will help reduce diseases.
Gradually reduce salt intake little by little, you will get used to the new taste being less salty.
Note down how many calories you have eaten today.
Reduce carb, fat and sugar will also help you lose weight.
You need to walk for 125 minutes to use up the calories from a cup of pearl milk tea.
Gradually reduce sugar intake little by little, you will get used to the new taste being less sweet.
Exercise will not be boring any longer if you find a friend who likes to exercise too.
Use stairs instead of elevator or escalator to reduce disease.
Walking helps strengthen your muscle and bones.
A chance of heart disease increase by two-fold if you don't do enough exercise.
Obesity, a silent condition that leads to diabetes, high blood pressure and heart diseases.
Daily weighing helps you control weight easier.
Thai people consume sugars 3 times more than the recommended amount.
Drink water instead of sweetening drinks for just a week and you will see the changes to your body.

Text messages
The happiness you can create. Our body can create happy substance from an exercise.
Exercise until your heart regularly beat fast for at least 20-30 minutes.
Meditating or listening to music you enjoy helps you to relax.
If you are stressed, try to meditate 10 minutes a day.
One in three Thai people is obese. How about you, are you obese?
If you are obese, you will be at risk for other chronic diseases in the future.
Over 40,000 million baht a year were spent on diabetes treatment in Thailand.
Conquer chronic diseases by modifying our behaviour.
Good health starts with a healthy diet and enough exercise.
Taking notes will help you know whether you eat more than you need each day.
The best medicine is to exercise 30 minutes a day, have you exercise today?
Think positive, reduce stress, conquer many diseases
If you have been working for a long time, don't forget to grab some water to drink.
Experts recommend that walking 2.5 - 3.5 kilometres a day reduce the chance of getting heart diseases.
Practice to think positive and relax. Reduce stress hormones that can hurt you.
Meditations help you to relax, just try to practice 10 minutes a day.
Reduce your salt intake by reducing fish sauces in your food. Reduce diseases.
Try to have bland food until you form a habit, then you will be accustomed to unsalted food.
Did you have too much food or snack more than your target today?
Reduce weight by reducing carbs, fatty food, and sugar intake. You don't need any diet pills.
A cup of ice milk tea gives you energy 1 in 5 of the amount you need per day.
Start to reduce sugar intake by ordering 'less sweetened' or 'non-sweetened' tea or coffee.
Exercise today. Your body and your heart will be stronger.
Instead of riding a car, start walking when you commute in short distance. Reduce diseases.
Motivate yourself to walk by finding friends who can walk with you.
Exercise for 30 minutes a day keeps your heart strong.
Make half of your plate vegetables or fruits for healthy life in the future.

Text messages
An effective way to control your weight is to measure and note down your weight every day.
Thai people consume on average 20 grams of sugar more than the recommended amount (6 grams).
Save money in your picky bag every time you can reduce sugar intake from sweetening drinks.
The happiness you can create, exercise with your friends after work.
Exercise half an hour a day makes your body stronger, away from diseases.
Yoga can help you relax and ease the back pain from office syndrome.
What activity do you enjoy? Don't forget to take your time to enjoy it to help you distress.

Appendix N: Developing a web-based online tool to automate blocked randomised list

1) Login page

Objective: to serve as security feature for intervention allocation to participants

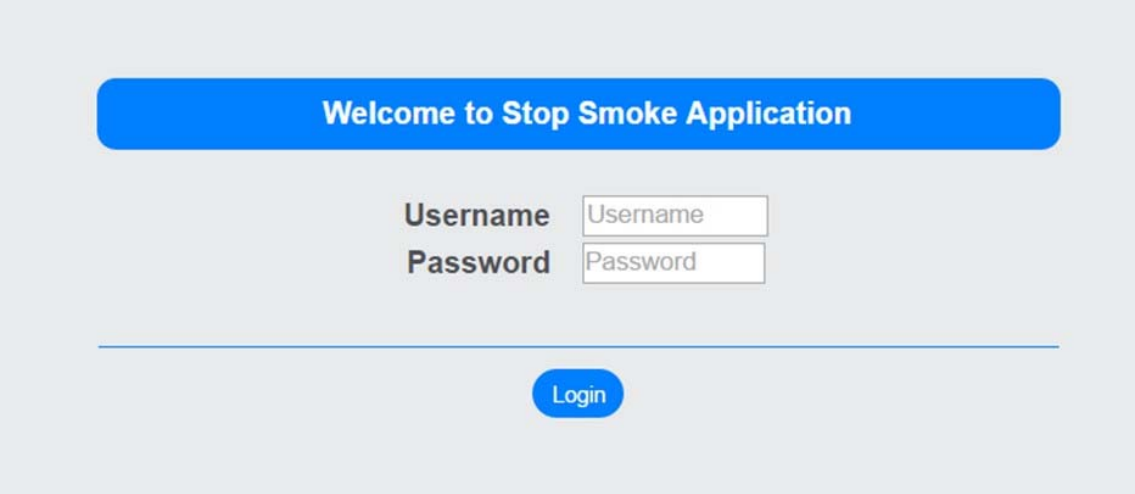

Figure N1 Screenshot of the programme login page, http://stopsmokephd.esy.es/

2) Input information

Objective: to allow data input information which will be linked to the ThaiBulkSMS

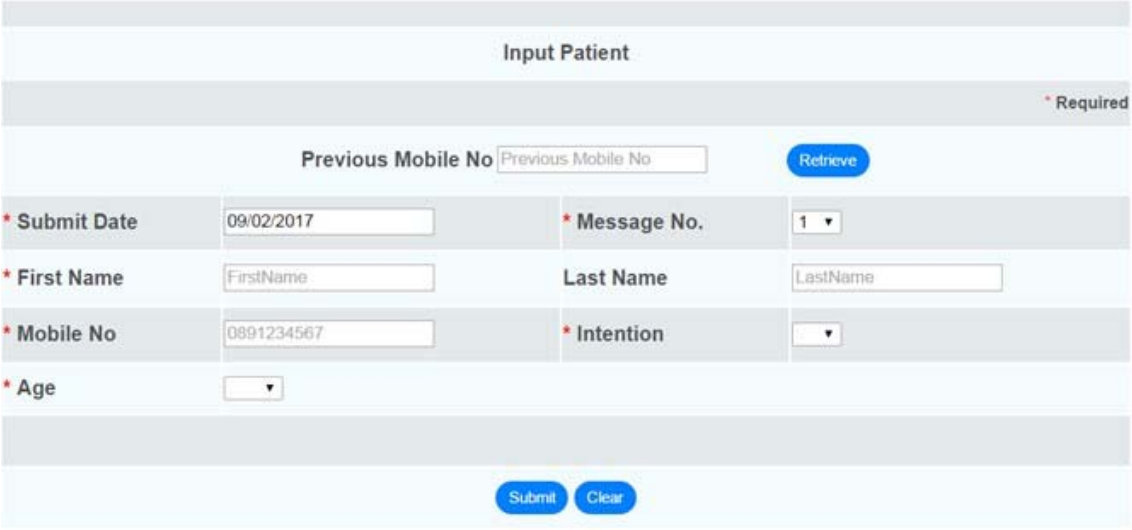

Figure N2 Screenshot of programme input information ("Input Patient Screen")

Input information rule

- **Submit Date:** Allow only date and set default as tomorrow date
- **Message No.:** A drop-down list, containing 1 to 63. Default value is 1.
- **First Name:** Allow only characters with maximum length of 80 characters
- **Last Name:** Allow only characters with maximum length of 80 characters
- **Mobile No:** Allow only numeric characters with maximum length of 10 characters
- **Age:** A drop-down list, containing values 18 to 100
- **Intention:** A drop-down list, containing values 1 to 10

Action rule

- **Submit button:** All fields except 'Last Name' and 'Previous Mobile No' should contain a value. Otherwise, display alert message "Please input required fields".
- **Clear button:** Clear the value of all fields except 'Submit Date' and 'Message No.'. Reset 'Submit Date' to tomorrow date and 'Message No.' to 1
- **Retrieve button:** Retrieve all data and set 'Message No' to blank

3) Programme flow

After clicking the 'Submit' button

1. If the mobile number exists in the database, alert message "Mobile No. duplicate" will be showed.
2. If the mobile number does not exist in the database, confirmation message "Are you sure you want to send the SMS?" will be showed, with OK and Cancel buttons.

After clicking 'OK'

1. "Block group" was determined from participant characteristics age and intention to quit. There are 6 groups in total which are:
   1) listAge1Int1: age from 18 - 30, and intention to quit from 1 - 5;
   2) listAge2Int1: age from 31 - 40, and intention to quit from 1 - 5;
   3) listAge3Int1: age from 41 - 100, and intention to quit from 1 - 5;
   4) listAge1Int2: age from 18 - 30, and intention to quit from 6 - 10;

5) listAge2Int2: age from 31 - 40, and intention to quit from 6 - 10; and

6) listAge3Int2: age from 41 - 100, and intention to quit from 6 – 10.

2. "Treatment group" was determined from the randomised list generation from Stata/IC 14 statistical software. This list was generated by a HITAP research assistant and were provided to the programmer directly. There are 8 groups in total which are: 1) NUL, 2) C, 3) O, 4) M, 5) CO, 6) CM, 7) OM, and 8) COM.
3. "Messages list" was determined from the "Treatment group" and was scheduled to be delivered in the table below

Message No.	Scheduled Delivery
1	Now
2	Submit Date field from "Input Patient Screen" , Time = 7:00 A.M.
3	Submit Date field from "Input Patient Screen", Time = 4:00 P.M.
4	Submit Date field from "Input Patient Screen" + 1 day, Time = 7:00 A.M.
5	Submit Date field from "Input Patient Screen" + 1 day, Time = 4:00 P.M.
6	Submit Date field from "Input Patient Screen" + 2 day, Time = 7:00 A.M.
7	Submit Date field from "Input Patient Screen" + 2 day, Time = 4:00 P.M.
8	Submit Date field from "Input Patient Screen" + 3 day, Time = 7:00 A.M.
9	Submit Date field from "Input Patient Screen" + 3 day, Time = 4:00 P.M.
10	Submit Date field from "Input Patient Screen" + 4 day, Time = 7:00 A.M.
11	Submit Date field from "Input Patient Screen" + 4 day, Time = 4:00 P.M.
12	Submit Date field from "Input Patient Screen" + 5 day, Time = 7:00 A.M.
13	Submit Date field from "Input Patient Screen" + 5 day, Time = 4:00 P.M.
14	Submit Date field from "Input Patient Screen" + 6 day, Time = 7:00 A.M.
15	Submit Date field from "Input Patient Screen" + 6 day, Time = 4:00 P.M.
16	Submit Date field from "Input Patient Screen" + 7 day, Time = 7:00 A.M.
17	Submit Date field from "Input Patient Screen" + 7 day, Time = 4:00 P.M.
18	Submit Date field from "Input Patient Screen" + 8 day, Time = 7:00 A.M.
19	Submit Date field from "Input Patient Screen" + 8 day, Time = 4:00 P.M.
20	Submit Date field from "Input Patient Screen" + 9 day, Time = 7:00 A.M.
21	Submit Date field from "Input Patient Screen" + 9 day, Time = 4:00 P.M.
22	Submit Date field from "Input Patient Screen" + 10 day, Time = 7:00 A.M.
23	Submit Date field from "Input Patient Screen" + 10 day, Time = 4:00 P.M.
24	Submit Date field from "Input Patient Screen" + 11 day, Time = 7:00 A.M.
25	Submit Date field from "Input Patient Screen" + 11 day, Time = 4:00 P.M.
26	Submit Date field from "Input Patient Screen" + 12 day, Time = 7:00 A.M.
27	Submit Date field from "Input Patient Screen" + 12 day, Time = 4:00 P.M.
28	Submit Date field from "Input Patient Screen" + 13 day, Time = 7:00 A.M.
29	Submit Date field from "Input Patient Screen" + 13 day, Time = 4:00 P.M.
30	Submit Date field from "Input Patient Screen" + 14 day, Time = 7:00 A.M.
31	Submit Date field from "Input Patient Screen" + 14 day, Time = 4:00 P.M.
32	Submit Date field from "Input Patient Screen" + 15 day, Time = 7:00 A.M.
33	Submit Date field from "Input Patient Screen" + 15 day, Time = 4:00 P.M.
34	Submit Date field from "Input Patient Screen" + 16 day, Time = 7:00 A.M.
35	Submit Date field from "Input Patient Screen" + 16 day, Time = 4:00 P.M.
36	Submit Date field from "Input Patient Screen" + 17 day, Time = 7:00 A.M.
37	Submit Date field from "Input Patient Screen" + 17 day, Time = 4:00 P.M.
38	Submit Date field from "Input Patient Screen" + 18 day, Time = 7:00 A.M.
39	Submit Date field from "Input Patient Screen" + 18 day, Time = 4:00 P.M.
40	Submit Date field from "Input Patient Screen" + 19 day, Time = 7:00 A.M.

Message No.	Scheduled Delivery
41	Submit Date field from "Input Patient Screen" + 19 day, Time = 4:00 P.M.
42	Submit Date field from "Input Patient Screen" + 20 day, Time = 7:00 A.M.
43	Submit Date field from "Input Patient Screen" + 20 day, Time = 4:00 P.M.
44	Submit Date field from "Input Patient Screen" + 21 day, Time = 7:00 A.M.
45	Submit Date field from "Input Patient Screen" + 21 day, Time = 4:00 P.M.
46	Submit Date field from "Input Patient Screen" + 22 day, Time = 7:00 A.M.
47	Submit Date field from "Input Patient Screen" + 22 day, Time = 4:00 P.M.
48	Submit Date field from "Input Patient Screen" + 23 day, Time = 7:00 A.M.
49	Submit Date field from "Input Patient Screen" + 23 day, Time = 4:00 P.M.
50	Submit Date field from "Input Patient Screen" + 24 day, Time = 7:00 A.M.
51	Submit Date field from "Input Patient Screen" + 24 day, Time = 4:00 P.M.
52	Submit Date field from "Input Patient Screen" + 25 day, Time = 7:00 A.M.
53	Submit Date field from "Input Patient Screen" + 25 day, Time = 4:00 P.M.
54	Submit Date field from "Input Patient Screen" + 26 day, Time = 7:00 A.M.
55	Submit Date field from "Input Patient Screen" + 26 day, Time = 4:00 P.M.
56	Submit Date field from "Input Patient Screen" + 27 day, Time = 7:00 A.M.
57	Submit Date field from "Input Patient Screen" + 27 day, Time = 4:00 P.M.
58	Submit Date field from "Input Patient Screen" + 28 day, Time = 7:00 A.M.
59	Submit Date field from "Input Patient Screen" + 28 day, Time = 4:00 P.M.
60	Submit Date field from "Input Patient Screen" + 29 day, Time = 7:00 A.M.
61	Submit Date field from "Input Patient Screen" + 29 day, Time = 4:00 P.M.
62	Submit Date field from "Input Patient Screen" + 30 day, Time = 7:00 A.M.
63	Submit Date field from "Input Patient Screen" + 180 day, Time =7:00 A.M.

After clicking the 'Retrieve' button

1. All data is retrieved and 'Message No' is set to blank. A new mobile number can be filled. The 'Message No' must be selected prior to a **click on the 'Submit' button**.

Appendix O: CONSORT 2010 checklist

Section/Topic	Item No	Checklist item	Locations
Title and abstract			
	1a	Identification as a randomised trial in the title	p.87, p.116
	1b	Structured summary of trial design, methods, results and conclusions	p.v
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Ch.1 and 2
	2b	Specific objectives or hypotheses	Ch.5, p.87-88
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Ch.5, p.90
	3b	Important charges to methods after trial commencement (such as eligibility criteria), with reasons	Ch.5, p.92
Participations	4a	Eligibility criteria for participants	Ch.5, p.91-92
	4b	Settings and locations where the data were collected	Ch.5, p. 91-92
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Ch.5, p.92-98
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Ch.5, 100
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Ch.6
Sample size	7a	How sample size was determined	Ch.5, p.100
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	Ch.5, p.96-97
	8b	Type of randomisation, details of any restriction (such as blocking and block size)	Ch.5, p.96-97
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Ch.5, p.97-98
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Ch.5, p.98
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Ch.5, p.98
	11b	If relevant, description of the similarity of interventions	N/A

Section/Topic	Item No	Checklist item	Locations
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Ch.5, p.112-116
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Ch.5, p.116-117
Results			
Participant flow	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for primary outcome	Ch.7, p.143-146
	13b	For each group, losses and exclusions after randomisation, together with reasons	Ch.7, p.143-146
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Ch.7, p.143
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Ch.7, p.147-157
Number analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Ch.7, p.146
Outcomes and estimation	17a	For each primary and secondary outcomes, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Ch.7, p.163
	17b	For binary outcomes, presentation of both absolute and relative effect sizes in recommended	Ch.7, p.161, 163
Ancillary analyses	18	Results of any other analyses perform, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Ch.7, p.167-183
Harms	19	All important harms or unintended effects in each group	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Ch.7, p.182
Generalisability	21	Generalisability (external validity, applicability) of trial findings	Ch.7, p.181, 184
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Ch.7, p.180-181
Other information			
Registration	23	Registration number and name of trial registry	Ch.5, p.91
Protocol	24	Where the full trial protocol can be accessed, if available	Ch.5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Ch.2, p.23

Appendix P: Participant information sheets and consent forms: randomised control trial

Leeds Institute of Health Sciences, Faculty of Medicines and Health

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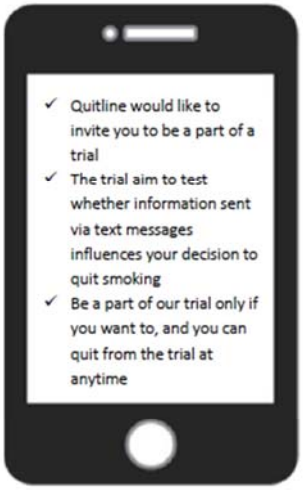
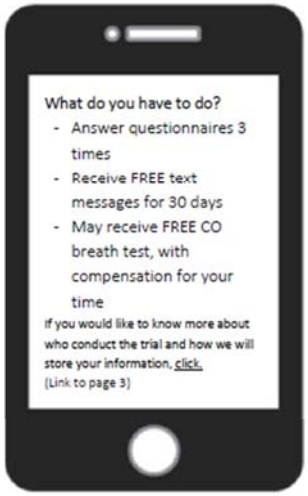
Participant information sheet

Research title: "Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

Page 1



Page 2



Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Participant information sheet - Quantitative	5	24/02/2017

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Page 3: the full version of participant information sheet

Can text messages help improve the Thailand National Quitline service uptake and smoking cessation rates?

You are invited to participate in this trial through recruitment from the Thailand National Quitline. Please take your time to understand the following information. If you are unclear about any of the information below, please do not hesitate to ask the researcher using the contact information listed below.

Purpose of this research

This trial aims to investigate whether information sent via text messages influences your decision to quit smoking.

Do you have to take part?

Participating in this research should be on a voluntary basis only. If you decide to join the trial, you will be asked to provide consent via an online form. Please be informed that once you join the trial, you can withdraw at any time without any negative consequence regarding receiving services from the Thailand National Quitline. However, the responses that you have already provided will be used for the research unless you withdraw from this study within 48 hours. This is because the researcher will start to analyse the information that has been given and will no longer take your response out from the report.

What will your participation involve?

You will be asked to answer online questionnaires after you have provided consent. When you have completed the questionnaires, you will be receive text messages from us.

At the end of the first and sixth months, you will be asked to answer similar online questionnaires again. If you do not have an email address or prefer not to answer by email, a questionnaire will be sent to you via post with a prepaid return envelope. It should take around 20-30 minutes to complete the questionnaires.

At the end of the sixth month, you may be asked to come to a smoking cessation clinic to receive a free carbon monoxide test in order to confirm your smoking status. Once again, this is on a voluntary basis. Compensation will be provided for your time along with transportation.

How many people will be involved?

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Participant information sheet - Quantitative	5	24/02/2017

What are the possible benefits of taking part?

There is no direct benefit from participating in this trial but we hope that you will gain more knowledge about the harm of smoking and the benefits of quitting smoking. Also, the information that you provide will help improve the Thailand National Quitline in the future.

What are the possible disadvantages of taking part?

You may feel uncomfortable being a part of this trial. If so, you can withdraw by contacting Pritaporn Kingkaew without giving a reason. The questionnaires that we ask you to answer should take around 20-30 minutes of your time. You may feel uncomfortable answering some of the questions within the questionnaire. If so, please feel free to skip these or stop. If you are experiencing distress from being involved in this trial, the Mental Health hotline (1667) may be able to support you.

All responses will be confidential

Your personal information, such as name and contact details, will not be linked with your answers. Your responses will be kept strictly confidential. Members of the research team and individuals from the University of Leeds will have access to your online survey responses only when they are permitted. For the use of this research in the future, other genuine researchers will be able to access to your anonymised responses or use your anonymised responses only if they agree to preserve the confidentiality of the information. Any personal information that could identify you will be removed before files are shared with other researchers.

How will your information be used?

All information collected from this trial will be kept confidential. The data will be stored electronically in an anonymised form for 5 years and may be used for future relevant research. All publications from this trial will not contain your name or any information that can identify you.

Who is organizing and funding this research?

This is a part of PhD research project conducted by Pritaporn Kingkaew, a PhD candidate from University of Leeds, United Kingdom and a researcher from Health Intervention and Technology Assessment Program, Thailand. This PhD research project is supervised by Liz Glidewell and Rebecca Walwyn from the University of Leeds and Jeremy C. Wyatt from the University of Southampton, United Kingdom. This research is funded by Network coordinator for economic evaluation of health promotion interventions and Health Intervention and Technology Assessment Program.

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Participant information sheet - Quantitative	5	24/02/2017

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If you have any questions or concerns regarding the research project, please contact

Pritaporn Kingkaew

Researcher
Health Intervention and Technology Assessment Program (HITAP)
6th Floor, 6th Building, Department of Health, Ministry of Public Health, Tiwanon road,
Muang, Nonthaburi, 11000, Thailand
Email: pritaporn.k@hitap.net
Tel: +66-89-164-3777

or

PhD student
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Room G.02, Charles Thackrah Building
101 Clarendon Road, Leeds, LS2 9LJ, United Kingdom
Email: umpk@leeds.ac.uk
Tel: +44-74-4806-7250

This study has been reviewed by the School of Medicine Research Ethics Committee, University of Leeds (MREC16-001) and the Institute for the Development of Human Research Protections, Thailand.

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Participant information sheet - Quantitative	5	24/02/2017

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Consent to take part in

Research title "Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

Page 1

☐ By clicking sign up, you are agree to take part in research and consent to terms and conditions

(Terms and conditions will be link to another page for more information)

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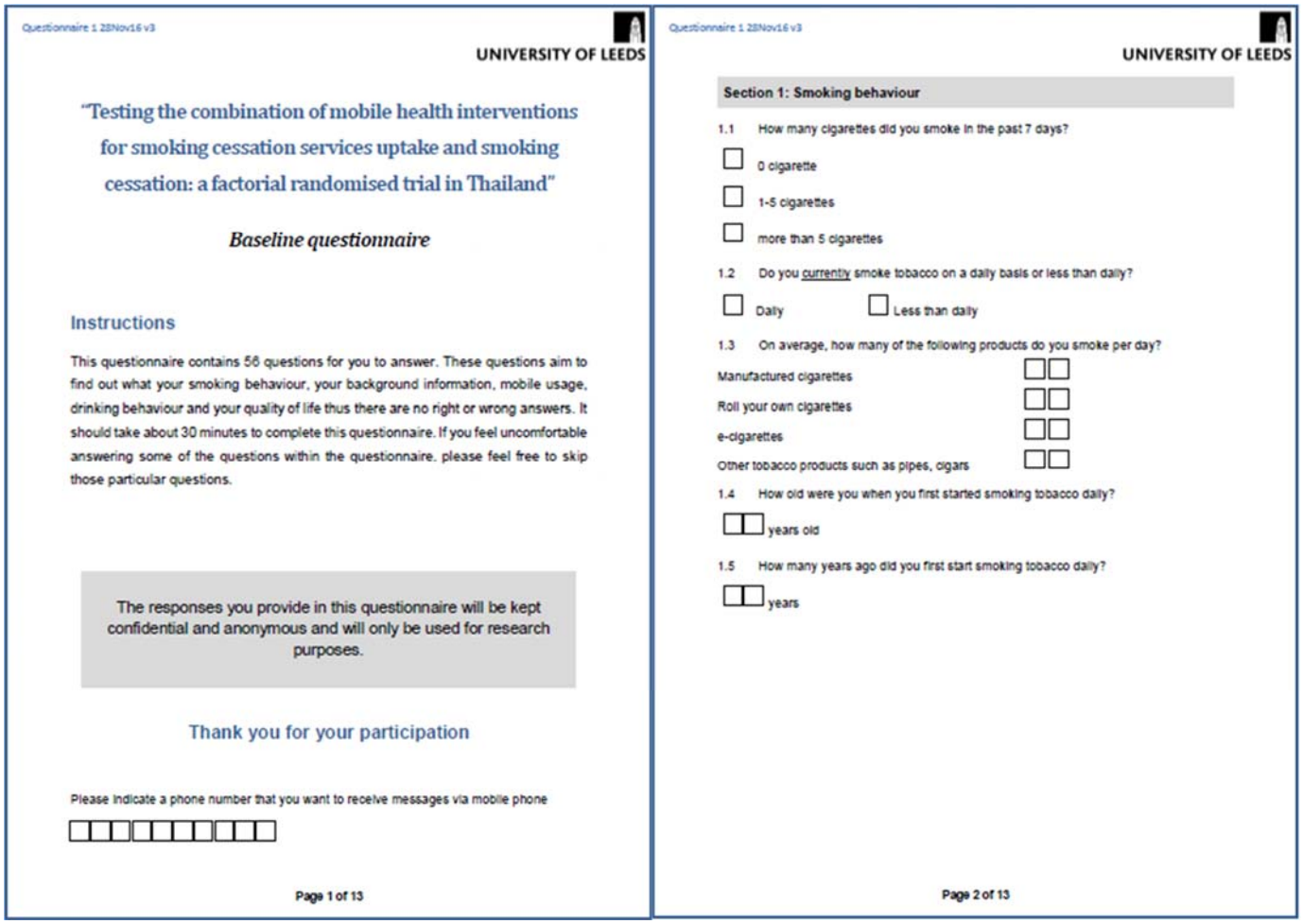
Page 2

I confirm that I have read and understand the participant information sheet explaining the research project and have had the opportunity to ask questions about the project by contacting Pritaporn Kingkaew at +66-89-164-3777 or umpk@leeds.ac.uk and pritaporn.k@hitap.net.
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without any negative consequence regarding receiving services from the Thailand National Quitline. In addition, should I wish to not answer any particular question or questions, I am free to decline.
I understand that the responses that I have already given to members of the research team will be used for the research, unless I withdraw within 48 hours.
I give permission for members of the research team to have access to my anonymised responses. I understand that my name or personal details will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. I understand that my responses will be kept strictly confidential.
I agree for the data collected from me to be stored and used in relevant future research in an anonymised form.
I understand that other genuine researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.
I understand that other genuine researchers may use my answers in publications, reports, web pages, and other research outputs only if they agree to preserve the confidentiality of the information as requested in this form.
I understand that relevant sections of the data collected during the study may be looked at by individuals from the University of Leeds or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
I agree to take part in the above research project and will inform Pritaporn Kingkaew should my contact details change.

Project title	*Document type*	*Version #*	*Date*
Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand	Consent form - Quantitative	5	24/02/2017

Appendix Q: Trial baseline and 1-month follow-up questionnaires



Questionnaire 1 28Nov16 v3

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"Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

Baseline questionnaire

Instructions

This questionnaire contains 56 questions for you to answer. These questions aim to find out what your smoking behaviour, your background information, mobile usage, drinking behaviour and your quality of life thus there are no right or wrong answers. It should take about 30 minutes to complete this questionnaire. If you feel uncomfortable answering some of the questions within the questionnaire, please feel free to skip those particular questions.

The responses you provide in this questionnaire will be kept confidential and anonymous and will only be used for research purposes.

Thank you for your participation

Please indicate a phone number that you want to receive messages via mobile phone

☐☐☐☐☐☐☐☐☐☐

Page 1 of 13

Questionnaire 1 28Nov16 v3

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Section 1: Smoking behaviour

1.1 How many cigarettes did you smoke in the past 7 days?

☐ 0 cigarette

☐ 1-5 cigarettes

☐ more than 5 cigarettes

1.2 Do you currently smoke tobacco on a daily basis or less than daily?

☐ Daily ☐ Less than daily

1.3 On average, how many of the following products do you smoke per day?

Manufactured cigarettes ☐☐

Roll your own cigarettes ☐☐

e-cigarettes ☐☐

Other tobacco products such as pipes, cigars ☐☐

1.4 How old were you when you first started smoking tobacco daily?

☐☐ years old

1.5 How many years ago did you first start smoking tobacco daily?

☐☐ years

Page 2 of 13

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Fagerstrom Test for Nicotine Dependence

1.6 How soon after waking do you smoke your first cigarette?

☐ Within 5 minutes

☐ 5-30 minutes

☐ 31-60 minutes

1.7 Do you find it difficult to refrain from smoking in places where it is forbidden? e.g. temple, department store, etc.

☐ Yes ☐ No

1.8 Which cigarette would you hate to give up?

☐ The first in the morning ☐ Any other

1.9 How many cigarettes a day do you smoke?

☐ 10 or less

☐ 11-20

☐ 21-30

☐ 31 or more

1.10 Do you smoke more frequently in the morning?

☐ Yes ☐ No

1.11 Do you smoke even if you are sick in bed most of the day?

☐ Yes ☐ No

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1.12 Have you tried to quit smoking in the past 6 months?

☐ Yes ☐ No

1.13 During the past 6 months, did you use any of the following to try to stop smoking tobacco?

Counselling, including at a smoking cessation clinic	☐ Yes	☐ No	☐ Refused
Nicotine replacement therapy, such as nicotine gum, nicotine patch	☐ Yes	☐ No	☐ Refused
Other prescription medications	☐ Yes	☐ No	☐ Refused
Traditional medicines	☐ Yes	☐ No	☐ Refused
A quit line	☐ Yes	☐ No	☐ Refused
Quit on my own/ will power	☐ Yes	☐ No	☐ Refused
Other methods	☐ Yes	☐ No	☐ Refused

1.14 During the past 6 months, how long have you stopped smoking?

Months ☐☐

Weeks ☐☐

Days ☐☐

1.15 Please describe the reasons why you have started smoking again/or continue to smoke.

Because I have an urge to smoke when I see or smell the cigarette	☐ Yes	☐ No	☐ Refused
Because I am in a bad mood such as stress concerns bored lonely	☐ Yes	☐ No	☐ Refused
Because I am in a good mood such as relaxed happy satisfy excited	☐ Yes	☐ No	☐ Refused
Because of weight gain or increased appetite	☐ Yes	☐ No	☐ Refused
Because of insomnia, irritability, restlessness, lack of concentration when I don't smoke	☐ Yes	☐ No	☐ Refused

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Because I suffer from constipation	☐ Yes	☐ No	☐ Refused
Because of my peers encourage me to smoke	☐ Yes	☐ No	☐ Refused
Because smoking is a habit such as smoking after meal, smoking with drinking alcohol	☐ Yes	☐ No	☐ Refused
Other reasons, please indicate	☐ Yes	☐ No	☐ Refused

1.16 Are you willing to try and quit in the next month?

☐ Yes ☐ No

Intention to quit:

1.17 How would you rate your intention to quit from a scale from 1 to 10?

☐☐

1.18 **INSTRUCTIONS:** Please indicate whether you agree or disagree with the following statements, with 10 being strongly agree and 1 being strongly disagree, by placing a check mark in the appropriate box.

Statements	1	2	3	4	5	6	7	8	9	10
I know that smoking can harm myself and others around me										
I have enough knowledge and required skills to be able to quit smoking such as how to deal with craving										
I know that many things have been done in our society to stop people from smoking such as banning smoking in public places, sale restriction, stop smoking campaign, etc.										
I have received enough support (from my family, friends and the government) in order to quit smoking										
My life will be better off if I quit smoking										
It is important to me that I should quit smoking now										

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1.19 **INSTRUCTIONS:** Please indicate how confident you are with the following situations, with 10 being very confident and 1 being not confident, by placing a check mark in the appropriate box.

Situations	1	2	3	4	5	6	7	8	9	10
You feel agitated or tense. Are you confident that you will not smoke?										
You are (very) angry. Are you confident that you will not smoke?										
You are in a cafe, at a party, or paying a visit. Are you confident that you will not smoke?										
You feel (very) sad. Are you confident that you will not smoke?										
Someone offers you a cigarette of your own brand. Are you confident that you will not smoke?										
You see someone enjoy smoking. Are you confident that you will not smoke?										

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Section 2: Your information

2.1 Gender

☐ Male ☐ Female

2.2 How old are you?

☐☐ years old

2.3 marital status

☐ Single ☐ Widower

☐ Married/with a partner ☐ Separeted/divorced

2.4 What is your religion?

☐ Buddhism ☐ Islam

☐ Christianity ☐ Others

☐ None

2.5 Do you have children living at home with you?

☐ Yes ☐ No

2.6 Which of the following best describes your work?

☐ Unemployed ☐ Trades

☐ Agriculture ☐ Students

☐ Government employee ☐ Others .....

☐ State enterprise ☐ Retired

☐ Contractors ☐ Refused

2.7 What is the highest level of education you have completed?

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☐ No formal schooling ☐ High school completed

☐ Less than primary school completed ☐ College/University degree completed

☐ Primary school completed ☐ Post graduate degree completed

☐ Less than secondary school completed ☐ Don't know

☐ Secondary school completed ☐ Refused

2.8 Please indicate if you currently have any health problem

☐ No health problems ☐ Liver disease

☐ Heart disease ☐ Anemia or other blood disease

☐ High blood pressure ☐ Cancer

☐ Lung disease ☐ Depression

☐ Diabetes ☐ Osteoarthritis, degenerative arthritis

☐ Ulcer or stomach disease ☐ Back pain

☐ Kidney disease ☐ Rheumatoid arthritis

☐ Other medical problems, ...

2.9 Does your family have any medical history related to smoking? (Please choose any that appropriate)

☐ Don't have ☐ Don't know

☐ Heart disease/Heart attack ☐ Stroke

☐ Lung cancer ☐ Chronic obstructive pulmonary disease

☐ Other cancer ☐ Ulcer or stomach disease

☐ Other medical problems, ...

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2.10 Please list whether your household or any person who lives in the household has the following items

Items	Owned	Don't have/ Have but do not owned	Don't know	Refused
Bicycle				
Motorcycle				
Car				
Bed, wood or metal				
Gas cooker				
Electric stove				
Microwave				
Kettle				
Electric cooking pot				
Refrigerator				
Irons				
Washing machine				
Radio				
Television (traditional)				
LCD / LED / Plasma / digital television				
VCR / VCD / DVD / Blu-ray players				
Fan				
Air conditioner				
Water heater in the bathroom				
Desktop computer				
Portable computer (Laptop/ notebook)				
Internet connection				
Landline telephone				
Fax				
Mobile phone				

2.11 On average, how much money do you and your family members earn per month, including income from all sources work or investments (baht)?

☐☐☐☐☐☐

2.12 Are there any smokers in the family or among friends (Please choose any that appropriate)

☐ None

☐ Parents

☐ Partner/spouse

☐ Sibling

☐ Friends

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Section 3: Mobile usage

3.1 What type of mobile phone do you own?

☐ Smartphone with web access, camera, text messaging, apps, etc.

☐ Phone with calling and text messaging only

☐ Phone for making calls only

3.2 Do you carry your mobile phone with you at all time?

☐ Yes ☐ No

3.3 How often you use text messaging?

☐ Multiple times per day ☐ Everyday

☐ Weekly ☐ Never

3.4 How often you use instance messaging services? (iMessage, Line, WhatsApp, Skype, Facebook Messenger)

☐ Multiple times per day ☐ Everyday

☐ Weekly ☐ Never

3.5 How often you use mobile apps for health-related communication?

☐ Multiple times per day ☐ Everyday

☐ Weekly ☐ Never

3.6 How often you use mobile apps for non-health related communication?

☐ Multiple times per day ☐ Everyday

☐ Weekly ☐ Never

3.7 On average, how much do you spend time on your mobile?

☐☐ hours ☐☐ minutes

3.8 On average, how much of this is related to work?

☐☐ hours ☐☐ minutes

3.9 On average, how much of this is related to leisure?

☐☐ hours ☐☐ minutes

Section 4: Drinking behaviour

Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest. Place an X in one box that best describes your answer to each question

Questions	0	1	2	3	4
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 or 9	10 or more
3. How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year

Section 5: Quality of life

Under each heading, please tick the ONE box that best describes your health TODAY.

1. Mobility

1. I have no problems in walking about ☐
2. I have slight problems in walking about ☐
3. I have moderate problems in walking about ☐
4. I have severe problems in walking about ☐
5. I am unable to walk about ☐

2. Self-Care

1. I have no problems washing or dressing myself ☐
2. I have slight problems washing or dressing myself ☐
3. I am moderate problems washing or dressing myself ☐
4. I am severe problems washing or dressing myself ☐
5. I am unable to wash or dress myself ☐

3. Usual Activities *(e.g. work, study, housework, family or leisure activities)*

1. I have no problems doing my usual activities ☐
2. I have slight problems doing my usual activities ☐
3. I have moderate problems doing my usual activities ☐
4. I have severe problems doing my usual activities ☐
5. I am unable to do my usual activities ☐

4. Pain/Discomfort

1. I have no pain or discomfort ☐
2. I have slight pain or discomfort ☐
3. I have moderate pain or discomfort ☐
4. I have severe pain or discomfort ☐
5. I have extreme pain or discomfort ☐

5. Anxiety/Depression

1. I am not anxious or depressed ☐
2. I am slightly anxious or depressed ☐
3. I am moderately anxious or depressed ☐
4. I am severely anxious or depressed ☐
5. I am extremely anxious or depressed ☐

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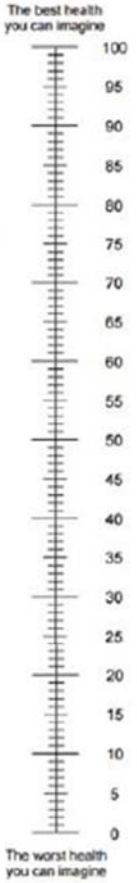
- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.



YOUR HEALTH TODAY = ☐

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"Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

1 month follow-up questionnaire

Instructions

This questionnaire contains 37 questions for you to answer. These questions aim to find out what your smoking status, experience about text messages program, drinking behaviour and your quality of life thus there are no right or wrong answers. It should take about 20-30 minutes to complete this questionnaire. If you feel uncomfortable answering some of the questions within the questionnaire, please feel free to skip those particular questions.

The responses you provide in this questionnaire will be kept confidential and anonymous and will only be used for research purposes.

Thank you for your participation

Please indicate a phone number that you want to receive messages via mobile phone

☐☐☐☐☐☐☐☐☐☐

In the case where you have changed your mobile number, please indicate the number that you have used previously to receive messages

☐☐☐☐☐☐☐☐☐☐

Questionnaire 2 05Aug16 v03

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Section 1: Smoking behaviour

1.1 How many cigarettes did you smoke in the past 7 days?

☐ 0 cigarette (skip to question 1.16)

☐ 1-5 cigarettes

☐ more than 5 cigarettes

1.2 Do you currently smoke tobacco on a daily basis or less than daily?

☐ Daily ☐ Less than daily

1.3 On average, how many of the following products do you smoke per day?

Manufactured cigarettes ☐☐

Roll your own cigarettes ☐☐

e-cigarettes ☐☐

Other tobacco products such as pipes, cigars ☐☐

Fagerstrom Test for Nicotine Dependence

1.4 How soon after waking do you smoke your first cigarette?

☐ Within 5 minutes

☐ 5-30 minutes

☐ 31-60 minutes

1.5 Do you find it difficult to refrain from smoking in places where it is forbidden? e.g. temple, department store, etc.

☐ Yes ☐ No

1.6 Which cigarette would you hate to give up?

☐ The first in the morning ☐ Any other

1.7 How many cigarettes a day do you smoke?

☐ 10 or less

☐ 11-20

☐ 21-30

☐ 31 or more

1.8 Do you smoke more frequently in the morning?

☐ Yes ☐ No

1.9 Do you smoke even if you are sick in bed most of the day?

☐ Yes ☐ No

1.10 Have you tried to quit smoking in the past month?

☐ Yes ☐ No

1.11 During the past month, did you use any of the following to try to stop smoking tobacco?

Counselling, including at a smoking cessation clinic	☐ Yes	☐ No	☐ Refused
Nicotine replacement therapy, such as nicotine gum, nicotine patch	☐ Yes	☐ No	☐ Refused
Other prescription medications	☐ Yes	☐ No	☐ Refused
Traditional medicines	☐ Yes	☐ No	☐ Refused
A quit line	☐ Yes	☐ No	☐ Refused
Quit on my own/ will power	☐ Yes	☐ No	☐ Refused
Other methods	☐ Yes	☐ No	☐ Refused

1.12 During the past month, how long have you stopped smoking?

Days ☐☐

Questionnaire 2 05Aug16 v03

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1.13 Please describe the reasons why you have started smoking again/or continue to smoke.

Because I have an urge to smoke when I see or smell the cigarette	☐ Yes	☐ No	☐ Refused
Because I am in a bad mood such as stress concerns bored lonely	☐ Yes	☐ No	☐ Refused
Because I am in a good mood such as relaxed happy satisfy excited	☐ Yes	☐ No	☐ Refused
Because of weight gain or increased appetite	☐ Yes	☐ No	☐ Refused
Because of insomnia, irritability, restlessness, lack of concentration when I don't smoke	☐ Yes	☐ No	☐ Refused
Because I suffer from constipation	☐ Yes	☐ No	☐ Refused
Because of my peers encourage me to smoke	☐ Yes	☐ No	☐ Refused
Because smoking is a habit such as smoking after meal, smoking with drinking alcohol	☐ Yes	☐ No	☐ Refused
Other reasons, please indicate	☐ Yes	☐ No	☐ Refused

1.14 Are you willing to try and quit in the next month?

☐ Yes ☐ No

Intention to quit:

1.15 How would you rate your intention to quit from a scale from 1 to 10?

☐☐

UNIVERSITY OF LEEDS

1.16 **INSTRUCTIONS:** Please indicate whether you agree or disagree with the following statements, with 10 being strongly agree and 1 being strongly disagree, by placing a check mark in the appropriate box.

Statements	1	2	3	4	5	6	7	8	9	10
I know that smoking can harm myself and others around me										
I have enough knowledge and required skills to be able to quit smoking such as how to deal with craving										
I know that many things have been done in our society to stop people from smoking such as banning smoking in public places, sale restriction, stop smoking campaign, etc.										
I have received enough support (from my family, friends and the government) in order to quit smoking										
My life will be better off if I quit smoking										
It is important to me that I should quit smoking now										

1.17 **INSTRUCTIONS:** Please indicate how confident you are with the following situations, with 10 being very confident and 1 being not confident, by placing a check mark in the appropriate box.

Situations	1	2	3	4	5	6	7	8	9	10
You feel agitated or tense. Are you confident that you will not smoke?										
You are (very) angry. Are you confident that you will not smoke?										
You are in a café, at a party, or paying a visit. Are you confident that you will not smoke?										
You feel (very) sad. Are you confident that you will not smoke?										
Someone offers you a cigarette of your own brand. Are you confident that you will not smoke?										
You see someone enjoy smoking. Are you confident that you will not smoke?										

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Section 2: Intervention received

2.1 How often you have received text messages to support smoking cessation from this research?

- ☐ Never received
- ☐ Received once a day
- ☐ Received twice a day

2.2 What time in a day do you usually open and read text messages to support smoking cessation?

- ☐ Before breakfast
- ☐ Before lunch
- ☐ Before dinner
- ☐ Before bed time
- ☐ Never open
- ☐ Open but never read

2.3 How often you have shared text messages to other smokers that you have known?

- ☐ Never share any text that I have received
- ☐ Share a few text
- ☐ Share every text that I have received

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2.4 **INSTRUCTIONS:** Please indicate whether you agree or disagree with the following statements, with 10 being strongly agree and 1 being strongly disagree, by placing a check mark in the appropriate box.

Statements	1	2	3	4	5	6	7	8	9	10
Text messages that I have received are too long and boring										
Text messages that I have received cannot help me quit smoking										
Text messages that I have received are too confusing/ are in an unreadable format										
Text messages that I have received contain useful information										
Text messages that I have received encourage me to seek support from my friends and family										
Text messages that I have received can help me quit smoking										
I would like to subscribe to this programme to receive more information in the future										

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Section 3: Drinking behaviour

Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest. Place an X in one box that best describes your answer to each question

Questions	0	1	2	3	4
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 or 9	10 or more
3. How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year

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Section 4: Quality of life

Under each heading, please tick the ONE box that best describes your health TODAY.

1. Mobility

1. I have no problems in walking about ☐
2. I have slight problems in walking about ☐
3. I have moderate problems in walking about ☐
4. I have severe problems in walking about ☐
5. I am unable to walk about ☐

2. Self-Care

1. I have no problems washing or dressing myself ☐
2. I have slight problems washing or dressing myself ☐
3. I am moderate problems washing or dressing myself ☐
4. I am severe problems washing or dressing myself ☐
5. I am unable to wash or dress myself ☐

3. Usual Activities *(e.g. work, study, housework, family or leisure activities)*

1. I have no problems doing my usual activities ☐
2. I have slight problems doing my usual activities ☐
3. I have moderate problems doing my usual activities ☐
4. I have severe problems doing my usual activities ☐
5. I am unable to do my usual activities ☐

4. Pain/Discomfort

1. I have no pain or discomfort ☐
2. I have slight pain or discomfort ☐
3. I have moderate pain or discomfort ☐
4. I have severe pain or discomfort ☐
5. I have extreme pain or discomfort ☐

5. Anxiety/Depression

1. I am not anxious or depressed ☐
2. I am slightly anxious or depressed ☐
3. I am moderately anxious or depressed ☐
4. I am severely anxious or depressed ☐
5. I am extremely anxious or depressed ☐

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- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

Appendix R: Supplemental material for trial recruitment

1) Recruitment material-v1

You are invited to participate in research

"Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand"

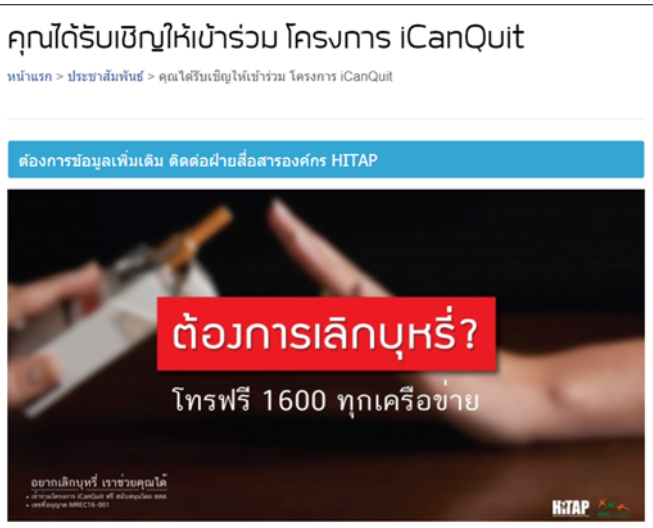
This research aims to investigate whether information sent via text messages influences your decision to quit smoking. If you are smokers and would like to receive text messages about smoking cessation with no cost, please contact the Thailand National Quitline 1600.

This is a part of PhD research project conducted by Pritaporn Kingkaew, a PhD candidate from University of Leeds, United Kingdom and a researcher from Health Intervention and Technology Assessment Program. (IRB number: MREC16-001)

For more information or to participate,

Call 1600 or visit https://leeds.onlinesurveys.ac.uk/icanquitbaseline.

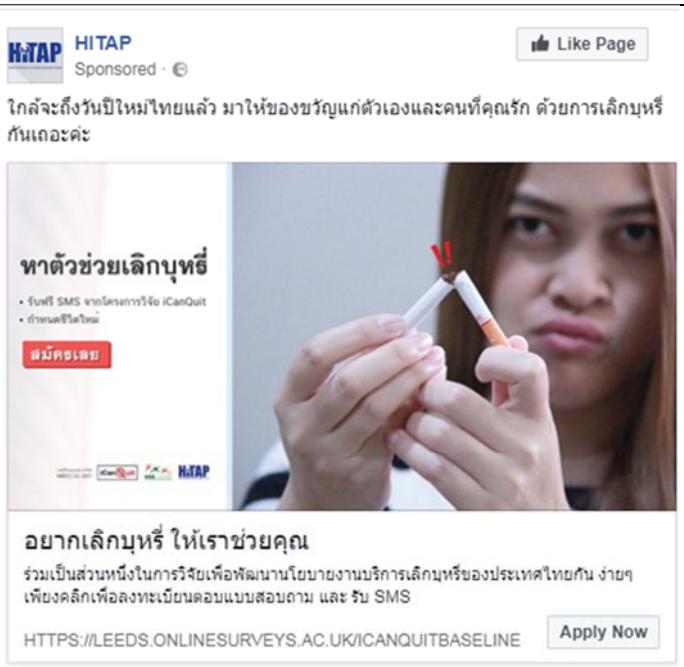
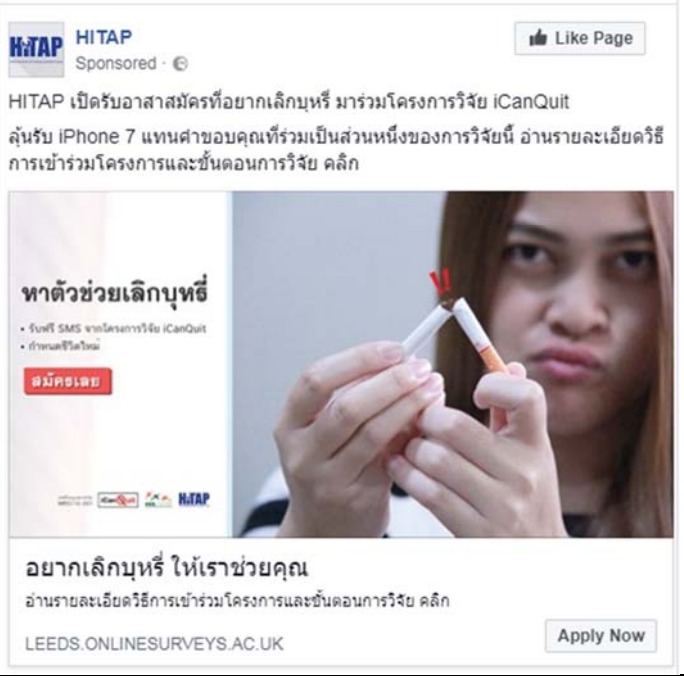
2) Examples of unpaid advertisement

Media sources	Media screenshot
Recruitment to iCanQuit project **Content:** Recruitment material **Date post:** 25 January 2017 **Source:** http://www.hitap.net/news/167909	
World No Tobacco Day campaign **Content:** Recruitment material and iPhone lucky draw **Date post:** 31 May 2017 **Source:** http://www.hitap.net/168629	

Media sources	Media screenshot
World No Tobacco Day campaign **Content:** Recruitment material and iPhone lucky draw **Date post:** 30 May 2017 **Source:** http://morning-news.bectero.com/pr-news/30-May-2017/103313	
World No Tobacco Day campaign **Content:** Recruitment material and iPhone lucky draw **Date post:** 10 June 2017 **Source:** http://www.ryt9.com/s/tpd/2662460	

3) Paid advertisement through Facebook

Content	Media screenshot
Advertisement 1: **Above text:** we are recruiting volunteers who want to quit smoking to be a part of iCanQuit project. If you are interested, click here to register. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - More information, call 1600 for free **Below text:** want to quit smoking, let we help you If you are thinking about quitting smoking, let we help you. Join this research to help improve smoking cessation policy in Thailand. Very simple, click to register.	
Advertisement 2: **Above text:** enter to win iPhone 7 and be a part of iCanQuit project. If you want to stop smoking, click here to register and receive SMS for free from iCanQuit research project. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - More information, call 1600 for free **Below text:** want to quit smoking, let we help you Join this research to help improve smoking cessation policy in Thailand. Very simple, click to register.	

Content	Media screenshot
Advertisement 3: **Above text:** New Year is approaching. Give gifts to yourself and love ones by stop smoking. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - Begin a new life **Below text:** want to quit smoking, let we help you Join this research to help improve smoking cessation policy in Thailand. Very simple, click to register and received SMS.	
Advertisement 4, 5, and 6: **Above text:** HITAP is recruiting volunteers who would like to quit smoking, enter to win iPhone 7 and be a part of iCanQuit project. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - Begin a new life **Below text:** want to quit smoking, let we help you For more information or to participate, click	

Content	Media screenshot
Advertisement 7: **Above text:** Last chance, enter to win iPhone 7 to be a part of iCanQuit project. HITAP is recruiting volunteers who would like to quit smoking. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - Begin a new life **Below text:** want to quit smoking, let we help you For more information or to participate, click	
Advertisement 8: **Above text:** Ending on 30 September, enter to win iPhone 7 to be a part of iCanQuit project. HITAP is recruiting volunteers who would like to quit smoking. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - Begin a new life **Below text:** want to quit smoking, let we help you For more information or to participate, click	

Content	Media screenshot
Advertisement 9: **Above text:** Last chance to receive free SMS to help stop smoking from iCanQuit project. Receive a bag pack for free when you enter the project. **In figure text:** seeking for helps to quit smoking - Get free SMS from iCanQuit project - Begin a new life **Below text:** want to quit smoking, let we help you For more information or to participate, click	

Appendix S: Additional trial results table

Table S1 Missing data summaries and predictors of missingness of 7-day self-reported smoking abstinence at 1-month follow-up

Baseline characteristics	All (N = 1,571)		P-value
	Present (0)	Absent (1)	
Treatment adherence: received allocated intervention as intended (60 texts vs 0-59 texts)	1117 (85.27%)	143 (54.79%)	**<0.001**
Capability scores at baseline	16.95 (3.13), 1301	16.23 (3.66), 255	**0.001**
Education levels			**0.006**
No formal schooling, less than primary school completed, primary school completed	243 (18.93%)	57 (22.01%)	
Less than secondary school completed, Secondary school completed, High school completed	748 (58.26%)	166 (64.09%)	
College/University degree completed, post graduate degree completed	293 (22.82%)	36 (13.90%)	
Age at randomisation	35.55 (13.33), 1310	33.23 (13.54), 261	**0.010**
Carry mobile phone at all time (vs no)	1195 (91.99%)	224 (87.16%)	**0.012**
Data collection: Quitline (vs non-quitline)	1151 (87.86%)	215 (82.38%)	**0.016**
Frequency of instant messaging services usage			**0.025**
Never	190 (14.66%)	44 (16.92%)	
Weekly	42 (3.24%)	18 (6.92%)	
Everyday	154 (11.88%)	27 (10.38%)	
Multiple times per day	910 (70.22%)	171 (65.77%)	
Age started smoking (years)	17.07 (4.39), 1303	16.50 (16.07), 260	**0.046**
Motivation scores at baseline	18.95 (2.56), 1296	18.60 (2.99), 259	**0.055**
Length of smoking (years)	17.57 (12.67), 1303	16.05 (12.75), 260	**0.078**
Smoker network (vs none)	993 (75.80%)	211 (80.84%)	**0.079**
Intention-to-quit	8.16 (2.11), 1310	7.92 (2.22), 261	**0.092**
Types of mobile phone owned	1146 (88.02%)	218 (84.50%)	**0.094**
Quality of life	0.9463 (0.0899), 1288	0.9358 (0.1004), 257	**0.096**
Children at home	557 (42.85%)	124 (48.44%)	**0.099**
Randomised groups: received messages aimed at increasing motivation to quit	665 (50.76%)	118 (45.21%)	0.101

Baseline characteristics	All (N = 1,571)		P-value
	Present (0)	Absent (1)	
Self-efficacy scores at baseline	40.91 (13.92), 1288	39.38 (13.88), 255	0.108
Asset index			0.138
SES 1	513 (50.44%)	122 (60.10%)	
SES 2	273 (26.84%)	47 (23.15%)	
SES 3	156 (15.34%)	24 (11.82%)	
SES 4	12 (1.18%)	1 (0.49%)	
SES 5	63 (6.19%)	9 (4.43%)	
Family medical history (vs none)	162 (12.37%)	41 (15.71%)	0.142
Opportunity scores at baseline	16.92 (3.78), 1301	16.58 (4.07), 257	0.188
Fagerstrom Test for Nicotine Dependence scores at baseline	3.21 (2.33), 1272	3.37 (2.44), 252	0.319
Frequency of text messaging services usage			0.327
Never	439 (33.80%)	97 (37.45%)	
Weekly	245 (18.86%)	54 (20.85%)	
Everyday	301 (23.17%)	48 (18.53%)	
Multiple times per day	314 (24.17%)	60 (23.17%)	
Religion, Buddhist (vs others)	1239 (94.58%)	243 (93.10%)	0.346
Co-morbidities (vs none)	487 (37.18%)	89 (34.10%)	0.346
Randomised groups: received messages aimed at increasing opportunity to support smoking cessation	660 (50.38%)	124 (47.51%)	0.397
Incomes	54,845 (583,886), 1204	26,156 (30,265), 248	0.439
Number of tobacco used per day at baseline	9.68 (8.26), 1296	10.09 (9.29), 258	0.469
AUDIT score at baseline	6.15 (7.88), 1279	6.54 (7.80), 251	0.472
Male (vs female)	1,184 (90.38%)	233 (89.27%)	0.582
Married/with a partner	622 (48.22%)	120 (46.51%)	0.617
Days quitting smoking at baseline	19.70 (85.92), 1299	22.26 (76.56), 259	0.655
Willingness-to-quit (vs no)	1258 (98.13%)	253 (98.44%)	0.730
Daily smoker (vs less than daily)	1060 (81.29%)	210 (80.46%)	0.755
History of quitting smoking in the past 6 months	1192 (92.12%)	240 (92.66%)	0.764
Randomised groups: received messages aimed at increasing smokers' capability to quit	652 (49.77%)	128 (49.04%)	0.830
Data collection: Self (vs interview)	270 (20.61%)	55 (21.07%)	0.866
Minutes spent on mobile phone per day	283 (296), 1299	282 (282), 259	0.959
Employment status	1066 (82.57%)	214 (82.63%)	0.983

Table S2 Logistic regression analysis for self-reported 7-day point prevalence abstinence, with pre-specified covariates: assuming all missing outcome variables are smokers

Covariates	Odds Ratio	SE	z	P>z	95% CI	
					Lower	Upper
Stratification factors						
High ITQ	2.86	0.50	6.0400	0.0000	2.0342	4.0221
Age group: 31 - 40	0.96	0.14	-0.2600	0.7970	0.7282	1.2759
Age group: above 40	1.00	0.12	0.0000	0.9980	0.7832	1.2761
Main effects						
C	1.31	0.28	1.2400	0.2140	0.8564	1.9944
O	1.22	0.26	0.9000	0.3660	0.7959	1.8589
M	1.23	0.26	0.9500	0.3420	0.8043	1.8743
Interactions						
C and O	0.52	0.16	-2.1400	0.0330	0.2823	0.9469
C and M	0.75	0.23	-0.9300	0.3510	0.4156	1.3657
O and M	0.89	0.27	-0.4000	0.6910	0.4899	1.6045
C, O, and M	1.07	0.47	0.1500	0.8790	0.4535	2.5203
Constant	0.19	0.04	-7.3900	0.0000	0.1192	0.2909

Table S3 Predicted probability of 7-day self-reported smoking abstinence at 1-month follow-up among experimental groups: primary analysis model

Groups	Complete case				Multiple imputations		
	Probability of quitting	SE	95% CI		Probability of quitting	95% CI	
			Lower	Upper		Lower	Upper
Placebo	0.398	0.039	0.323	0.474	0.393	0.320	0.471
C	0.448	0.038	0.373	0.523	0.437	0.364	0.513
O	0.423	0.038	0.349	0.497	0.405	0.333	0.481
M	0.432	0.038	0.358	0.507	0.423	0.349	0.501
CO	0.341	0.037	0.269	0.414	0.332	0.261	0.410
CM	0.418	0.038	0.344	0.493	0.411	0.336	0.490
OM	0.426	0.037	0.354	0.499	0.408	0.337	0.483
COM	0.291	0.035	0.223	0.359	0.284	0.220	0.359

Table S4 Predicted probability of 7-day self-reported smoking abstinence at 1-month follow-up among experimental groups: subgroup analysis of intention-to-quit groups

Groups	Complete case				Multiple imputations		
	Probability of quitting	SE	95% CI		Probability of quitting	95% CI	
			Lower	Upper		Lower	Upper
Low intention-to-quit scores at baseline							
Placebo	0.067	0.046	-0.023	0.156	0.088	0.024	0.273
C	0.344	0.088	0.171	0.516	0.327	0.184	0.512
O	0.296	0.088	0.124	0.468	0.283	0.151	0.468
M	0.259	0.084	0.094	0.424	0.265	0.137	0.452
CO	0.306	0.090	0.129	0.483	0.274	0.143	0.461
CM	0.193	0.077	0.041	0.344	0.181	0.079	0.365
OM	0.083	0.056	-0.027	0.194	0.087	0.023	0.282
COM	0.103	0.057	-0.007	0.214	0.112	0.036	0.298
High intention-to-quit scores at baseline							
Placebo	0.469	0.044	0.383	0.556	0.463	0.382	0.545
C	0.467	0.043	0.383	0.551	0.465	0.385	0.546
O	0.449	0.042	0.366	0.532	0.436	0.357	0.518
M	0.467	0.043	0.384	0.551	0.461	0.380	0.544
CO	0.349	0.041	0.267	0.430	0.352	0.275	0.438
CM	0.463	0.042	0.380	0.546	0.464	0.381	0.549
OM	0.489	0.041	0.409	0.570	0.479	0.401	0.558
COM	0.329	0.040	0.250	0.408	0.329	0.255	0.411