

**Use of smartphone-based interventions
to support smoking cessation and
pharmacotherapy use.**

by

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Thesis submitted for the Degree of Doctor of Philosophy

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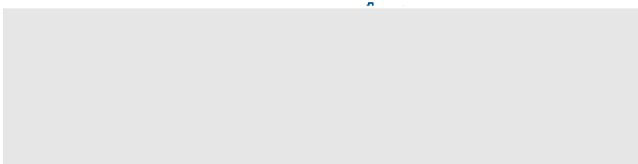
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Declaration

I, Aleksandra Herbec, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.



Abstract

This thesis reports findings from seven studies to develop and provide a preliminary evaluation of three smartphone apps tackling a different aspect of quitting. Study 1 was a pragmatic randomised controlled trial (RCT) of the NRT2Quit app that focused on improving adherence to nicotine replacement therapy (NRT) during quitting. Due to slow recruitment, the study was terminated early, but there was some evidence that the app could aid cessation. Study 2 was a theory-informed qualitative study of smokers' and ex-smokers' use of NRT, which identified barriers in capability, opportunity and motivation to NRT use and engagement with support on NRT use, which could also explain the poor recruitment into the NRT2Quit trial. Study 3 was a think-aloud study about NRT2Quit that showed that smokers were interested in the advice offered within the app, but preferred more comprehensive support, including craving management tools (CMTs). Study 4 was a pragmatic RCT of the BupaQuit app that offered CMTs versus an app version without them and found no detectable impact on cessation and several challenges to conducting pragmatic RCTs of apps. Study 5 identified barriers to verification of abstinence in such trials using personal carbon monoxide (CO) monitors. Study 6 involved follow-up interviews with the BupaQuit trial participants and found that while they were interested in CMTs, the app failed to meet their perceived needs, and many used unassigned cessation support. Study 7 used a mixed-methods approach to explore smokers' views on personal, smartphone-enabled CO monitors and associated apps, which found that smokers were interested in such support but also highlighted challenges for the development and evaluation of such programmes. This PhD suggests that smokers can articulate a number of desired features in cessation apps, but making these appealing, engaging and effective remains a major challenge, and many barriers exist to appropriate evaluation.

Impact statement

Digital behaviour change interventions, including those delivered by smartphone apps, could help smokers to quit. Despite the proliferation of cessation apps, there is still a scarcity of evidence on their effectiveness and acceptability to smokers. Many of the studies published to date had limited ecological validity. Furthermore, substantial gaps still exist in our understanding of how to deliver smartphone-based support for key aspects of quitting smoking, including the use of over-the-counter medications and provision of biofeedback.

The research described in this thesis addressed several important aspects of the development and evaluation of smoking cessation apps. It employed mixed-methods research to identify the preferences and perceived needs of adult smokers in the UK regarding app-based cessation support, with a focus on the use of nicotine replacement therapy, craving management, and use of personal carbon monoxide monitors. It also identified several elements and qualities of apps that adult smokers in the UK would find desirable. These findings should help when designing new apps.

The randomised controlled trials in this research programme provided useful lessons regarding the conduct of future trials and showing that what one might consider to be valuable app design features were not sufficient to maintain engagement. Even with an experienced design team, basing an app on one that has a reasonably high level of engagement, and strong links with large organisations who wished to help recruit participants, recruitment and engagement were low. New ideas are required to overcome these hurdles, and without this, smartphone apps are unlikely to reach their potential as cessation aids.

The findings from this research have either been published in peer-reviewed journals or submitted for publication. They have been presented at conferences in the UK and abroad and informed decision making in a large healthcare organisation with whom we collaborated.

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Chapter 1: A review of smoking cessation approaches in the context of tobacco control

1.1. Chapter 1 Overview

This Chapter sets out the rationale for the studies reported in this Thesis. It reviews evidence regarding the tobacco epidemic, tobacco control and smoking cessation, with a focus on behavioural support and nicotine replacement therapy. It discusses the possible role that digital interventions can play in the treatment of tobacco dependence. Finally, it outlines the scope of the thesis and the individual studies.

1.2. Introduction

Smoking remains a major cause of premature mortality and morbidity worldwide and is responsible for over eight million deaths annually (Peacock et al. 2018, WHO 2018a). The population impact of smoking cessation aids has thus far been limited (Fiore et al. 2008, West et al. 2015). New technological advances hold a hitherto unrealised promise for improving the reach of cessation interventions (West et al. 2018).

1.3. Tobacco epidemic and burden

In the past decades, major advances in tobacco control have been achieved, resulting in considerable declines in smoking prevalence, especially in high- and middle-income countries (WHO 2018b). Nevertheless, there are considerable differences in smoking prevalence across and within World Health Organization (WHO) regions, as well as between sexes, age-cohorts and socio-demographic groups within individual countries (Thun et al. 2012, Peacock et al. 2018). While many developed countries have seen the daily cigarette smoking prevalence decline from around 30-50% in the 1980s to 12-18% in 2010s in some countries (e.g. Australia, UK and US), in many others, including the Czech Republic and Germany, the prevalence remains over 30% (World Bank 2016).

There are no safe levels of tobacco use, with smoking contributing to morbidity

and mortality from a range of conditions, including cardiovascular diseases (CVD), primary and secondary cancers, and chronic obstructive pulmonary disease (COPD). There is a dose-response relationship between smoking and some cancers, especially lung cancer (Ruano-Ravina et al. 2003). A non-linear relationship was observed for pancreatic cancers (Zou et al. 2014) and heart conditions (Hackshaw et al. 2018). Light (e.g. <5 cigarettes/day) and passive (or second-hand) smoking also contribute to acute CVD events, other health conditions and all-cause mortality (Hou et al. 2017, Hackshaw et al. 2018). Smokeless tobacco, although having a lower health risk, is also associated with many conditions, and particularly an increased risk of localised cancers of the head and neck (Critchley and Unal 2003), although this relation was not observed for the Swedish snus (Luo et al. 2007).

Tobacco use and exposure also lead to poorer outcomes in dozens of other conditions, including pregnancy, diabetes, dementia, pain, surgery, as well as childhood conditions (e.g. low birth weight, cot death), and asthma (CDC 2014). It also contributes to excess deaths among patients suffering from infectious diseases, including tuberculosis and HIV (Jackson-Morris et al. 2015). Finally, smoking is associated with deteriorated mental health (Wootton et al. 2018), is a cause of deaths and injury due to fires (Leistikow et al. 2000), and leads to other societal costs, including loss of productivity (e.g. due to absenteeism) (Berman et al. 2014, Baker et al. 2017), and exacerbates poverty (Belvin et al. 2015).

Only complete abstinence and avoiding inhaling tobacco smoke can eliminate tobacco-related health risks. Complete cessation of tobacco smoking at any age can lead to improved health outcomes and lower morbidity and mortality (Pirie et al. 2013, CDC 2014).

1.4. Nicotine dependence and withdrawal

Nicotine is a psychoactive substance naturally occurring in tobacco leaves and is responsible for tobacco addiction (De Biasi and Dani 2011). Nicotine can be absorbed through the lungs (fastest), oral and nasal mucosa, as well as the skin. Nicotine inhaled with cigarette smoke is carried through the respiratory tract to the bronchi in the lungs, from where it is absorbed into the bloodstream and rapidly (within 10 seconds) reaches

the brain. Nicotine crosses the blood-brain barrier and is a potent stimulant of the central nervous system and the reward pathways. It binds to the nicotinic acetylcholine receptors nAChR, which triggers a release of other neurotransmitters at the nerve terminal into the synaptic cleft (most importantly dopamine, serotonin and norepinephrine receptors), leading to numerous physiological, neurological and behavioural responses including hypertension, increased respiration, hyperglycaemia, tachycardia, enhanced working memory storage, improved concentration, as well as appetite suppression (Heishman et al. 1993, Heishman et al. 2010).

Nicotine addiction is a chronic condition acquired through repeated engagement with the behaviour (tobacco use), whereby smokers experience powerful motivation to engage in the rewarding behaviour, and which has the potential for unintended harm (West and Brown 2013). With regular and frequent administration, dependence on nicotine is formed. Due to the accessibility of nicotine, the prevalence of ever-users of nicotine who become dependent is greater than for any other substance (CDC 2004, CDC). Tobacco Use Disorder features in the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), and nicotine dependence is classified under the Mental and Behavioural Disorders due to psychoactive substance use in the International Classification of Diseases (F17 in ICD-10-CM).

As with other addictive substances, the cessation of nicotine administration leads to withdrawal symptoms. Nicotine half-life is about two hours, and some of these symptoms start to appear already an hour after the last administration. Nicotine withdrawal includes behavioural, physiological, affective and cognitive symptoms, such as irritability, restlessness, poor concentration, depression, as well as increased appetite (Shiffman et al. 2004a, Shiffman et al. 2004b, Aubin et al. 2012, Rigotti and Clair 2018). Cravings for cigarettes are other important withdrawal symptoms. These can be defined as strong motivation (desire, need or urge) to smoke, and have been shown to predict relapse during quit attempts (Killen and Fortmann 1997, Allen et al. 2008, Herd et al. 2009, Zhou et al. 2009, Fidler et al. 2011, Fidler and West 2011). There is considerable variability in the severity and time course of these symptoms (Shiffman et al. 2004a). Withdrawal severity makes the experience of smoking cessation more aversive and thus may play a role in deterring or frustrating quit attempts (West et al. 2009).

1.5. Smoking and cessation behaviour among smokers

A considerable proportion of smokers are motivated to quit, especially among those who are knowledgeable of the harms of smoking (WHO 2018a). Around 40% of smokers in the developed countries (Australia, Canada, England, and the US) report having tried to quit in the past year, and many are reporting more than two attempts per year, with over a third reporting any cessation-related behaviour every month (Borland et al. 2012).

The majority of smokers report managing to refrain from smoking for at least one month in the past, and a considerable proportion reports managing to abstain for over six months before relapsing (Borland et al. 2012). However, most smokers relapse to smoking within the first week of quitting (Hughes et al. 2004). Successful cessation among those who attempt to quit with no evidence-based support stands at around 5% at one-year follow-up (Lemmens et al. 2008, Borland et al. 2012). Estimates of the average number of quit attempts required before achieving lasting cessation success vary between 6.1 and 142, depending on assumptions made by the researchers (Chaiton et al. 2016). The main factors, which are associated with making a quit attempt and succeeding in population-based studies are listed in Box 1.1 below.

Box 1.1. Example of factors that have been found to be associated with making a quit attempt and succeeding at quitting in population-based studies

Factors associated with initiating a quit attempt

- High nicotine-dependence
- High self-efficacy
- Health concerns
- Expected benefits of quitting
- Intentions to quit
- Low enjoying of smoking
- Lower income
- Lower educational attainment
- Greater number of past quit attempts

Sources: (John et al. 2004, Li et al. 2010, Fidler and West 2011, Vangeli et al. 2011, Jardin and Carpenter 2012, Rafful et al. 2013)

Factors associated with succeeding at quitting at 12 months follow-up

Positive association

- Lower dependence
- Intentions to quit in the near future
- Higher self-efficacy
-

Negative association

- High nicotine-dependence
- Younger age of first cigarette
- Low education
- Experiencing withdrawals and cravings,
- Exposure to smoking cues
- Lower socio-economic status
- Having other smokers in their household
- Smoking to cope or when experiencing negative emotions, as opposed to smoking for pleasure, socialising, drinking alcohol or coffee

Sources: (West et al. 2001, John et al. 2004, Ferguson et al. 2005, Shiffman et al. 2007, Zhou et al. 2009, Hagimoto et al. 2010, Li et al. 2010, Reid et al. 2010, Li et al. 2011, Jardin and Carpenter 2012, Ussher et al. 2016, Wehbe et al. 2018)

1.6. Tobacco control

Tobacco control is a broad field of research, practice and policy within public health that focuses on limiting the use of tobacco products and their impact. The WHO Framework Convention on Tobacco Control (FCTC) identified policies required to address the tobacco epidemic and its burden (WHO 2015). These were translated into

six country-level MPOWER measures, some of which, including sufficiently high tax increases, indoor smoking bans, or media campaigns, can help reduce the prevalence of tobacco use (Gilbert and Cornuz 2003, WHO 2008b, WHO 2008a, Leao et al. 2018, West et al. 2018). One of the MPOWER measures that has been identified as conducive to limiting smoking morbidity and mortality within the next decades is *Offering support with treatment of tobacco dependence* (WHO 2008b, Peto et al. 2010, Joosens and Raw 2014, WHO 2015).

1.7. Treatment of tobacco dependence

Offering support with treatment of tobacco dependence can involve a number of actions: (1) increasing the number of smokers who make a serious quit attempt, for example through clinicians offering brief advice, as at least a minority of those attempts will lead to long-term success (Chaiton et al. 2016, Anraad et al. 2018); (2) increasing smokers' access to, and uptake of, effective cessation interventions (e.g. providing affordable pharmacotherapy); (3) improving the quality of the cessation support offered (Bauld et al. 2010, West et al. 2013, Lorencatto et al. 2016); (4) improving smokers' adherence to treatment, e.g. pharmacotherapy (Raupach et al. 2014); as well as (5) implementing programmes that prevent relapse long-term (Borland et al. 2012).

Treatment of tobacco dependence can be divided into behavioural support and pharmacological support. Table 1.1 shows that both behavioural support and pharmacotherapy are effective when delivered on their own (Cahill et al. 2013, Lancaster and Stead 2017). However, a combination of the two is the most effective (Fiore et al. 2008, Stead and Lancaster 2012, Jain et al. 2016, Lancaster and Stead 2017).

Nevertheless, the distinction between behavioural and pharmacological support is not always clear-cut. The latter can involve behavioural elements, including recommendations to use medications, offering reimbursement or free medications, or providing a prescription, as well as brief advice on quitting smoking. Similarly, brief evidence-based behavioural advice (e.g. the so-called '3 As': assess, advise, arrange/act) usually involves recommendations to use medication or provision of a prescription (Quinn et al. 2009).

Table 1.1. Summary of estimates of the effectiveness of different cessation support.

	OR (95% CI) [a]	OR¹ [b]	% increase in quit rates² [c]	RR³ [d]
Combination therapies				
Combination therapy group	-	-	300%	-
Combination therapy (individual)	-	-	200-300%	-
Pharmacotherapy with minimal support (initial visit and follow-up)	-	-	50-100%	-
Mono-behavioural therapies				
Brief advice from HCPs / GPs	2.17 (1.37-3.45)	1.40	-	1.66 (1.42-1.94)
Intensive physician advice	2.04 (1.71-2.43)		-	1.84 (1.60-2.23)
Nursing interventions	1.47 (1.29-1.67)		-	1.29 (1.20-1.39)
Individual counselling	1.56 (1.32-1.84)	1.40	-	1.39 (1.24-1.57)
Group behavioural therapy	1.56 (1.38-1.77)	2.00	-	
Telephone counselling	-	1.40	50-100%	1.37 (1.26-1.50)
Self-help interventions				
SMS	-	1.71	40-80%	
Tailored self-help interventions	1.42 (1.26-1.61)		-	-
Printed self-help materials	-	1.19		-
Online	-		Unknown	-
Mobile (apps)	-		Unknown	-
NRT				
NRT (overall)	1.77 (1.66-1.88)		-	1.49 (1.40-1.60)
NRT (OTC)				
NRT (Rx) single product	-	1.60	-	
NRT (Rx) combination	-	2.14	-	
Varenicline				
Varenicline standard	-	2.30	-	2.88 (2.4-3.47)
Varenicline extended	-	2.76	-	
Cytisine	-	3.98	-	
Bupropion	2.06 (1.77-2.40)	1.60	-	1.82 (1.6-2.06)

¹ OR=odd ratio in comparison to control condition; ² increase from control condition or no support,

³RR=relative risk, in comparison to control or placebo a=(Lemmens et al. 2008), b=(Anraad et al. 2018), c=(PHE 2017), d= (U.S. National Cancer Institute and World Health Organization, 2016)

1.8. Behavioural support in smoking cessation

Behavioural cessation support is a broad category encompassing complex, multicomponent interventions of different intensity (e.g. ranging from one-off, brief advice to intensive weekly support). Trained advisors can deliver these through a range of modalities: face-to-face (e.g. as part of individual and group sessions), over the phone (e.g. Quitlines) or digitally (synchronously, e.g. through chat rooms or video calls, or asynchronously, e.g. through discussion forums or emails). Behavioural support also includes standardised or personalised self-help aids delivered through printed materials (e.g. leaflets, booklets, letters), or through mobile or other digital devices (e.g. SMS texting, websites, and smartphone apps – the latter are discussed in detail in section 1.11).

The effectiveness of behavioural support varies depending on its type, context, and possibly also intensity (West et al. 2010). Face-to-face support shows modest effectiveness at one-year follow-up, e.g. 10% success rate for brief intervention with NRT and 30% for intensive support with pharmacotherapy (Ferguson et al. 2005). Very brief advice to quit offered by healthcare professionals (HCPs), e.g. general practitioners (GPs), may increase the number of quit attempts made. However, offering cessation support (e.g. NRT), as opposed to just recommending smokers to quit by clinicians leads to better outcomes (Aveyard et al. 2012).

One meta-analysis (Jain et al. 2016) showed that differences in cessation success depend on who provides the support, with psychologists (RR=1.94), physicians (RR=1.87), and nurses (RR=1.76) having higher success rates in comparison to placebo. Meanwhile, support by providers classified as counsellors, unknown sources, other help, or self-help did not improve cessation success rates. The same analysis showed that providing NRT further increases the effectiveness of treatment offered by psychologists and nurses, but not one offered by the other groups (Jain et al. 2016).

The UK has been a notable example of a country providing community-based stop smoking service (SSS) available to all smokers free at the point of access, and where full or partial reimbursement has been offered for all medications (McNeill et al. 2005). The real world effectiveness of the UK SSS could be as high as 53% for biochemically verified quit rates at 4-weeks (61% for self-reports) and 15% at 1-year follow-up (18% for self-reports), but there is considerable variability in the outcomes (Ferguson et al.

2005, Judge et al. 2005, Bauld et al. 2010). Smokers attending SSS are likely to be self-selecting and more motivated to quit than those in the general population. The support offered in SSS is often of higher intensity than brief advice, but may not be as intensive as the support offered during clinical trials (Ferguson et al. 2005). The success rates among smokers attending SSS are positively associated with smokers' older age, determination to quit, and negatively associated with female sex, lower socio-economic status, greater dependence and poorer health (Ferguson et al. 2005, Judge et al. 2005, Bauld et al. 2010).

1.8.1. Behavioural support – active ingredients

Behavioural support involves a number of active ingredients, or behaviour change techniques (BCTs). BCTs are defined as 'observable, replicable, and irreducible components of interventions, which have the potential to change behaviour' (Michie et al. 2013). Over the past years, researchers have identified and classified dozens of BCTs into taxonomies - scientific classifications of categories, which use standardised terminology, definitions and groupings or hierarchical categorisations of individual components (Michie et al. 2011a). Such taxonomies have been developed for BCTs for interventions targeting a range of behaviours, including alcohol use (Michie et al. 2012d) or diet and physical activity (Michie et al. 2011a, Samdal et al. 2017). A widely used unifying general taxonomy, with 93 BCTs in its first version (BCTTv1), has also been developed (Michie et al. 2013).

An analysis of cessation services and treatment manuals in the UK identified 43 individual BCTs to be forming part of comprehensive cessation treatment. These fall into the following categories: a) boosting motivation to quit, b) improving self-regularity capacity or skills, c) promoting adjuvant activities, e.g. using cessation medications, and d) other supporting activities, e.g. building rapport with patients (Michie et al. 2011b). Several BCTs were found to be associated with improved cessation outcomes when delivered in SSS, including the use of biofeedback (carbon monoxide (CO) testing – described below in 1.8.2), offering rewards contingent on abstinence, strengthening non-smoker identity, offering advice on pharmacotherapy, and providing social support (West et al. 2010). The quality of delivery of individual BCTs, e.g. goal setting, was also shown to contribute to treatment effectiveness (West et al. 2010, Lorencatto et al. 2016).

1.8.2. Use of carbon monoxide (CO) testing as part of cessation support

CO is an invisible, odourless, and toxic gas that is formed during tobacco smoking and can be measured in the exhaled air of smokers (Middleton and Morice 2000, Goldstein et al. 2018). CO levels below 10 particles per million (ppm) are commonly used as an indication of tobacco smoking abstinence (West et al. 2005, Brose et al. 2013). However, light smoking may result in readings of 5-9 ppm (Beard and West 2012), and more recent research suggests that a lower cut-off of 5ppm should be used to determine abstinence (Perkins et al. 2013).

CO testing in a non-invasive measure of harm (e.g. no biological samples are required), and CO levels are not affected by concurrent use of NRT or e-cigarettes (Goldstein et al. 2018). However, as the body eliminates CO rapidly, the temporal applicability of CO testing is limited (Benowitz et al. 2002). Moreover, CO results may be affected by several factors such as smokers' health status (e.g. asthma or COPD) (Yamaya 2001, Sato et al. 2003) or exhalation speed into the CO device (Raiff et al. 2010).

Notwithstanding these limitations, assessment of CO levels has been commonly used in many cessation programmes as a diagnostic or educational tool (West et al. 2010, Bittoun 2012, Goldstein et al. 2018), and to biochemically confirm abstinence in treatment (Brose et al. 2013, Goldstein et al. 2018) and in research (West et al. 2005, Louwagie et al. 2014). Additionally, CO monitors have been used as monitoring and feedback components of effective stop smoking programmes (West et al. 2010, Shahab et al. 2011, Lorencatto et al. 2012). Smokers were shown to be accepting of CO testing and to value it as a motivational tool (Shahab et al. 2011, Beard and West 2012, McClure et al. 2015, Alessi and Rash 2017, Goldstein et al. 2018).

1.8.3. Relapse prevention and craving management

A major challenge in treating tobacco addiction is addressing the high rates of relapse (Borland et al. 2012). Most smokers return to smoking within a week of initiating a quit attempt (Hughes et al. 2004). Relapse can be caused by stressors (Borland et al. 2012) and cue-reactivity in response to different stimuli, including

external or environmental factors, internal states (e.g. low mood), cognitions (e.g. knowledge that a drug is available) (Brandon et al. 2007), permissive environments, availability of cigarettes, and presence of smokers (Shiffman et al. 1996).

Programmes focused on preventing relapse have often incorporated skill training in two areas. The first focuses on identifying high-risk situations or stimuli that may lead to urges, and then avoiding them (e.g. avoiding drinking alcohol during social gatherings), or developing restorative strategies in the aftermath of lapses (Shiffman et al. 1996). Some interventions based on this approach showed some promise, e.g. self-help booklets on relapse prevention posted to ex-smokers (Brandon et al. 2000, Taggar et al. 2015). However, there is a scarcity of evidence for the effectiveness of any behavioural or pharmacotherapy programmes on long-term relapse prevention among ex-smokers (Hajek et al. 2013).

The second approach is to help smokers to develop and implement a range of techniques that could help them resist momentary cravings for cigarettes, especially during the early stages of quitting when such urges may be particularly frequent and strong. Such techniques include the ‘four Ds of quitting’: delaying smoking (i.e. waiting for the urge to pass), deep breathing, drinking water, and distracting oneself (Ploderer et al. 2014)). Cognitive distraction (e.g. focusing attention on cognitively-engaging content), has been used with some success to cope with pain (Johnson 2005) and to reduce cravings for food (Skorka-Brown et al. 2014). Smokers also self-report using different distraction techniques while trying to quit, e.g. breathing, exercising, drinking, and eating (O’Connell et al. 1998). Experimental studies identified several other techniques as potentially effective at reducing momentary cigarette cravings, including engagement in visuospatial tasks, such as imagining pleasant experiences and outdoor spaces (Knauper et al. 2011), physical exercises, e.g. brisk walking (Taylor et al. 2007, Scerbo et al. 2010, Ussher et al. 2012b), breathing exercises, e.g. yogic breathing (Shahab et al. 2013b), body scanning (Cropley et al. 2007), and muscle tensing (Ussher et al. 2009).

1.9. Pharmacotherapy in smoking cessation

A range of medicines can support smoking cessation. These include pharmacotherapy acting on the central nervous system (e.g. varenicline, cytisine, bupropion), as well as NRT (described in more detail below in 1.9.1) (see Table 1.1. above). All these forms of licensed pharmacotherapy have been shown to be effective and safe at aiding cessation, with the highest success rates achieved with varenicline and combination NRT (i.e. using a nicotine patch together with another nicotine product) (Cahill et al. 2013, Anthenelli et al. 2016).

The first group of pharmaceuticals is based on substances that act as nicotine receptor partial agonist. The molecules of these substances bind to the nicotine receptors (nAChRs) (e.g. the $\alpha 4\beta 2$ or $\alpha 6\beta 2$), which helps to manage withdrawal symptoms and cravings. They also prevent nicotine from the cigarettes from binding to nAChRs as they have a higher affinity for the receptor than the natural ligand, nicotine. This lowers the rewarding impact of cigarette smoking on smokers. To date, two substances have been used as partial agonists of $\alpha 4\beta 2$ -nicotinic receptors. The first is cytisine (branded as Tabex and Desmoxan, primarily sold in countries of the former Soviet Bloc, with the most prevalent current use in Poland) (Zatonski and Zatonski 2015). The second is cytisine's synthetic counterpart, varenicline, that is available only on prescription (under the trade name Champix in the UK and Chantix in the United States) (Leaviss et al. 2014). Two antidepressants (bupropion hydrochloride, sold as Zyban, and nortriptyline) were also shown to improve cessation (Hughes et al. 2014).

1.9.1. Nicotine replacement therapy

NRT delivers nicotine that can alleviate withdrawal symptoms during quitting (Bauld et al. 2012). It is the most commonly used medically-licensed pharmacotherapy for smoking cessation, although its use has been declining over the past decade and has now been overtaken by electronic cigarettes in some countries, including the UK and Australia (Fix et al. 2011, Beard et al. 2016b). In countries such as the UK, NRT is also licensed for harm reduction (e.g. cutting down or abstaining temporarily from cigarettes)(Beard et al. 2013).

NRT comprises a wide range of products, including slow acting forms (nicotine transdermal patches) and fast acting forms (e.g. nicotine gums, mouth and nasal sprays, lozenges, sublingual tablets, oral film strips, and inhalators). The different NRT

products are similarly effective (Stead et al. 2012), are meant to be used for at least eight weeks, and have been shown to be generally safe, also for long-term use (Eliasson et al. 1996, Sims and Fiore 2002, Moore et al. 2009, Murray et al. 2009, Anthenelli et al. 2016). There is some evidence to suggest that better adherence to NRT could improve cessation, but more research is needed (Hatsukami et al. 2007, Shiffman 2007, Hollands et al. 2013, Ferguson et al. 2014, Raupach et al. 2014, Beard et al. 2015, Schlam et al. 2018).

The various NRT products differ considerably in their method of use, strength (i.e. nicotine content) and speed of nicotine release and absorption (Wadgave and Nagesh 2016). It is also worth noting that the actual nicotine dose absorbed from the medications is considerably lower than the dose indicated on the pack (Hollands et al. 2013). The nicotine patch is considered to be a ‘slow acting product’ in comparison to other forms of NRT, while the mouth and nasal sprays are the fastest acting products (Shahab et al. 2013a). The patch should be applied daily for 16 or 24 hours, while the fast-acting nicotine forms, such as nicotine gum, lozenges and sprays to be taken as frequently as every 1-2 hours throughout the day.

There have been some concerns over nicotine increasing the risk of cardiovascular, respiratory, gastrointestinal disorders, negatively impacting the reproductive health and the immune system, and promoting cancers through affecting cell proliferation, apoptosis, oxidative stress, and DNA mutations (Mishra et al. 2015). NRT is also associated with several short-lived, and relatively harmless acute side-effects (e.g. burning sensations, hiccups, heart palpitations in rare cases), many of which can be minimised with appropriate application techniques (e.g. correct chewing technique, correct application of patch on the skin). Moreover, evidence suggests that there are no circumstances in which it would be safer to smoke cigarettes than to use NRT (Eliasson et al. 1996, Sims and Fiore 2002, Moore et al. 2009, Murray et al. 2009).

In some countries most of the NRT products are available both on prescription (Rx) and over the counter (OTC), including in Europe, Canada, the United States, and Australia (Shiffman et al. 1997, Balmford et al. 2011), which contributes to their popularity (Raw et al. 2009). NRT is the most commonly used medically licenced pharmacotherapy for smoking cessation worldwide, and it is most often purchased OTC (West and Fidler 2011). In the UK all forms of NRT are available both on prescription (at no or lower cost) or for OTC purchase in pharmacies, supermarkets and some local

stores (Kotz et al. 2014b).

1.9.2. Non-combustible electronic nicotine delivery devices

Recent years have seen a rapid emergence of a broad range of other non-combustible electronic nicotine delivery devices, which increase the pool of potential cessation and harm reduction aids. These products include electronic cigarettes that contain liquid with nicotine that is warmed and vaporised by a battery (Huang et al. 2018), as well as heat-not-burn products, where the tobacco content is allegedly only heated, but no combustion takes place, thus lowering the harms of smoking (Davis et al. 2018). There is a consensus among the scientific and medical community that while electronic cigarettes are not risk-free, they are less harmful than combustible cigarettes. Preliminary research suggests that these products can aid cessation among some smokers (McNeill et al. 2018, National Academies of Sciences 2018).

1.10. Challenges to delivering traditional smoking cessation support

1.10.1. Limited access, uptake, and impact

Even intensive tobacco treatment and use of pharmacotherapy are associated with limited effectiveness and high relapse rates (Ferguson et al. 2005, Judge et al. 2005). The reach and effectiveness of behavioural support and pharmacotherapy are limited for a number of reasons. First, there are stark differences between countries in the level of access and type of cessation support available to smokers, with only about a third of the world's population having access to any form of cessation assistance, including brief advice from HCPs (Raw et al. 2009, Pine-Abata et al. 2013, WHO 2018a). Secondly, most countries do not offer comprehensive training on treatment of tobacco dependence for HCPs, and there are also differences in training on smoking cessation offered, e.g. on cessation medications, which is likely reflecting the local situation (Kruse et al. 2017). Thirdly, traditional face-to-face interventions are time- and resource-intensive, and are often underfunded, which affects their availability (ASH 2017, ASH 2018).

Moreover, considerable heterogeneity exists in the type and quality of behavioural support offered within a given country, with the support likely to be dependent on local

funding and policies (the so-called ‘postcode lottery’) (Aveyard et al. 2007, West et al. 2013, ASH 2018). Research on SSSs in the UK has shown poor fidelity to treatment protocols and differences in the quality of delivery of individual BCTs (e.g. goal setting), all of which could affect effectiveness (Lorenatto et al. 2013, McDermott et al. 2013, Brose et al. 2014, Lorenatto et al. 2016). Furthermore, even when behavioural support is classified as intensive and meets the recommended duration, it is still often limited to several 30-60 minute-long appointments spread across several weeks (Reports 2012), with limited assistant offered in-between the sessions when it may be most needed (e.g. when smokers struggle with cravings).

Finally, the uptake of behavioural support by smokers remains very low. Even in settings where SSSs are widely available, actively promoted, and free at the point of access (e.g. in the UK or Canada), only <5% of smokers in the general population access them (Kotz et al. 2009, Raupach et al. 2013, ASH 2017). Similarly, very few primary and secondary care patients take up offers or referrals to SSSs, including veterans in the US (Berg et al. 2016, Myers et al. 2016) or pregnant women in the UK (Bauld et al. 2012, Campbell et al. 2017). Furthermore, the cessation support landscape has been changing in Europe, with a reported increase in the use of electronic cigarettes and a decline in all other forms of support (Filippidis et al. 2018). In the UK fewer quit attempts set through SSS have been recorded (NHS Digital 2017). Some of these trends are reflecting preferences of the smokers themselves, but also barriers to access, such as inconvenience, concerns over privacy, and low expectations (Herbec et al. 2014a).

There are similar challenges in accessing cessation pharmacotherapy. Cross-sectional studies conducted in the UK and other European countries show very low use of cessation pharmacotherapy in previous quit attempts (Beard et al. 2016b, Filippidis et al. 2018). Additionally, countries differ in what cessation pharmacotherapy they offer (e.g. cytisine in any form is only available in several countries, e.g. Poland, Bulgaria, Italy, New Zealand, Australia and Canada). Furthermore, only certain countries offer several NRT products OTC, and only a few of them offer at least partial reimbursement for cessation medications, which can be very costly if purchased out-of-pocket (Raw et al. 2009). Finally, the recent funding cuts in the UK have resulted in fewer prescriptions for cessation medications issued to smokers (British Lung Foundation 2018).

1.10.2. NRT – low effectiveness of OTC NRT

OTC NRT remains the most commonly used pharmacological intervention globally (U.S. National Cancer Institute and World Health Organization 2016). High-quality evidence from RCTs shows that NRT is effective when provided with at least some form of professional support (Stead et al. 2012). However, large-scale surveys and prospective studies found that the quit rates with OTC NRT (often offered without any additional behavioural support) are similar to, or lower, than those for unaided attempts, even when adjusting for a range of potential confounding variables (Leischow et al. 2004, Hughes et al. 2011, Kasza et al. 2013, Kotz et al. 2014b, Kotz et al. 2014a, Beard et al. 2015)

Several factors could contribute to the low effectiveness of NRT outside of the trials. First, findings from the clinical trials could overestimate NRT effectiveness due to several biases, e.g. industry funding. Thus, the lower effectiveness of real-world NRT use might reflect more closely the medication's actual effectiveness (Stanley and Massey 2016, Hughes et al. 2017). Secondly, smokers tend to use NRT for different purposes (e.g. quitting or temporary abstinence), which are often not accounted for in the population-based studies (Hammond et al. 2008). Thirdly, the monitoring or the brief support from HCPs or researchers offered as part of the trials (Hammond et al. 2008, Kotz et al. 2014b), or having a greater sense of accountability that may accompany smokers' participation in research or treatment with Rx NRT, could all contribute to better cessation success (Walsh 2008).

Fourthly, users of OTC and Rx NRT tend to differ on a range of dimensions, all of which could affect patterns of NRT use and treatment effectiveness (Hughes et al. 2011). Obtaining OTC NRT is convenient although often incurs a higher cost. In the UK the price is fixed at about £8.60 per prescription for medications, in contrast to around £8-22 for OTC NRT products, and some patient could obtain Rx medications for free (e.g. pregnant smokers, those aged ≥ 60 years, or receiving income-based benefits). Moreover, studies showed that smokers in England who are using Rx cessation medications (most often NRT) were more likely to be older, have lower socioeconomic status (Kotz et al. 2014b), and be more cigarette dependent (Kotz et al. 2014a).

1.10.3. NRT – poor adherence and suboptimal use

Another plausible reason for the low effectiveness of OTC NRT is poor medication adherence, or suboptimal use¹. Although there is considerable heterogeneity in the manner in which adherence to cessation medication has been evaluated (see Chapter 2.5.5.), there is an overall agreement that cessation pharmacotherapy, including NRT, should be used continuously over a period of at least 8 weeks, usually on a daily basis, and according to the regimen for that medication (Pacek et al. 2017).

Non-adherence to pharmacotherapy is a well-documented challenge in many health conditions (Horne et al. 2005). A meta-analysis of 569 studies published between 1948 and 1998 showed that the average non-adherence rate to different medications is 25% (DiMatteo 2004). Poor adherence to NRT has also been documented in many trials and population-based studies, with smokers using too little NRT, incorrectly, or for too short a time to produce a clinical benefit (Curry et al. 2003, Shiffman 2003, Wiggers et al. 2006, Amodei and Lamb 2008, Hammond et al. 2008, Foulds et al. 2009, Balmford et al. 2011, Raupach et al. 2014, Beard et al. 2015). Notably, however, some studies of intensive face-to-face cessation support with close monitoring of NRT use reported very high adherence (up to 90%) (Hollands et al. 2013).

Over 200 factors were identified that could influence the use of different medications (Haynes 1976, Meichenbaum and Turk 1987). A recent review of 48 studies examining correlates and self-reported reasons for the suboptimal use of NRT and other cessation pharmacotherapy proposed to distinguish between non-preventable factors (e.g. comorbidities, tobacco dependence and socio-demographic characteristics), and preventable factors (e.g. beliefs, attitudes, and psychosocial characteristics) (Pacek et al. 2017).

¹ The literature distinguishes between *compliance*, *adherence*, and *concordance* in relation to medication use, although these terms are often used interchangeably (Horne et al., 20107):

- *Compliance* - the extent to which the patient's behaviour matches the recommendations;
- *Adherence* - the extent to which the patient's behaviour matches the recommendations that have been *agreed* together with the prescriber;
- *Concordance* – encompasses a range of behaviours and processes related to the outcomes of communications between patients and prescribers or other HCPs in selecting, co-developing, and managing pharmacological treatments.

For this thesis, a broad definition of *adherence* is used that refers to using NRT in line with the recommendations and best clinical practice. Additionally, a broader term of '*optimal* NRT use' is used that additionally encompasses other behaviours that may be necessary to produce the clinical benefit from OTC NRT during quit attempts (e.g. changing or adding NRT products).

Several other frameworks of non-adherence can also help to understand NRT use, including a broad distinction between intentional (e.g. not wanting to use medications) and non-intentional (e.g. forgetting) non-adherence (Lowry et al. 2005, Clifford et al. 2008). The Necessity-Concerns Framework (Horne et al. 2013) suggests that adherence is affected by participants' implicit evaluations of medicines in terms of *perceived* need (i.e. how important is the medication to improve patient's condition) and views on side effects and potential harm. The Attitudes Toward Nicotine Replacement Therapy scale (Etter and Perneger 2001) assesses similar attitudinal factors, as well as knowledge of NRT.

Many quantitative and qualitative studies lend support for these frameworks, showing that misconceptions, concerns over safety, and low efficacy beliefs are linked to NRT non-adherence (Etter and Perneger 2001, Bansal et al. 2004, Mooney et al. 2006, Shiffman et al. 2008a, Vogt et al. 2008, Yerger et al. 2008, Foulds et al. 2009, Carpenter et al. 2011, Ferguson et al. 2011, Beard et al. 2012, Kardas et al. 2013, Silla et al. 2014, Tsang et al. 2014, Pacek et al. 2017).

1.10.4. NRT – interventions supporting adherence

There remains little direct evidence that could guide the creation of interventions supporting NRT use (McDonald et al. 2002, Hollands et al. 2015b). Interventions that target cognitions and attitudes, and include reminders to use medications or materials with educational and problem-solving components, have shown a positive but limited impact on adherence and subsequent abstinence (Mooney et al. 2006, Amodei and Lamb 2008, Hollands et al. 2015b, Hollands et al. 2015a). Informing smokers that their NRT dose is tailored to their genotype was also not effective (Marteau et al. 2012). Moreover, most interventions supporting medication adherence had been adjunct to other cessation interventions (Hollands et al. 2015b), and so we still lack programmes that could support smokers who are using medications with no traditional behavioural support, e.g. OTC NRT.

1.11. Digital behaviour change interventions

Given the limited availability, uptake and impact of the available evidence-based cessation support, there is a need for new approaches to improve quit attempt success and use of pharmacotherapy. Digital behaviour change interventions (DBCI) offer new opportunities for smoking cessation (Marsch et al. 2014). These tend to be complex (i.e. multicomponent) interventions that can be delivered through computers, online, mobile phones or smart devices, such as tablets, smartphones or wearables (smart watches), or interactive voice response systems. DBCI could also address some of the existing challenges in the provision and access to evidence-based treatment (Curry et al. 2003, Pulverman and Yellowlees 2014, Munafo 2017, Rigotti et al. 2017).

There is little expectation and also limited evidence to suggest that the effectiveness of DBCI could approximate that of traditional cessation interventions (Taylor et al. 2017). Nevertheless, if DBCI had a sufficiently wide reach and uptake, even small effect sizes would be clinically important at the population level (West 2007a). Additionally, DBCI have the potential to be cost-effective, although the initial cost of developing them may vary greatly depending on the type of the intervention, the technology used, and the team working on it. Nevertheless, once developed and provided a sufficiently big pool of participants, DBCI could be deployed with a relatively low cost per new users (Guerriero et al. 2013).

Furthermore, technological advances are continually increasing the remit of the digital support that can be offered to smokers (Munafo 2017). For example, mobile phones, including smartphones, could deliver craving management support, as they can offer both behavioural distraction (i.e. keeping one's fingers busy) and cognitive distraction (e.g. engaging with interesting content such as multimedia) (O'Connell et al. 1998, Rodgers et al. 2005, Whittaker et al. 2008, Ploderer et al. 2014). DBCI can also be used to deliver interventions that rely on social support or communication with HCPs, and which could also be offered anonymously (Bock et al. 2004) and at greater reach and lower cost than face-to-face meetings. Such interventions can be delivered through chat-rooms, discussion forums, social media, e.g. Facebook, or WhatsApp (Cheung et al. 2015). Finally, many BCTs can be delivered through DBCI, including goal setting, monitoring and feedback, and promotion of adjunct behaviours.

1.11.1. Mobile-based SMS texting interventions for quitting smoking

Many early DBCIs for smoking cessation were based on SMS-texting technology, and some countries still offer such support to smokers (e.g. the USA). These often involved developing a library of SMS texts that include supporting, motivational or educational messages, and delivering these one-way at a pre-determined schedule (messages sent by the provider only) (Mussener et al. 2016). Other interventions supported an automated, two-way interaction, whereby recipients can also respond to questions sent via the text (e.g. on the level of cravings or smoking status), and to receive tailored advice. The txt2stop intervention was shown to double the quitting rates (Free et al. 2011, Guerriero et al. 2013). An analysis of almost 900 text messages forming part of 'txt2stop' identified 34 BCTs used, and found that most texts focused on enhancing self-regulatory skills and maintaining engagement with the intervention, a quarter focused on maintaining motivation to remain abstinent, and only a small proportion addressed adjunct behaviours (e.g. using pharmacotherapy) (Michie et al. 2012c).

SMS texting has many benefits, but also limitations. The texts can be standardised and delivered at a pre-determined schedule, and cannot be switched off or ignored easily (in comparison to smartphone app notifications). However, often the messages are triggered centrally and automatically (e.g. based on date and time), and thus there may be limited scope for personalisation, which is a limitation (Naughton et al. 2013). The texts display differently on smartphones screens (as a string of communications), and notifications of incoming SMS texts are presented together with system and app notifications, thus competing for user attention. Importantly, there is a limit to the number and type of characters that can be delivered by each text, which poses challenges for delivering complex messages or to adapting such interventions to other languages. Finally, although individual SMS texts are inexpensive, for intensive interventions the cost per participant could be high.

SMS texting has been shown to be an acceptable and promising treatment for addiction to cigarettes and alcohol (Fidler et al. 2011, Naughton et al. 2013, Keoleian et al. 2015, Mussener et al. 2016, Grau et al. 2017). In a review of 12 RCTs, of which seven were assessing SMS-only interventions, SMS texting interventions have shown to support quit rates, with a relative risk of 1.6, regardless of the study design, amount of

in-person contact, or the type of control used (Whittaker et al. 2012).

1.11.2. Online and web-based interventions

Internet-based DBCIs, delivered primarily through websites accessible on desktop computers, offer another medium to deliver cessation support. Access to internet-connected digital devices is growing globally, but considerable differences exist between countries. Smokers were shown to engage in relevant to them health information-seeking online (i.e. about quitting) more often than other patient groups do (Shahab et al. 2014). Additionally, almost half of smokers in England (46.6%) report that they would be interested to use online smoking cessation support, but the actual use in past quit attempts is low at 0.3% (Brown et al. 2013).

In comparison to texting, websites offer more screen space and functionality to deliver complex and rich in content interventions, as well as greater scope for personalisation. The web user is also expected to be seated in front of the screen for longer than when accessing SMSs, thus allowing for greater engagement. However, the limitation of using online interventions is that they require uninterrupted access to the internet and often also a desktop computer, as many older websites may not be suitable for display and navigation using mobile or tablet platforms.

Internet-based support was shown to be acceptable to some smokers at least (Escoffery et al. 2004, Raiff et al. 2013, Herbec et al. 2014a), and some cessation websites produced promising quit rates (e.g. >20% self-reported abstinence at 12 months) (Bricker et al. 2018). Web-based interventions that are interactive and tailored could improve quit rates in comparison to static or non-active conditions among smokers in the general population (Shahab and McEwen 2009, Fidler et al. 2011, Chen et al. 2012, Balhara and Verma 2014, Brown et al. 2014, Taylor et al. 2017), and pregnant women (Naughton et al. 2008, Herbec et al. 2014b). Some evidence also shows that internet interventions are more effective when supplemented by SMS texting or other support (Webb et al. 2010).

Some studies found that engagement with such programmes is related to effectiveness, for example in case a web-based tailored relapse prevention programme (Elfeddali et al. 2012). Similarly, a dose-response relationship between engagement and

effectiveness was observed in a recent study of an online intervention comparing arms with different combinations of NRT, web-based behavioural, and social support (Graham et al. 2017).

A 2004 review of web-based programmes available outside of the research setting has identified a number of cessation websites but concluded that many of these were of mixed quality, did not adhere to clinical guidelines, were written at high reading level, and thus it would be difficult for smokers and clinicians to identify the more helpful websites (Bock et al. 2004).

1.11.3. Smartphone application (apps) for behaviour change and health promotion

Smartphones, and specifically, smartphone apps are among the newest medium to deliver DBCIs. To date, apps were developed for a range of health conditions, including migraines, asthma, diabetes, depression and CVD (Zapata et al. 2015, Higgins 2016, McKay et al. 2018), and medication use (Morrissey et al. 2016, Santo et al. 2016, Ahmed et al. 2018). Health apps also tend to be among the most commonly downloaded apps (Jahns 2015). In a survey of over 1600 US smartphone users, almost 60% had downloaded a health-related app, primarily for fitness and nutrition, and these tended to be used daily (Krebs and Duncan 2015). In another study, a third of smartphone users had at least one health-related app on their phone (Jake-Schoffman et al. 2017).

Smartphone apps have many advantages over other digital platforms. First, smartphones are almost ubiquitous in the developed countries, with their market penetration growing year-on-year, and currently standing at 85% in the UK (Deloitte 2017, Michie et al. 2018). Notable differences exist between developing countries, however (e.g. 4% in Pakistan, 55% in China) (Pew Research Center 2015). Importantly, smartphone owners tend to carry the devices with them throughout the day, and smartphones are increasingly becoming the main way of accessing internet, with the UK users spending almost two hours per day accessing internet on their smartphones (Ofcom 2015) and devoting more time to apps than to websites (BuildFire 2017).

Thus, smartphones are likely to become the main point through which most DBCIs will be offered or accessed in the future, including SMS texting, mobile-friendly web-based interventions, as well as apps. Furthermore, in contrast to purposefully

developed hand-held devices or other computer systems (e.g. decision aids for clinicians (Curl and Robinson 1994, Garg et al. 2005, Koplan et al. 2008)), smartphone can be owned by both HCPs and patients, allowing for easier communication, use of shared platforms, as well as efficient data collection. Therefore, smartphone apps can, at least in principle, reduce barriers to uptake of cessation support (Kumar et al. 2013).

Moreover, smartphones can harness technology that can extend the support offered by SMS texting on websites, and which also enables creating and testing novel approaches to cessation. First of all, apps can be programmed for both online and offline use. Secondly, they can include features, such as notifications and in-app settings, that can be customised by the users, which should improve relevance and acceptability (Naughton et al. 2013).

Depending on data protection laws and other regulations, smartphone-based technology can be used to collect and synthesise information from multiple sources about an individual to enable personalisation (e.g. whether other apps are used on the same device). One such example is the use of the global positioning system (GPS) that can define users' location and geographical boundaries around them (so-called geofencing). This technology can be used as part of DBCIs to record and study patterns, locations and timing of smoking or quitting-behaviour, together with their psychological (e.g. craving or stress levels) or environmental correlates (Naughton et al. 2016, Schick et al. 2018). Such context-sensing can support the so-called just-in-time interventions (Naughton et al. 2016).

The functionality of smartphone-based DBCIs can be further extended by built-in sensors or hardware (e.g. phone's cameras). Smart watches or bracelets offer further possibilities to assess users remotely, detect behavioural patterns from hand movements (e.g. smoking vs other behaviours) (Parate et al. 2014, Morrissey et al. 2018) and deliver bio-feedback, including electroencephalograms (EEGs), blood pressure, and heart rate (Coppetti et al. 2017). Finally, analysing the rich data collected from apps and sensors using machine learning could help design interventions relying on anticipator mobile computing to deliver highly more personalised support (Pejovic and Musolesi 2014).

1.11.4. Smartphone quitting apps – research to date

Hundreds of apps offering some support with quitting smoking exist on the market. Qualitative and cross-sectional studies have shown that some smokers are interested and accepting of such programmes (Ploderer et al. 2014, Hicks et al. 2017, Perski et al. 2017a, Baskerville et al. 2018). There is also some evidence that such interventions may reach people who had never accessed other behavioural or pharmacological support, but who are ‘serious’ about quitting, as is suggested by characteristics of participants who sign up to such apps (BinDhim et al. 2014a, Ubhi et al. 2015, BinDhim et al. 2018).

However, despite the proliferation of stop smoking apps, there is minimal evidence that such programmes aid quitting, and the research on the more sophisticated technological interventions mentioned in 1.11.3 is still in its infancy. First of all, reviews of content and quality of English-language stop smoking apps found that few of them include BCTs shown to be effective in cessation or follow clinical recommendations, with the advice on cessation medications being particularly uncommon (Abroms et al. 2011, Abroms et al. 2013, Bricker et al. 2014, Buller et al. 2014, Choi et al. 2014, Jacobs et al. 2014, Ubhi et al. 2015, Hoepfner et al. 2016, Ubhi et al. 2016b, Bricker et al. 2017, Cheng et al. 2017, Ferron et al. 2017, Haskins et al. 2017, Iacoviello et al. 2017, Thornton et al. 2017, Ahmed et al. 2018, BinDhim et al. 2018).

Secondly, one review (Haskins et al. 2017) found that among the top 50 quitting apps listed in the app stores, only two (4%) had any identifiable scientific basis. Among apps that had undergone scientific evaluation, only half were available to consumers beyond the research studies, and these were difficult to identify from among all the other apps (Haskins et al. 2017). In another recent review (Gibbons et al. 2018), only four stop smoking apps were identified that scored sufficiently high on Mobile Application Rating Scale (MARS) (Stoyanov et al. 2015) that assess qualities of health apps.

Research on the effectiveness of cessation apps remains particularly limited and inconclusive (these studies are summarised in more detail in Chapter 2, Tables 2.2.a-b and Tables 2.2.a-b). To date, there have been three single-arm observational studies that found some promising results in that the quit rates observed were higher than might

have been expected with unaided cessation (Ubhi et al. 2015, Bricker et al. 2017, Iacoviello et al. 2017). Additionally, the engagement levels were also relatively high, especially for one of the apps (on average over 100 logins across eight weeks, (Iacoviello et al. 2017)), and engagement was positively associated with better outcomes (Ubhi et al. 2015, Iacoviello et al. 2017).

Findings from four published RCTs, including five two-arm studies (Hertzberg et al. 2013, Bricker et al. 2014, Buller et al. 2014, BinDhim et al. 2018, Garrison et al. 2018) and one factorial trial (Tombor et al. 2018) bring limited evidence for app effectiveness. The first three RCTs were small ($n < 200$) and relied on self-reported quit rates. One study found that an app based on Acceptance and Commitment Therapy (Hayes et al. 2006) was more engaging and effective than an app developed by the National Cancer Institute, (15% vs 8% quit rates, respectively, (Bricker et al. 2014)). The second study showed that a text-based intervention was more effective compared to an app at six weeks follow up (Buller et al. 2014).

More recently, a mindfulness-based app did not produce higher quit rates over a control app (Garrison et al. 2018), and a factorial trial of an app tailored to pregnant smokers also failed to find an effect, which the authors explained by low engagement (Tombor et al. 2018). More recently, however, in a well-powered ($n = 684$) and multi-country study, a cessation app for iOS devices, which supported decision-making in selection of cessation aids and developing a quit plan, was shown to improve self-reported quit rates in comparison with an information-only app (28.5% vs 16.9% at 1 month, 10.2% vs 4.8% at 6 months) (BinDhim et al. 2018). This study also resulted in very low attrition and good response rate to the follow-up, which the authors attributed to the use of push notifications (reminders).

Taken together, in the past five years there have been only a handful of studies published that evaluated the effectiveness of very different cessation apps and bringing only limited support that these programmes can aid cessation.

1.11.5. The Smartphone app landscape and challenges for dissemination

Although smartphones could, in theory, offset several of the challenges to stop smoking intervention access and reach, promoting them as cessation aids could prove difficult. For example, the actual usage of many health apps is low, smartphone users report different barriers to downloading health apps, including costs or limited interest, as well as a high burden of data entry (Cropsey et al. 2017). With regards to smoking apps, very few English smokers reported using a digital tool in their most recent quit attempt (Beard et al. 2016a).

Despite a relatively low demand for health apps, there has been a considerable increase in the supply of such apps between 2013 and 2016 (Jahns 2015, Pohl 2017). Already in 2013, this proliferation of health apps has been referred to as ‘app overload’ (Kasza et al. 2013) and the app stores as a ‘flea market’ (Higgins 2016). Estimates show that hundreds of new health apps are entering the market every week (Ma et al. 2016), and in 2017 there were over 350.000 such apps available across the Google Play and iTunes stores (Santo et al. 2016). This situation is enabled by the low bar to enter the market. Except for resource-constraints and certain technical and security criteria set by the stores themselves, there are few barriers to creating and releasing apps (Gibbons et al. 2018).

Additionally, only apps that are classified as medical devices could be scrutinised by institutions such as the Food and Drug Administration (FDA 2018) or the Medicines and Healthcare products Regulatory Agency (MHRA, (MHRA 2018)). As a result, health-related apps, including those aimed at smoking and medication use, can be created by any entities, including organisations with vested commercial interests, as well as amateur developers (Powell et al. 2014). This situation makes it difficult for the general public, patients, and clinicians to identify apps that could be helpful and safe (Gibbons et al. 2018).

Indeed, many of the health apps do not implement clinical guidelines or evidence-based support, do not engage HCPs in their development, and lack data on effectiveness, usability and safety, including in the domain of cancer prevention and detection (Bender et al. 2013), anxiety reduction (Perkins et al. 2013) or alcohol reduction (Anraad et al. 2018). Additional concerns surround data safety and privacy of health apps (May et al. 2003, Huckvale et al. 2015, Cropsey et al. 2017).

The great challenge in navigating the app market has sparked a number of

initiatives aimed at selecting and curating apps. Some of these included accreditation systems and use of so-called clearinghouses that offered links to vetted apps (Gibbons et al. 2018), e.g. NHS Choices Health Apps Library², iMedicalApps³. However, due to the volume of apps and the shortcomings of the review process (see Chapter 2.4.1.), the feasibility of such initiatives remains low. Moreover, app users rarely access such curated libraries, and instead select apps based on recommendations from friends and family and through browsing the app stores, with the choice to engage often influenced by other users' ratings, knowledge of brand names, and also by the visceral reactions to apps' visual aspects (Perski et al. 2017a, Perski et al. 2017b, Laja 2018). As a result, even if a cessation app was found to be effective, promoting it among smokers would remain a major challenge.

1.12. Chapter 1 Summary

Tobacco use, and particularly smoking of cigarettes, leads to morbidity and premature mortality from a range of conditions. Only complete abstinence can eliminate the harms from smoking, and there exist several behavioural and pharmacological interventions that can improve cessation. However, none of the existing interventions leads to high cessation rates long term. Additionally, access and uptake of such support by smokers are low. DBCIs, such as SMS texting and websites can aid quitting. Smartphone apps have not been adequately tested to date, but where they have been tested, the evidence on their effectiveness remains limited.

² <https://apps.beta.nhs.uk/>

³ <http://www.imedicalapps.com/#>

1.13. Overview of the Thesis scope, aims and methods

1.13.1. Thesis scope

This PhD programme aimed to further our understanding of how smartphone-based interventions (apps), can be used to support smoking cessation and cessation medication use among adult smokers in the general population. Additionally, the research in this thesis explored the methodological processes involved in both development and evaluation of such apps.

Contrary to several other studies in the field described in Chapters 1.11.4 and 2.5.7, this PhD concerned smartphone-based intervention that could be used in a context of no direct involvement of HCPs or the researchers at enrolment or during app use, and no reimbursement for engagement with the intervention itself or provision of self-reported data at follow-up. This was considered important in order to increase the generalisability of the findings and enable scaling up the interventions in the future.

Additionally, the thesis focused on low-intensity interventions that enable *ad libitum* use, but which have the potential for wide reach, and thus could lead to clinically important outcomes if used at scale (West 2007a). Finally, the thesis adopts a mixed-methods approach to evaluate such programmes, which, depending on the study, combined qualitative evaluation (e.g. a think-aloud method or in-depth interviews), with quantitative assessments (pragmatic RCTs). The quantitative evaluation focused on short-term success (i.e. at eight weeks since the registration, or at four weeks since the quit date), as a surrogate for long-term success (West and Stapleton 2008).

1.13.2. Overview of thesis core themes

This PhD programme explored the use of smartphone apps as aids for different aspects of quitting smoking, as outlined in more details below. The three core themes were: 1) supporting optimal use of NRT, with focus on OTC NRT, 2) management of

momentary cravings for cigarettes, and 3) CO testing using personal CO monitors to support quitting or cutting down. The studies reported in this thesis were led by me, but were conducted in collaboration with other UCL researchers as well as external partners and IT companies commissioned to design and programme the apps. Table 1.2 outlines the different tasks for each study and my role in each of these.

Together the different studies aimed to provide insights on (a) estimates of the effectiveness of such interventions; (b) estimates of engagement levels, (c) acceptability, preferences and views among potential end-users on these programmes and their components; as well as on feasibility of (d) delivering clinically-relevant components via apps, and (e) evaluating effectiveness of such apps through pragmatic RCTs, including validating self-reported abstinence remotely. It was expected that the results of the PhD could inform the development and evaluation of more comprehensive smartphone-based cessation support in the future.

Theme 1: Supporting optimal use of NRT (Studies 1-3, Chapters 3-6),

Overview: The studies under this theme aimed to inform the creation of smartphone-based aids supporting optimal use of NRT during quit attempts, with focus on OTC NRT. In the process, a new theory-informed app was developed (called NRT2Quit, described in Chapter 3). The first study (Study 1, Chapter 4) involved a pragmatic RCT evaluating NRT2Quit among UK-based smokers who obtained NRT to quit. Subsequently, a theory-informed qualitative study (Study 2, Chapter 5) aimed to more comprehensively assess smokers' and ex-smokers' experiences with NRT use to identify additional needs and preferences for support with NRT use that could inform new interventions. During the same interview session, and in line with person-centred iterative intervention development, a think-aloud study on NRT2Quit was conducted (Study 3, Chapter 6) that aimed to obtain feedback on NRT2Quit and to identify ways in which the app and similar programmes could be developed in the future.

Collaborators: The RCT was conducted in collaboration and assistance from Prof Tobias Raupach (TR), Dr Jamie Brown (JB), Dr Lion Shahab, (LS), and Prof Robert West (RW). Additionally, Dr Ildiko Tombor (IT) contributed to Study 2 and Rhea Kohli (RK) to Study 3.

Funding and role of funders: The costs associated with the development of NRT2Quit and conducting the RCT were covered by the Global Research Awards on Nicotine Dependence (GRAND) 2013 funding from Pfizer obtained by TR. My BHF Studentship covered the cost of conducting the qualitative studies. Neither Pfizer nor BHF impacted on conducting, analysing and disseminating the research reported in this thesis.

Theme 2: Management of momentary cravings for cigarettes (Studies 4-6; Chapters 7-10)

Overview: Studies under this theme aimed to develop and evaluate using a mixed-methods approach an app supporting craving management during a serious quit attempt (the BupaQuit app, described in Chapter 7). A secondary aim of the project was to assess the feasibility of the methodology involved in remotely evaluating the app through an RCT and verifying abstinence using personal CO monitors. Study 4 (Chapter 8) was a pragmatic RCTs of BupaQuit. Study 5 (Chapter 9) was a nested feasibility study of using personal carbon monoxide (CO) monitors to remotely assess abstinence in the BupaQuit trial. The final study (Study 6, Chapter 10) was a nested qualitative telephone interview with a subsample of trial participants that explored their experiences with participation in the study and with using the app and their suggestions for its improvement.

Collaborators: The following researchers at UCL provided guidance and support during the development and evaluation of BupaQuit: RW, LS, JB, Dr Harveen Kaur Ubhi (HKU), Dr Emma Beard (EB) and Olga Perski (OP). The BupaQuit project was conducted in close collaboration with Bupa, a healthcare company (www.bupa.com), who provided the financial, staff and space resources as well as IT expertise to develop the app. The main collaborator at Bupa was Dr Alex Matei (AM). The different studies were supported by three research assistants: Georgina Knock (GK, Studies 4-6), Courtney Kwan (CK, Studies 4-6), and Rhea Kohli (RK, Study 6).

Funding and role of funders: My work on the project and participant reimbursement in the qualitative Study 6 were supported by my BHF studentship. I was also employed at Bupa as a Research Partner and Expert Advisor for activities concerning app development at Bupa. Bupa supported the research by offering resources and funding to

cover the costs of developing the app and conducting the trial (e.g. the cost of study promotion, CO monitors, follow-up, and salaries of research assistants; offering office space). Bupa collaborated on the project, but all research decision (e.g. about the study design and dissemination of findings) and decision concerning the clinical aspects of BupaQuit (e.g. content, features) were made by myself in discussion with the UCL collaborators. Collection, management and analysis of data from the trial and the nested interviews were overseen or conducted independently by myself.

Bupa managed raw data from the BupaQuit app, but I was able to regularly audit the data during the trial. Data management and sharing of the data with UTARG was governed by a bespoke Data Licence Agreement that I co-drafted, according to which Bupa shared anonymised data from BupaQuit with RW's team for further independent processing, analysis, and dissemination. In line with the Data Licence Agreement, the final manuscripts and chapters arising from the BupaQuit studies were submitted to Bupa for a review prior to publication to ensure that no confidential or patentable information was included in the manuscript. The Agreement specified that authors could accept any suggestions in good faith but were under no obligation to make any suggested changes to the manuscript. Following Bupa review, no changes were made to the manuscripts or the Thesis. BHF had no impact on conducting, analysing and disseminating work reported in this thesis.

Theme 3: CO testing using personal CO monitors to support quitting or cutting down (Study 7, Chapter 11)

Overview: This study aimed to inform the creation of a novel app, or dedicated components within complex apps, which could support smokers with quitting or cutting down with the assistance of personal CO monitors that connect to smartphones. It involved a mixed-methods qualitative study combining interviews and think-aloud methodology to explore smokers' views and preferences regarding one model of CO monitors available in the UK, as well as apps that could accompany it.

Collaboration: The project was conducted with the support from Dario Baretta (DB) and Shamaila Muzammil (SM) who assisted with data collection, and from LS and RW, as well as OP.

Funding and role of the funders: My BHF studentship covered the cost of conducting

the study, but BHF had no influence on the conduct, analysis or dissemination of the study.

1.14. Reflexivity

Before commencing my PhD, I had already started my training as a mixed-methods researcher within the field of smoking cessation and digital health. I completed an undergraduate degree in psychology, followed by an MSc Health Psychology at UCL, during which I worked with RW, LS, and JB, as well as other members of the UCL Tobacco and Alcohol Research Group (UTARG) on several smoking cessation projects. The latter included research on MumsQuit – a web-based intervention supporting pregnant women to quit smoking, which resulted in two publications reporting findings from a pilot pragmatic RCT of MumsQuit (Herbec et al. 2014b) and from a nested in-depth interview study about smoking, quitting and use of digital cessation aids, which was analysed using Framework Analysis (Herbec et al. 2014a). Before commencing work on this thesis, I had also attended UCL-based training on the use of BCTs taxonomies, the COM-B (‘Capability, Opportunity, Motivation’ – ‘Behaviour’) and the Theoretical Domains Framework (TDF), and on the use of Behaviour Change Wheel (BCW, (Michie et al. 2011c)) to develop complex interventions.

I was also familiar with the stop smoking support offered in the UK, and I had completed training on the treatment of tobacco dependence (e.g. the NCSCT online courses). I was acquainted with the literature on NRT use and on digital interventions for quitting smoking. I expected that at least some of our participants would have used stop smoking apps before and that some would have obtained detailed advice on quitting and NRT use from HCPs. I also anticipated that those purchasing NRT OTC might have had less contact with HCPs (e.g. to discuss NRT), but nonetheless might have been more active in seeking information about their medications on their own. In line with a realist perspective (Madill et al. 2000), I hoped that the participants’ insights offered as part of the interview studies in this thesis would help us develop better smartphone-based support for quitting smoking, and understand the potential role of stop smoking apps in the context of the wider cessation landscape.

Finally, over the years the UTARG members have been collectively gaining expertise in the development and evaluation of web-based and smartphone-based DBCIs, which has contributed to new guidelines and recommendations for those working in the field of digital health (e.g. (Michie and West 2016)).

However, it was only during my PhD programme that I gained experience in developing and evaluating smartphone-based interventions for smoking cessation and medication use, completed training in the person-centred intervention development, user experience design and research, agile project management, as well as developed project and product management skills. Table 1.2 below lists the core tasks I was leading or contributing to as a collaborator while conducting the different studies for this thesis.

Table 1.2. List of core tasks for each study conducted as part of this thesis and my role.

(L=I was leading on the task, C=I was contributing).

	Studies around NRT2Quit (Studies 1-3)	Studies around BupaQuit (Studies 4-6)	Study on CO Monitor (Study 7)
Initiation, idea and planning	1 (C) 2 (L) & 3 (L)	Yes (L)	Yes (L)
Designing the app			
Preparing briefs for developers	Yes (L)	Yes (L)	-
Creating wireframes and user journeys	Yes (L)	Yes (C)	Yes (C)
Preparing content	Yes (L)	Yes (C)	Yes (C)
Internal testing and usability testing	Yes (L)	Yes (C)	Yes (C)
Quantitative assessment (RCT)	Study 1	Study 4-5	-
Final Study Protocol	Yes (C)	Yes (L)	N/A
Development of data collection instruments	Yes (L)	Yes (L)	N/A
Securing ethical approval	Yes (C)	Yes (L)	N/A
Data protection registration	-	Yes (L)	N/A
Trial registration	Yes (L)	Yes (L)	N/A
Designing recruitment materials	Yes (L)	Yes (L/C)	N/A
Overseeing the recruitment campaign	Yes (L)	Yes (L/C)	N/A
Monitoring recruitment	Yes (L)	Yes (L/C)	N/A
Qualitative evaluation	Studies 2-3	Study 6	Study 7
Study design	Yes (L)	Yes (L)	Yes (L)
Securing ethical approval	Yes (L)	Yes (L)	Yes (L)
Data protection registration	Yes (L)	Yes (L)	Yes (L)
Participant recruitment	Yes (L)	Yes (L)	Yes (L)
Data collection (Interview/think-aloud study)	Yes (L)	Yes (L/C)	Yes (L/C)
Data analysis	Yes (L)	Yes (L)	Yes (L)
Write-up	Yes (L)	Yes (L)	Yes (L)

Chapter 2: Methods and concepts in the development and evaluation of smartphone-based cessation interventions

2.1. Chapter 2 overview

This chapter discusses approaches, methods and challenges in the development and evaluation of smartphone-based Digital Behaviour Change Interventions (DBCIs) that focus on smoking cessation and cessation medication use.

2.2. Introduction

Numerous approaches and guidelines for the development and evaluation of DBCIs exist, some of which are discussed in more detail below. Importantly, the past two decades have witnessed the emergence of new research methodologies as well as several paradigm shifts in the field that were motivated by a greater understanding of the complexities involved in these two processes and incorporation of expertise from non-medical fields.

The first major paradigm shift in the field was that the development and evaluation shifted from a linear process focused on preparing and conducting randomised controlled trials (RCT) to much more iterative and mixed-methods approaches. Secondly, this has resulted in blurring of what used to be a definite division between the development and evaluation of DBCIs. Some of these changes are shown in Figure 2.1.

However, as will be discussed in this chapter, the current methods of evaluating smartphone-based cessation interventions still suffer from important limitations, and numerous unresolved challenges exist to evaluating the effectiveness of stop smoking apps.

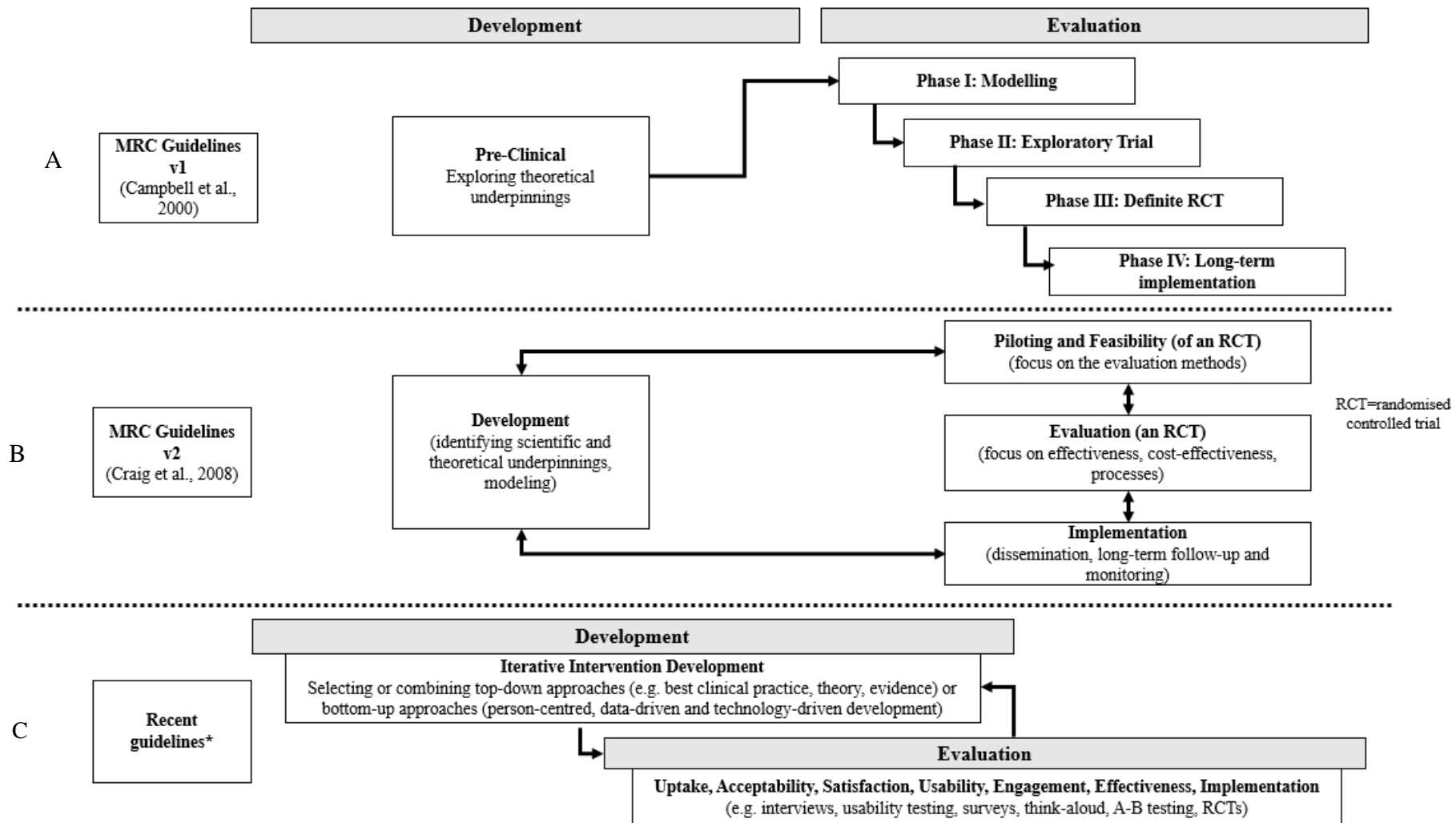


Figure 2.1. The changes in guidelines for the development and evaluation of complex interventions as applicable to digital interventions (*recent guidelines include: (Michie and West 2016, Murray et al. 2016, Michie et al. 2017))

Given that DBCIs are usually complex interventions, some of the early work and research on them drew on the Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions (Figure 2.1.A.) (Tombor et al. 2016, Blandford et al. 2018, Garnett et al. 2018). Its first edition adopted linear, standardised and rather rigid processes from drug development and evaluation (Campbell et al. 2000). The updated, second edition of the MRC guidelines placed a greater emphasis on the feasibility and piloting of the methods of the planned randomised controlled trial (RCT) before conducting the RCT, and on process evaluation. It also accepted that the processes of intervention development and evaluation are not always linear, encouraged tailoring of the intervention to the local context as opposed to standardisation, and suggested several alternative designs (e.g. N-of-1 and step wedge designs) (Figure 2.1.B) (Craig et al. 2013). However, the MRC evaluation was nevertheless focused on conducting RCTs. As the field had progressed further, the limitations of the latest MRC guidelines became apparent, and updated guidelines are due to be released in 2019 (Skivington et al. 2018).

Meanwhile, the more recently published guidelines for the development and evaluation of DBCIs often build on the latest MRC framework, but advocate for these two phases to be multistage and iterative, to draw on insights and methods from other disciplines (e.g. business and engineering), to place an even greater emphasis on the research during intervention development, as well as on implementation and process evaluation, and to engage the end-users at all stages of developing evaluating DBIs (Figure 2.1.C) (Collins et al. 2007, Martin et al. 2012, Kumar et al. 2013, Riley et al. 2013, Yardley et al. 2015, Michie and West 2016, Murray et al. 2016, Jake-Schoffman et al. 2017, Michie et al. 2017). Some of the new guidelines additionally recognise the value of qualitative methodology (Michie et al. 2017) and novel designs (e.g. Multiphase Optimization Strategy, or MOST design (Collins et al. 2007)).

2.3. The development of Behaviour Change Interventions

In general, and regardless of the different approaches to DBCIs development, it is important to differentiate between two distinct phases that are discussed in detail below:

*intervention development*⁴ and *software development* (Blandford et al. 2018).

Intervention development refers to all the steps and processes required to conceptualise the intervention in terms of its clinical elements, structure, decision rules, and content (i.e. what does the intervention do and deliver). Software development involves all the steps and processes required to implement the intervention in a digital platform, such as a smartphone app. These two phases are governed by different factors and decision-making processes and require divergent expertise. However, while in many projects the distinction between these two phases is apparent, in other cases, and perhaps increasingly commonly and in line with the recent guidelines, the two stages can take place almost in parallel, and can inform one another (Blandford et al. 2018), which is discussed below. The expertise and skills within the clinical team who leads on developing a DBCI is likely to impact on the extent to which these two phases overlap.

2.3.1. Software development

Although software development does not normally precede intervention development, it is useful to outline the former first as it can have a bearing on the shape of the final DBCI. First of all, developing software for DBCIs follows the same steps and faces the same opportunities and challenges as do other software projects. The common obstacles include high costs, trade-offs in choosing between different technological solutions, and barriers to sustainability (Joorabchi et al. 2013, Jake-Schoffman et al. 2017, Turner-McGrievy et al. 2017, West et al. 2018). The process also requires close collaboration with third parties that have different skills and approaches, most notably the IT teams composed of programmers, designers, and often also project managers and business analysts (Roth et al. 2014).

Software development involves several stages (outlined in Figures 2.2 and 2.3). These processes can assume different levels of complexity and together may require

⁴ A note on terminology on interventions used in the subsequent chapters: unless specified otherwise in the context, when the word '*intervention*' is used on its own it refers to the clinically-relevant aspects of an intervention (e.g. the active ingredients, or BCTs, that are expected to change the behaviour, and which can then be implemented in a software, such as an app); when the term Digital Behaviour Change Intervention (DBCI) is used it always refers to the overall package combining the clinical intervention together with the software in which it is implemented (i.e. a version of a stop smoking app, such as NRT2Quit, would be an example of a DBCI)

anything from a few weeks to several months to complete.

Approaches to software development can be generally divided into a *waterfall* (the traditional approach) and increasingly more popular *agile* methods (French et al. 2012, Rubinstein et al. 2015). The waterfall approaches tend to be more linear and rigid, with detailed specifications for the software and an execution plan agreed before software development commences (see Figure 2.2). Such projects aim to deliver the software as per the upfront and fixed specifications. However, in such projects, the resource and time demands may change as a project progresses and challenges are encountered requiring re-programming (Aljaber 2018). Some estimates suggest that over a half of the outputs of waterfall projects in industry settings are rejected (Morien 2005).

In contrast, the agile approaches emphasise iterative and ‘lean’ software development that minimises waste and focuses on delivering a viable solution quickly, and then iteratively developing it further (Morien 2005). It also relies on a close collaboration between the client or commissioning team (e.g. the researchers) and the IT team, and often also the end-users (see Figure 2.3). Instead of a detailed execution plan, this approach requires establishing a general scope for the project and priorities for features in the first software iteration, as well as agreeing on fixed budgets and timelines (Aljaber 2018). The decisions regarding the individual components are finalised during regular collaborative sprints. Agile approaches involve adaptive decision-making and problem-solving as the project evolves and new information is acquired.

Agile processes are recommended for projects with strict timelines, budget constraints, and technical unknowns, and when certain barriers and opportunities may surface only during software development or its testing (Aljaber 2018). Such challenges are common in the academic research on DBCIs, thus making agile approaches suitable. Indeed, the evolution of guidelines for the development and evaluation of DBCIs in recent years also favours agile-like research paradigms as opposed to their waterfall alternatives. Importantly, in contrast to the waterfall projects, at the outset of their agile counterparts the details of the final software, and thus the DBCIs itself, remain unknown. Instead, the final DBCI may be ‘discovered’ through a collective effort, which can pose challenges and should be accounted for during intervention development (Roth et al. 2014).

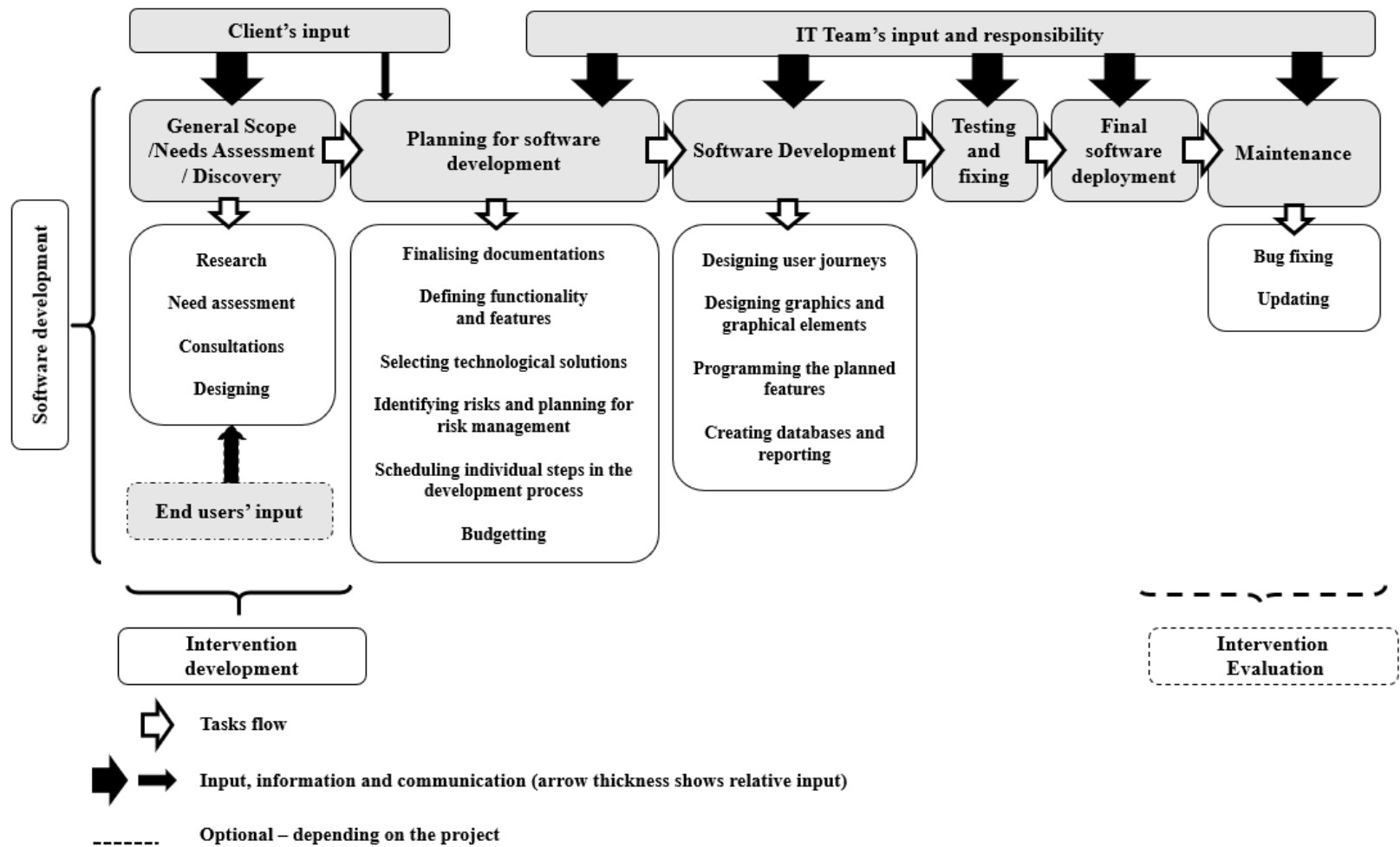


Figure 2.2. Outline of the key steps and task flow in software development informed by the waterfall approach. (Note: client refers to all representatives of the team commissioning software development, including the researchers; the list of the tasks is not exhaustive).

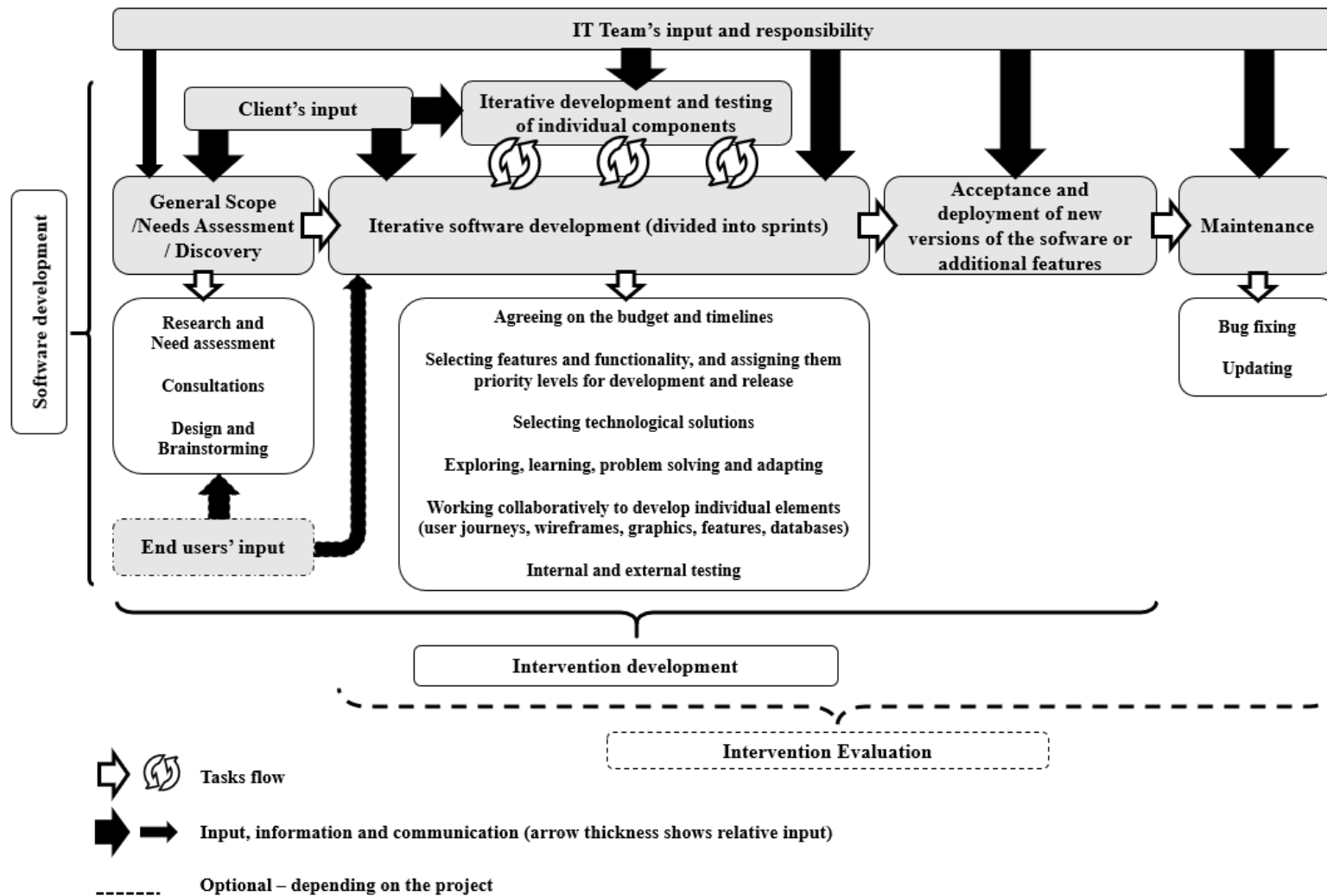


Figure 2.3. Outline of the key steps and task flow in software development informed by the agile approach
 (Note: client refers to the team commissioning software development, including the researchers; the list of the tasks is not exhaustive).

2.3.2. Intervention development

Notwithstanding the limitations of such a simplified classification, it is useful to distinguish between what could be referred to as top-down and bottom-up approaches to intervention development. It should be recognised, however, that while some projects employ a single approach, others may draw on the different elements from these two approaches. This will likely depend on the complexity of a given DBCIs, as well as the resources available to develop it, including the time, funding, and the expertise within the team.

Top-down approaches draw on best clinical practice and evidence for what works in programmes in health behaviour change to inform the DBCIs. This can involve implementing in DBCIs what has been demonstrated to be effective in traditional interventions (e.g. specific behaviour change techniques, BCTs) (Michie et al. 2012b, Tombor et al. 2016). Top-down approaches can also be informed by theory (Michie et al. 2012b), which refers to a representation (in the form of text or diagram) of the accumulation of knowledge and understanding about a behaviour, factors affecting it, and mechanisms of action (i.e. the processes through which BCTs affect the behaviour, e.g. increasing self-efficacy) (Davis et al. 2015, Michie et al. 2018). Theories can help to identify intervention targets and processes through which a given behaviour is expected to change.

Interventions that have a theoretical basis and deliver more BCTs have been shown to be more effective (Webb et al. 2010). However, poor application of theory or choice of irrelevant theories can preclude any benefits of the theory-informed approach (Davis et al. 2015, Moore and Evans 2017). The development of the NRT2Quit app as part of this thesis was informed by several theories, and the process is discussed in detail in Chapter 3.

In contrast, the bottom-up approaches prioritise other sources of influence when designing interventions and DBCIs, and these include person-centred (often also called user-centred), technology-driven, or data-driven approaches. Bottom-up approaches often involve some evaluation of the initial version of the DBCIs and using the results to inform its subsequent versions (Lyles et al. 2014, Blandford et al. 2018).

The person-centred approach is increasingly common and engages the potential

or actual end-users in the development of the DBCI (Martin et al. 2012, Craig et al. 2013, Yardley et al. 2015, Michie and West 2016). This could include formative research and needs assessment during intervention design, as well as consultations and pilot testing of individual components or new versions of the DBCIs. Increasingly, methods from other disciplines have been used, such as think-aloud studies with potential end-users to obtain their views on existing programmes or prototypes (e.g. on their functionality, designs, concepts) (Sarkar et al. 2016, Perski et al. 2017a). During such studies participants are presented with a prototype or final DBCIs, asked to interact with them naturally and to share out-loud any comments and thoughts they have about them (Charters 2003, Perski et al. 2017a).

An extension of person-centred approaches includes co-design and participatory research supporting creative and cooperative work between the teams developing the DBCIs and the different stakeholders and future beneficiaries, thus providing the latter with a considerable input into the development and implementation of the new intervention (Goodyear-Smith et al. 2015, Sarkar et al. 2016).

Person-centred approaches are particularly relevant for interventions that require tailoring to individuals or targeting to shared characteristics of user groups, e.g. pregnant smokers (Naughton et al. 2013, Herbec et al. 2014a, West et al. 2018) or unmotivated smokers (McClure et al. 2017). Furthermore, engaging the end-users in the development should, at least in theory, lead to more acceptable and engaging interventions, thus limiting attrition from such programmes and possibly also improving their effectiveness (Murray et al. 2016).

However, an important limitation of person-centred development is that it may lead to creating interventions that suit only a narrow group of users (Baskerville et al. 2018). Furthermore, the decisions are necessarily subjective, and thus a consensus may not be reached, especially for more granular and contested issues (e.g. aesthetics) (Perski et al. 2017a).

Data-driven app development involves creating predictive models of behaviours, for example using machine learning, to identify patterns in users' behaviour based on the data collected from the software or hardware (e.g. apps, wearables), and supplemented by any contextual data available (e.g. GPS, emotional states, sound ambience) (Pejovic and Musolesi 2014). This approach could help identify novel

opportunities to intervene and inform highly personalised and dynamically tailored adaptive interventions (Frohlich et al. 2018). However, it requires access to rich, valid and reliable data on individuals, which is particularly challenging given the attrition from apps and the noise in the data collected by apps, as discussed in section 2.5.3 below.

Technology-driven approaches focus on new technological solutions that hold promise to intervene in ways previously not possible. An example of this can be smartphone-enabled biofeedback on smoking and quitting progress, as well as wearables (e.g. bracelets) that can identify smoking behaviour, or use of geofencing to identify locations with a high risk of smoking to deliver just-in-time interventions (Naughton et al. 2016, Schick et al. 2018).

There are other examples of paradigms that use several approaches. These include n-of-1 studies, and study by design or action research (Sarkar et al. 2016). These involve detailed observations on an individual or small groups of individuals, commonly while they interact with a new DBCIs in the real world. This can form a basis for further development (Ploderer et al. 2014), as well as generate insights on how the intervention may be used in practice, rather than assuming that it will be used as intended by the designers.

2.4. Evaluation of smartphone-based cessation interventions

Numerous methods have been developed and implemented to assess health apps, and which can be applied to cessations apps as well. Several classifications of these methods have been proposed (e.g. (BinDhim et al. 2015)(Jake-Schoffman et al. 2017)(Riley et al. 2013, Grundy et al. 2016)). Crucially, the proliferation and sophistication of the evaluation methods for DBCIs are a testimony to the enormity of the challenge to develop good quality cessation apps.

One broad distinction to make is between assessing (i) apps' clinical utility, which has been the focus of much academic research to date (i.e. what potential or actual clinical value do these apps bring in terms of their content, features, and impact on clinically-relevant outcomes), and (ii) their digital quality (i.e. to what extent the software is meeting a set of industry standards). A further distinction can be made

between evaluations that are expert-led (e.g. the researchers make the final assessment) and user-led (i.e. end-users assess the interventions from their perspective). No single evaluation approach is comprehensive (Grundy et al. 2016), and with some exceptions (Ubhi et al. 2016a, Ubhi et al. 2016b, Haskins et al. 2017), many of the evaluation approaches focus on assessing only selected aspects within these two broad domains. Common evaluation approaches are discussed below and summarised in Table 2.1.

Table 2.1. Evaluation of app-based DBCIs in terms of clinical utility and digital quality – example of common outcomes of interest, study designs and measures.

Examples of outcomes, designs and measures	Clinical Utility	Digital Quality
Expert-led		
Common outcomes of interest	<ul style="list-style-type: none"> • Potential clinical value (e.g. presence of relevant BCTs and other recommended content) • Change in behaviour of interest or its proxies • Change in health and clinically-relevant outcomes or their proxies • Changes in psychological or theoretical constructs • Users' engagement 	<ul style="list-style-type: none"> • Presence of features that meet industry standards for apps • Attractiveness • Learnability, • Operability • Understandability • Usage level and patterns among actual users • Reaction times and errors-made by users
Example of study designs and measures	<ul style="list-style-type: none"> • RCTs, • Observational studies • Surveys and scales • Content analysis • Analysis of usage data 	<ul style="list-style-type: none"> • Surveys and scales (e.g. SUS, MARS) • Expert review • Content analysis • Usability studies among actual or potential end-users • Analysis of usage data
User-led		
Common outcomes of interest	<ul style="list-style-type: none"> • Value to users (e.g. helpfulness, relevance) • Acceptability 	<ul style="list-style-type: none"> • Evaluations of appearance and functionality • Satisfaction • Enjoyment • Ease of use
Example of study designs and measures	<ul style="list-style-type: none"> • Interviews, think-aloud studies • Surveys • Ratings and reviews online 	<ul style="list-style-type: none"> • Surveys and Scales (e.g. user-version of SUS) • Think-aloud studies • Ratings and reviews online

2.4.1. Content analysis assessing clinical utility and digital quality

Content analysis has been commonly used to assess apps' clinical utility. This method can assume different levels of complexity and standardisation and involves downloading selected apps (including relevant metadata, such as data on app developers), and assessing them against a set of pre-determined criteria or checklists. The checklists can be informed by guidelines for treatment (Abroms et al. 2011, Abroms et al. 2013), taxonomies of BCTs or theoretical underpinnings (Ubhi et al. 2016a, Ubhi et al. 2016b). This methodology has many limitations, as reviewed below, but it has nevertheless generated insights regarding the possible clinical utility of many cessation apps, as reviewed in Chapter 1.11.4 (Abroms et al. 2011, Abroms et al. 2013, Ubhi et al. 2016a, Ubhi et al. 2016b).

Similarly, several validated scales and checklists have been devised to assess digital qualities of DBCIs. These include the Systems Usability Scale (SUS) that assesses efficiency, effectiveness, and satisfaction based on the International Organization for Standardization (ISO) ISO 9241-11:2018 (ergonomics of human-system interactions) and ISO 9126-1 (attractiveness, learnability, operability and understandability) (Zapata et al. 2015).

An evaluation tool developed specifically for health apps is the Mobile App Rating Scale (MARS) (Stoyanov et al. 2015). MARS was created by a panel of multidisciplinary experts and synthesises criteria used for app and website appraisal identified from published literature, conference proceedings, protocols, and online resources created by three entities that the authors considered as 'key' in the field: the EU Usability Science, The Nielsen Norman Group, and The Healthcare Information and Management Systems Society. MARS criteria cover the following domains: aesthetics (e.g. layout, graphics, how good something looks), engagement (e.g. is it interesting, or interactive), functionality (e.g. use of gestural design, ease of use), information (quality and quantity of information, credibility, accuracy of app description), and subjective quality (e.g. recommending or paying for the app). Noteworthy, the authors of MARS have eliminated from the score the criterion 'evidence-base' due to the lack of measurable, relevant data (Stoyanov et al. 2015).

There are many limitations to using scales and checklists to assess clinical utility or digital quality of DBCIs. First, no scales are comprehensive and may fail to capture

important aspects of apps. For example, clinical scales do not appraise the quality of delivery of individual BCTs and guidelines (e.g. the intensity, frequency, mode of delivery), all of which could affect effectiveness. Secondly, such an assessment is necessarily subjective, which is especially problematic given the small number of reviewers involved in such studies and their profile (e.g. high academic attainment and literacy, IT proficiency). It is likely that experts' scores on aesthetics or navigation may not reflect the experiences that novice users or members of different socio-economic groups may have when using DBCIs. Similarly, items that have clinical utility according to findings from research studies may still fail to address users' needs and preferences.

Thirdly, the time and resources available to assess individual apps may be insufficient to identify and explore all the relevant content and features. Indeed, the reviews of apps are often limited to freely available apps or the content available within 10-20 minutes of browsing (Ubhi et al. 2016a, Ubhi et al. 2016b). This methodology would not allow for comprehensive assessment of apps that are tunnelled, personalised, which have paid content, deliver support over extended periods, or are updated regularly (Grundy et al. 2016, Ubhi et al. 2016a, Ubhi et al. 2016b). Furthermore, other relevant information may be unavailable to appraisers, such as data security, the existence of bugs, the responsiveness of developers to answers questions. Given the above, and recognising the often changing listings of apps on app stores, the reviews of apps available on app stores were criticised for being descriptive, unsystematic, unreplicable, and unexhaustive (Grundy et al. 2016). However, while at least in theory a certain standard of digital quality may be necessary for the DBCIs to have an impact, there is still insufficient research to demonstrate this complex relationship (Perski et al. 2017a, Blandford et al. 2018).

2.4.2. Evaluations by actual or potential end-users

Another method of evaluating apps involves their assessment by the actual or potential end-users. This approach aims to collect data on users' perspectives, views, and experiences with such programmes, and suggestions for their improvements. Ratings and reviews on app stores are relatively easily available sources of such data (Jake-Schoffman et al. 2017). However, these may be difficult to interpret (e.g. the basis

of the ratings may not be clearly stated), unrepresentative of all the users (as usually only a sub-sample of users provides ratings), and they are likely to primarily capture more extreme views (Bondaronek et al. 2018). The reviews may also no longer apply if the developers had already addressed the comments and released a new app version (Bondaronek et al. 2018).

Moreover, normally very little contextual data is available on the persons who provided the ratings, such as their socio-demographic characteristics, or levels of engagement with the programme. Finally, a majority of apps that receive little interest among users are not displayed on app store listings and may not be discoverable to both researchers and users (referred to as ‘zombie apps’ (Perez 2015))

Another approach involves conducting dedicated data collection sessions with potential end-users, which can be supported by multiple methods. Usability testing, conducted in labs or remotely, focuses on assessing the extent to which an app is easy to use and learnable, and whether the users can perform relevant tasks efficiently (e.g. they complete the tasks quickly and with few errors) (Lyles et al. 2014, Sarkar et al. 2016). It can also help identify immediate barriers to use (e.g. bugs, unclear instructions) (Jake-Schoffman et al. 2017). Other methods include individual qualitative interviews, focus groups, and think-aloud procedures, which can generate rich data to guide further development. Quantitative methods include analysis of usage data to identify desirable or possibly effective components (Heffner et al. 2015) and surveys, such as a user-focused MARS (Stoyanov et al. 2016) or SUS (Bangor et al. 2008).

However, these methods may have limited ecological validity (e.g. the interaction with the app is brief and often constrained to lab settings), while the qualitative studies may generate very rich data that can be time-consuming to analyse. Finally, these methods normally allow assessing only one or a few apps at a time (Perski et al. 2017a).

2.4.3. Studies of app effectiveness

Ultimately, the effectiveness of DBCIs is a key concern. It can be assessed through a range of research designs of different scientific rigour, which can be divided into non-experimental (observational) and experimental studies (e.g. AB testing, quasi-experiments, and RCTs, with the latter offering the most rigorous design). To date,

findings from three observational one-arm studies of cessation apps, five two-arm RCTs, and one factorial study have been published. These methodology of these studies is discussed section 2.5.7 below.

The observational studies can help estimate effectiveness and acceptability of the intervention, explore usage levels and patterns, predictors of outcomes, and can also involve studying the apps in the real world (e.g. by analysing app data collected automatically from apps available on app stores). However, due to a lack of comparators, observational studies cannot establish causality, and the findings may be confounded by several factors, including participants' characteristics or the passing time.

RCTs are regarded as the gold standard in the research on the effectiveness of healthcare interventions, including digital cessation programmes (Harbour & Miller, 2001). The core design elements of the RCT for cessation interventions are: (i) randomisation of participants to two or more study arms to minimise selection bias and ensure equal distribution of potential confounding factors across the conditions, which allows to isolate the effect of the intervention and make causal claims (Sibbald & Roland, 1998); (ii) the use of intention-to-treat approach, with those lost to follow-up presumed to have resumed smoking, (iii) blinding to condition allocation of participants and researchers, from enrolment up to trial completion; (iv) assessing abstinence using standardised measurements and at clinically-relevant follow-up time points; and (v) biochemical verification of abstinence (West et al. 2005).

RCTs can be broadly divided into efficacy (or explanatory) trials of the intervention impact under 'ideal' and strictly controlled conditions, and effectiveness (pragmatic) trials, that assess the benefit of the intervention in the 'real world' setting (Roland and Torgerson 1998, Godwin et al. 2003). Well-designed efficacy RCTs, with sufficient control over the study procedures (resulting in high internal validity), offer the greatest chance that the result obtained can be causally attributed to the experimental manipulation (Cartwright 2009). However, conducting an efficacy trial of a smartphone app would be very challenging, particularly due to the lack of controls over the participants' behaviours and their engagement with the intervention. Therefore, pragmatic RCTs are more suitable to assess apps.

However, conducting RCTs of apps has received considerable criticism (Riley et

al. 2013, Murray et al. 2016). First of all, trying to accomplish high internal validity in RCTs comes at a price of external validity, leading to limited generalisability of the findings (Cartwright 2009). Although pragmatic RCTs tend to be conducted in a more ecologically-valid setting, they still suffer from biases due to stricter procedures (e.g. eligibility criteria, enrolment procedures, monitoring). Secondly, conducting and subsequent reporting on RCTs requires following strict procedures that have a high administrative burden and extended timescales, and which additionally incur high costs (also in staff time).

Moreover, the RCT procedures are normally too rigid to adapt in response to the encountered challenges and opportunities, especially once recruitment commences. In that respect, RCTs tend to follow what could be described as a waterfall approach to research. As a result, by the time an RCT is completed and the findings can be reported, the original interventions may become obsolete, limiting the value of conducting an RCT (Riley et al. 2013, Murray et al. 2016).

Despite the associated burden, RCTs remain the best available method to assess the effectiveness of cessation interventions. Moreover, in addition to the administrative tasks (e.g. planning the trial and preparing research instruments, securing ethical approval and registering the trial), the greatest time cost is incurred during participant enrolment and to complete the necessary, clinically-meaningful follow-up. At least in theory, conducting RCTs embedded within apps (as discussed in detail below) should minimise some of the associated challenges by streamlining the recruitment procedures and supporting data collection and the follow-up. Additionally, being automated, app-based interventions do not require additional staff time to deliver or oversee the delivery of the intervention.

2.5. Challenges to evaluating stop smoking apps through RCTs

There are numerous challenges to delivering and evaluating DBCIs in general (Danaher and Seeley 2009), with several issues specific to smartphone apps. These include implementing the enrolment procedures, choosing a suitable comparator, assessing clinically-meaningful outcomes (e.g. verifying abstinence remotely), interpreting engagement data and evaluating adherence to medications, such as NRT.

These challenges are discussed below, together with some possible solutions.

2.5.1. Recruitment, enrolment and randomisation

Studies of DBCIs, particularly those involving large sample sizes, often require broad and remote recruitment, with enrolment relying on self-identification and self-selection in the absence of the researcher (Brown et al. 2014). The latter poses challenges for implementation of many of the research procedures, such as eligibility screening, securing informed consent, as well as data collection. Additionally, in case of apps, which tend to be consumer-facing products, the recruitment procedures should ideally strike a balance between fulfilling their research purpose as well as offering an acceptable user journey (e.g. quick and user-friendly onboarding) (Wehkamp 2014).

There are two main ways in which enrolment into RCT of apps can be conducted, each with important advantages and disadvantages: ‘two-step’ and ‘one-step’ enrolment. In the case of the former, the procedures of screening, enrolment, and randomisation all take place outside of the evaluated app (e.g. through a project website (Bricker et al. 2014, Buller et al. 2014, Garrison et al. 2018)). In the case of one-step enrolment, all these tasks are embedded within the app that acts as a self-contained research platform. Additionally, while the two-step enrolment often involves some communication between researchers and participants before randomisation, the one-step enrolment is automated. To date, only two recently published manuscripts reported findings from RCTs of cessation apps that involved a one-step, fully automated enrolment procedure within the app (BinDhim et al. 2018, Tombor et al. 2018).

Two-step enrolment is necessary for studies that compare different apps (Bricker et al. 2014) or an app with a non-app condition (Buller et al. 2014). It also facilitates screening of potential participants, and due to the relatively high burden and a likely greater sense of accountability, may result in enrolment of more motivated or diligent participants. Additionally, the communication with participants offers a chance to discuss study procedures. However, two-step enrolment limits scalability and generalisability of the findings to other app users accessing such apps outside of the research context.

In contrast, one-step enrolment may be advantageous when evaluating two or

more versions or components within the same app (Collins et al. 2014, Tombor et al. 2018). This approach also facilitates remote study promotion and enrolment (including self-enrolment), offers an opportunity to collect valuable and comparable data on usage from all app versions, and limits the risk of differential uptake of intervention and control arms.

2.5.2. Comparators in RCTs and Minimum Credible Intervention

Some of the commonly used controls in intervention research include waitlist or usual care, best available interventions, or brief advice, each being associated with limitations (Harmonization. 2000, Huitfeldt et al. 2001, Danaher and Seeley 2009). Providing a true inactive control in research on apps is challenging given the availability of hundreds of free cessation apps. In several published RCTs of cessation apps the comparators have been other active interventions, e.g. texting (Buller et al. 2014) or another app available on the market (Bricker et al. 2014). Such comparisons provide some insights into the relative effectiveness of the apps, but they also suffer from several limitations. First, without close collaboration with the owners of the third-party apps, the researchers may have no control over the content, availability, and quality of these apps, and additionally, they may not be able to collect comparable usage data (Jake-Schoffman et al. 2017). Secondly, it may be difficult to determine what factors are driving the effect (e.g. content, usability, graphics).

Another approach is to develop a bespoke control app for the trial. An important decision remains regarding how ‘active’ such a control should be. Although this decision should be informed by the research question, there are several practical considerations. For example, in an earlier study of a web-based StopAdvisor intervention, participants were randomised to either an interactive and personalised intervention, or a static, information-only website (analogous to a leaflet) (Brown et al. 2014). While this approach is possible with apps-based interventions as well, it is unlikely that a ‘static’ or overly simplistic app will offer a believable experience to its users. An inadequate control app could result in participants realising they are in the control condition, which could negatively impact engagement and cessation, or increase chances that these participants will seek additional support from other readily available

apps (Michie and West 2016).

One possible solution is to create a ‘minimum credible intervention’ (MCI) (Michie and West 2016). In the business and technology sectors, a minimum viable product (MVP) refers to the simplest version of a product or service that can offer value to customers, and which can be incrementally developed (Duc and Abrahamsson 2016). Analogously, an MCI refers to a version of the intervention that can be believable as an app delivering a behaviour change intervention, also in comparison to other such programmes available on the market. Thus, an MCI should (i) include components that can be realistically expected to be delivered through freely available stop smoking apps, and (ii) be similar to the intervention version in many respects (e.g. the registration flow, the visual design and layout). In practice, MCI can be offered as one of the app versions, or a ‘sub-app’ within the same app platform, making it particularly suitable for studies with one-step enrolment.

There are several advantages of using an MCI in a trial of a cessation app. First, from an ethical point of view, it is important to offer at least brief evidence-based advice to smokers who are interested in using an app to help them quit. Secondly, the similarities between the two arms may (i) increase credibility of the control app, (ii) help to disguise the experimental differences between the app versions and thus improves blinding to condition allocation, (iii) help to limit at least some of the differences in participant burden and user experience that could be potential confounds in evaluation, and (iv) may also minimise the seeking of alternative apps or support, which in turn could increase attrition from the trial and reduce power to detect an effect (Michie and West 2016). Therefore, an MCI may offer a fairer comparison for the intervention arm (Harmonization. 2000).

Furthermore, a bespoke MCI should offer matched data collection that facilitates evaluation and allows for the evaluation of specific app components while controlling for other aspects and characteristics of the control arm. Finally, MCI is especially advantageous in studies relying on broad recruitment campaigns and remote enrolment. This is especially important when the evaluated app is available freely on the app stores that require publishing app descriptions and screenshots that set expectations among potential users.

However, there are also important challenges associated with using MCI in RCTs

of cessation apps. This approach requires dedicated time and resources to develop and test the two app versions. It also involves the risk of creating a control app that may be too effective, leading to lower effect sizes and possibly inconclusive trial results (Harmonization. 2000).

2.5.3. Data collection and outcome evaluation in trials of cessation apps

Among the major barriers to the evaluation of DBCIs, including apps, is collecting relevant baseline, process and outcome data. On the one hand, apps offer possibilities to streamline the collection of rich data on their users. However, the feasibility of this is curtailed by several factors, including users' low acceptability to complete long surveys within apps (Wehkamp 2014), as well as due to the attrition from the intervention and the wider study, which are leading to loss of valuable primary and secondary data (Eysenbach 2005, Geraghty et al. 2013).

Furthermore, a clinically meaningful evaluation of cessation apps necessarily requires collecting data on a set of standardised indicators at clinically-meaningful follow-up time points, e.g. the Russell Standard, which should additionally include biochemical verification of abstinence (West et al. 2005). Collecting such data necessitates participants' long-term involvement with the trial (e.g. 6-12 months), which is likely to extend beyond the intended and actual use or access to the app itself. Given the attrition and limited contact with the participants in remote trials, accomplishing it is likely to be very difficult.

Several solutions are available to try to address the data loss in studies of DBCIs. For example, outcome data can be collected outside of the apps, e.g. through phone, e-mail, post or voice-response systems (Rigotti et al. 2016). However, this requires participants to provide valid contact details at registration, which may constitute a barrier to enrolment and limit the representativeness of the sample. Long baseline surveys within the app may further discourage enrolment. The alternatives are to limit the number of questions asked, make some questions optional, or to spread questions across multiple login sessions. However, only 34% of users downloading a stop smoking app called Quit Advisor (BinDhim et al. 2014b) completed an in-app questionnaire that collected key research and clinical data, such as dependence levels

and socio-demographics, suggesting that making data collection optional for users may lead poor uptake and biased evaluation due to self-selection.

Other studies of cessation apps tried to address attrition and missing data by introducing closer monitoring of participants (e.g. regular communication with the researchers) or additional reimbursement for providing data throughout the trial. Such methods are costly and tend to yield mixed results (Thrul et al. 2018). More importantly, these processes further limit the generalisability of findings.

2.5.4. Objective verification of cessation outcome

Verification of self-reported abstinence is crucial, but particularly challenging in DBCIs, especially when the studies rely on remote data collection. One option is to analyse saliva samples for nicotine metabolites (cotinine, and in case of concurrent use of nicotine-products - anabasine), which can be collected through the post and sent to a lab for testing (Brown et al. 2014). However, saliva testing is not possible when researchers have no access to a suitable lab. It is also a relatively costly procedure (e.g. in 2015 the costs of cotinine tests started at £20-£35 per sample, depending on the level of processing required, over £30 for anabasine tests, and around £5 for first-class postage, envelopes and salivettes). Additionally, previous studies offered participants reimbursement for providing saliva samples (e.g. vouchers of £20) (Brown et al. 2014).

A more recent strategy involves posting saliva kits for home-based testing (c. £12 per kit in the US, excluding postage), which could involve participants sending the results as photos or live video (Marrone et al. 2010). However, this method was recently shown to yield only 50% of returned results (Thrul et al. 2018). A potential future method that could be more cost-effective and convenient might involve remote assessment of heart rate variability through a smartphone (Heathers 2013, Harte and Meston 2014, Peng et al. 2015). However, this method requires validation.

Assessment of carbon monoxide (CO) in the exhaled breath has been among the most commonly used methods in cessation trials (West et al. 2010, Goldstein et al. 2018). CO testing has many advantages over other measurements, e.g. it is non-invasive and insensitive to concurrent use of nicotine products or e-cigarettes, and a single device

can be used for repeated tests. On the other hand, however, the temporal applicability of CO testing is limited due to rapid elimination of CO from the body (Benowitz et al. 2002, Goldstein et al. 2018). Moreover, the traditional CO monitors are very costly (starting at around £170 in the UK for Bedfont® devices), and their use has been primarily limited to clinical settings.

Measuring CO levels may be especially difficult if participants cannot travel for in-person testing. Some studies have accomplished CO testing by having research staff travel to participants' homes or organizing verification at local clinics (Kim et al. 2005), or by providing traditional CO monitors for home-based testing and requiring participants to share video streams of the procedure and to return the devices after the study is completed (Dallery and Glenn 2005, Hertzberg et al. 2013, Karelitz et al. 2017).

The advent of new CO monitors that connect to personal computers or smartphones and which are smaller and more affordable (under £50 in the UK for Bedfont® devices), offers new possibilities to post such CO devices to smokers for home-based testing. However, research on feasibility, acceptability and effectiveness of such devices and programmes that rely on smartphone-based CO testing is still in its infancy. One recent study using such devices and an app Coach2Quit did not find an effect on cessation, but the intervention was received well by the participants (Krishnan et al. 2018).

2.5.5. Assessing use and adherence to cessation medications in trials

For DBCIs that involve providing and evaluating the advice on cessation pharmacotherapy, e.g. NRT, collecting reliable and valid data on medication use and smoking status is particularly important. One reason for this is that medication use tends to be related to smoking status, with smokers often terminating medication use following a relapse. This can lead to confounded estimates of the association between adherence and cessation due to reverse causality (Raupach et al. 2014, Schlam et al. 2018). Equally importantly, such data is necessary to tailor the advice.

However, there are numerous methodological challenges for assessing medication use in general, many of which are magnified in app-based research. First of all, we have at our disposal imperfect instruments for collecting data on medication use. Many

studies rely on surveys to collect retrospective self-reported data on medication use (Pacek et al. 2017), which are prone to recall and desirability bias (Stirratt et al. 2015). The matter is further complicated by attrition and other sources of missing data, which are very common in DBCIs. These biases may be especially pronounced if the study arms differ on their emphasis on medication use, or involve different schedule or level of monitoring on medication use.

Several objective methods for assessing adherence to medications are available, but their feasibility for smartphone-based studies of NRT use is limited. Some studies have required participants to return medication packaging for counting (Hatsukami et al. 2007, Pacek et al. 2017). There now also exists technology that can track medication use, e.g. smart tablet blisters, wearable sensors, and computer vision (Aldeer et al. 2018). However, these are costly solutions that additionally require providing participants with bespoke medications or devices and are therefore not suitable in studies where participants can choose their products and change them (e.g. OTC NRT) or in remote trials with no researcher involvement.

Secondly, there is a lack of standardised measures of adherence to cessation pharmacotherapy and different researchers have operationalised adherence to NRT differently and somewhat arbitrarily. One definition of adherence is taking it for at least 80% of the recommended duration (DiMatteo et al. 2002), which has been applied to studies of varenicline (Catz et al. 2011) or bupropion (Fossati et al. 2007, Hays et al. 2010). Another general recommendation is using the cessation medications for at least eight weeks (Balmford et al. 2011). Still other researchers classified use into full/partial/no adherence, but without defining the criteria (Cooper et al. 2004), used different cut-offs, such as use of NRT for at least 4 weeks (Lam et al. 2005), or using the patch for at least 20/21 days (Shiffman et al. 2008b), for 50/56 days (Alterman et al. 1999) or just assessed the number of days when NRT was used in the previous week (Brendryen and Kraft 2008).

Thirdly, contrary to many medications that have a standardised regimen (e.g. varenicline, cytosine and bupropion have a specific number of pills to be taken in a given day), NRT use is more complex thus making assessments of adherence even more challenging. For example, the recommended schedule of NRT use involves graduate ‘weaning oneself off’ NRT in terms of the amount or strength of products and thus the time since the quit date should be accounted for as well. The patterns of NRT use can be

complicated further by the use of different forms of NRT (e.g. patch should be used once a day, while fast-acting NRT should be used as often as 10-16 times per day, depending on the product), or use of combination NRT. Furthermore, clinical recommendations for NRT use may vary from individual to individual, and may depend on the severity of withdrawal, cravings, and side effects. Therefore, adherence to NRT is a multicomponent behaviour and should incorporate assessment of the type of NRT used, the amount used, duration, the frequency of use during the day, and whether single or combination product is used.

Additionally, there are limitations in focusing on the patterns and frequencies of NRT use. This approach does not assess ‘correct’ or efficient use (e.g. placing the nicotine patch on clean and dry skin, using “chew & park” technique for the nicotine gum). As a result, participants who use fewer NRT products, but more effectively, may be obtaining similar or greater levels of nicotine than those who use the medication more frequently but incorrectly.

Finally, none of the available methods allows determining the dose of nicotine absorbed by participants (Hollands et al. 2013). There is also no biochemical measure which can determine adherence (anabasine and cotinine together can distinguish NRT from combustible cigarettes but not from e-cigarettes).

2.5.6. Collecting, analysing and interpreting the engagement data

Digital interventions offer opportunities to collect rich and complex data on engagement, which could help to evaluate their impact, improve them, or identify predictors of attrition or intervention success. Several engagement indices or metrics are commonly reported for DBCIs and are also among the recommended items in the E-Health Consort Checklist (Eysenbach and Group 2011), including the number of logins and time spent using the intervention (Danaher et al. 2006, Zeng et al. 2015). These metrics offer a useful summary of engagement and enable some comparison across DBCIs.

However, in recent years there has been a growing recognition that engagement with DBCIs is much more complex, especially as it is context-dependent and is likely affected by numerous factors related to the intervention itself (e.g. perceived usefulness

but also aesthetics), as well as individual and external factors (Perski et al. 2017b). The methodology for assessing, analysing and interpreting this complex data is still developing (e.g. (Arden-Close et al. 2015)).

Furthermore, while some research points to the existence of a dose-and-effect relationship in the trials of DBCIs (Graham et al. 2017, Iacoviello et al. 2017), the casual relationship is contested. Additionally, there is still insufficient research to inform the doses of engagement needed for a given effect, and it is also possible that for certain outcomes even brief interventions or low engagement may be effective (Perski et al. 2017b). In the case of smoking, disengagement and attrition may signal both relapse and successful cessation (Saul et al. 2016, Paz Castro et al. 2017). There are also other reasons to be sceptical about the engagement data: the technology may fail to record all activities with the programme, while biases, such as the Hawthorne effect, may limit generalisability of the findings to non-study settings (McCambridge et al. 2014).

2.5.7. Review of studies assessing the effectiveness of smoking cessation apps.

The design elements of the individual published studies on the effectiveness of cessation apps are summarised in Tables 2.2.a-b (design elements and procedures) and Tables 2.3.a-b (measures and data collection) on subsequent pages. These studies have evaluated very different interventions, and in the case of RCTs, used different active controls (from texting to other apps). This heterogeneity is making it difficult to compare the findings and incrementally build on them. Interestingly, no study used a waitlist condition or applied some of the more sophisticated designs, e.g. MOST.

Many studies relied on two-stage recruitment (e.g. pre-screening by the researchers or through a website) and some offered incentives at follow-ups. This limits their ecological validity and generalisability of the findings to non-research settings. In terms of the follow-up, almost all studies used online follow-up, although some conducted it through the app only (BinDhim et al. 2018), while others used email, phone and postal follow-up (Bricker et al. 2014, Bricker et al. 2017). Reimbursement was associated with higher follow-up rates. Only one study attempted biochemical verification through posting a traditional CO monitor (to be returned by participants) (Garrison et al. 2018).

Regarding data collection and app evaluation, these tended to focus on collecting data on socio-demographics, smoking and cessation behaviours, as well as usage indicators. Formal assessment of usability, satisfaction or process data, or qualitative evaluations, were rare. This is likely reflecting the challenges to collect large volumes of self-reported data in DBCIs and maintaining participant's engagement in the trials.

Table 2.2a. Design elements and procedures in observational (1-arm) studies of the effectiveness of smartphone-based cessation support (based on published reports).

	Published 1-arm Observational Study		
	Ubhi (2016)	Bricker (2017)	Iacoviello (2017)
Promotion	App store (passive, no active promotion)	Paid adds online & printed media & employers	Online advertisement
Recruitment and Enrolment	Automated /Remote /Via the app	Stages: Online survey and eligibility check > link to app download	Stages: pre-screening by phone > link to a website for consent and baseline > link to download the app
Sample (all adult smokers)	1170 (UK) iOS or Android	99 (US) iOS or Android	416 (US) ≥5 cig/day iOS only
Intervention (all standalone)	SF28 (based on Pre Theory and best clinical practice in the UK)	SmartQuit (2.0) Acceptance & Commitment Therapy (ACT)-based app	Clickotine based on US clinical practice guidelines + personalized components
Control	N/A	N/A	N/A
Follow-up	App	Email, phone, mail	Online survey
Reimbursement for follow-up	-	Yes (\$25 Amazon voucher/survey)	Yes (follow-up; \$25 Amazon voucher/survey; up to \$1000)
Follow-up rate (ITT)		85%	87.7%
Biochemical verification	-	-	-

Table 2.2.b. Design elements and procedures in experimental (2-arm and factorial) studies of the effectiveness of smartphone stop smoking apps (based on published reports).

	Published 2-arm RCTs					Factorial
	Hertzberg (2013)	Buller (2014)	Bricker (2014)	Garrison (2018)	BinDhim (2018)	Tombor (2018)
Promotion	N/A clinical services	Paid adds online & printed media	Paid adds online & printed media	Adds online (probably paid)	App store (details unknown)	Online and printed, emails; HCPs, apps store
Recruitment and Enrolment	Via HCPs	Stages: online survey > consent online > Phone contract > mail with smartphones + training with staff	Stages: Online and phone survey and eligibility check >link to app download	Stages: Online screening survey > link to baseline > randomised to receive app version	Automated /Remote /Via app	Automated /Remote /Via app
Sample (all adult smokers)	22 (US, PTSD-patients)	102 (US) 45% women, 18-30yrs	196 (US)	325 (UK)	684 (USA, Australia, Singapore UK) iPhone users	565 pregnant (Worldwide, 50% UK)
Intervention	Contingency management(CM) +2 counselling sessions + bupropion+NRT	Online QuitCoach + optional NRT + early app for Windows phone (REQ-Mobile)	ACT-based app (1.0)	Mindfulness training (+ control)	Ottawa Decision Support Framework	Multiple app versions and components
Control	Yoked CM+2 counselling sessions + bupropion +NRT	Online QuitCoach + optional NRT + SMS (onQ)	Another app (Clinical Guidelines)	Experience sampling	Control app version (general information)	Multiple app versions and components
Follow-up		Online	email, phone, post	Online	App	App
Reimbursement for follow-up	\$<690	-	Yes \$25 Amazon voucher	<\$116 at 6 months	-	-
Follow-up period	3 months	6 and 12 week	2 months (13% vs 8%)	6 months		
Follow-up rate (ITT)		67%	85%	72.6%		N/A
Biochemical verification	CO testing	-	-	remote CO testing (posted)	-	-

Table 2.3.a. Data collection in observational (1-arm) studies of the effectiveness of smartphone stop smoking apps (based on published reports).

	Published 1-arm		
	Ubhi (2015)	Bricker (2017)	Iacoviello (2017)
Baseline			
Socio-demographics	Yes	Yes	Yes
Smoking and quitting-related data	Yes	Yes	Yes
Prior experience with digital interventions and apps	-	-	-
Theory-related questions (if relevant)	-	Yes	-
Follow-up			
Smoking and quitting-related	Yes	Yes	Yes
Theory-related constructs	-	Yes	-
Negative health events	-	-	Yes
App usage (automatic)	Yes	Yes	Yes
App evaluation (reported by participants)			
formal usability scale	-	-	-
recommend to a friend	-	Yes	-
useful for the target behaviour	-	Yes	-
easy to use	-	-	-
Satisfaction	-	Yes	-
Other – examples			
Momentary assessments of smoking and quitting-related variables (e.g. smoking status)	(diary)	(diary)	-
Location / other contextual data	-	-	-
Qualitative data	-	-	-

Table 2.3.b. Data collection in experimental (2-arm and factorial) studies of effectiveness of smartphone stop smoking apps (based on published reports).

	Published 2-arm					Factorial
	Hertzberg (2013)	Buller (2014)	Bricker (2014)	Garrison (2018)	BinDhim (2018)	Tombor (2018)
Baseline						
Socio-demographics	Yes	Yes	Yes	Yes	Yes	Yes
Smoking and quitting-related	Yes	Yes	Yes	Yes	Yes	Yes
Attitudes or Prior experience with digital interventions and apps	-	-	-	-	-	Yes
Theory-related questions (if intervention based on theory)	-	-	Yes	Yes	-	-
Follow-up						
Smoking and quitting-related	Yes	Yes	Yes	Yes	Yes	Yes
Theory-related constructs	-	-	Yes	Yes	Yes	-
Other	adherence			-	-	
App usage (automatic)	-	Yes	No, self-report	Yes	-	Yes
App evaluation (reported by participants)						
formal usability scale	-	Yes	-	-	-	-
recommend to a friend	-	-	Yes	-	-	-
useful for the target behaviour	-	-	Yes	-	-	Yes
easy to use	-	-	Yes	-	-	Yes
satisfaction	-	-	Yes	-	-	-
Other						
Momentary assessments of smoking and quitting (e.g. smoking status)	-	-	(diary)	(diary)	-	-
Location / contextual data	-	-	-	-	-	-
Qualitative data	-	-	-	-	-	Yes (separate)

2.6. Smartphone ecosystem – implications for development and evaluation

A final issue to consider when developing, implementing and evaluating cessation apps is the smartphone ecosystem. It is governed by constantly evolving national and international regulations ((e.g. laws pertaining to data protection or medical devices (Barton 2012, Boulos et al. 2014)), changing app store policies, and specific guidelines and trends adopted by app developers and graphic designers. App development and maintenance are further influenced by updates to hardware (e.g. release of new phone models) and software (e.g. updates to the phone's operating system, but also changes to the software that is used to develop a given app). As a result, while the rapid technological advancements offer ever new possibilities, they may also negatively affect acceptability, relevance or usability of earlier versions of a DBCI. Moreover, additional resources are required to keep interventions up-to-date or to test and implement them across multiple platforms, all of which poses challenges for sustainability and scalability of such programmes.

With the popularisation of smartphones, the age and socioeconomic disparities in access to these devices are decreasing (Deloitte 2018). However, older adults are still less likely to own a smartphone, and socio-economic groups were shown to differ on what phones and operating systems they use, and for what purposes (e.g. for leisure or information seeking (Tsetsi and Rains 2017)). Some research suggests that those from lower socio-economic status may be more interested to engage with DBCIs for quitting or to benefit from them (Brown et al. 2014). Nevertheless, concerns remain that smartphone-based stop smoking interventions may contribute to the digital divide and exacerbate health inequalities by attracting particularly keen, technology-proficient and more affluent early adopters, and failing to propagate across the socio-economic and demographic spectrum (Kontos et al. 2014, Mackert et al. 2016, Hamilton et al. 2018).

2.6.1. Android and iOS Operating Systems

The smartphone market is dominated (97%) by phones with Android and iOS operating systems (BuildFire 2017). Android phones tend to be more common in the US

and globally owing to greater device and price range, which attracts customers in countries with wide income disparities, e.g. Africa and Asia (BuildFire 2017). In the UK the difference in popularity between iOS and Android has been smaller and more fluid, with iOS devices currently capturing just over 50% of the market (BuildFire 2017).

Although devices for Android (e.g. most commonly Samsung, but also Huawei and LGT) and iOS (iPhones) are becoming relatively similar, the two operating systems differ in many important respects, such as technological opportunities and limitations, aesthetics, security, and compatibility with external devices. Moreover, iOS tends to offer a more standardised experience to its customers, which exerts pressure on developers to use consistent standards for graphics and navigation. iOS-based apps also undergo a much more rigorous process of app review before they are released on iTunes.

Android apps, on the other hand, are subject to a much less stringent review process and fewer regulations. Additionally, Android apps run on very different devices in terms of brands, screen sizes, and also versions of the operating systems (Android users rarely update their systems), as well as often enable more customisability to their users than iOS apps do (Richter 2018). Therefore, users who open the same app on different Android devices may have different experiences with it, while the Android developers have to work with a very complex and fragmented app ecosystem (BuildFire 2017) (Richter 2018).

Given the above, creating a single app version for all operating systems could negatively impact experiences for some users, while developing an app with ‘native’ versions for both iOS or Android can lead to creating very different programmes for these users. Therefore, the differences between iOS and Android have a nontrivial impact on how the apps are designed, delivered, and used by the end-users, and possibly also with what effect, but systematic research on the latter is limited.

2.6.2. Android and iOS user profile and behaviour

Android and iOS users tend to have different characteristics and also behaviour (Albanesius 2011, Ubhi et al. 2015), which could impact on engagement with apps and

their effectiveness. For example, in comparison to Android users, iOS users tend to engage with the apps more, including signing up to paid services, making in-app purchases, as well as engaging with more content (BuildFire 2017). iOS users, at least in the early days of the smartphone era, were also more interested in healthcare apps (Peck et al. 2014). iOS users tend to be younger, more knowledgeable about technology, view phones as a status symbol, and have a higher income (Schonfeld 2011, Shaw et al. 2016, BuildFire 2017).

There is also some research to suggest that iOS and Android users engage differently with smartphone features and apps. For example, notifications are very rarely opened by the smartphone users. This is especially the case of the iOS users (1.8% vs. 3.5% among Android users), which can be explained by the differences in how these messages are displayed by these two operating systems (BuildFire 2017). However, iOS users open their notifications quicker (after seven vs 48 minutes, on average) (BuildFire 2017), which could impact on interventions relying on just-in-time components or other scheduled communications.

iOS and Android users may also use cessation apps differently. One study in 2012 found that 73% of users who downloaded one stop smoking app (Quit Advisor) in three English speaking countries (Australia, the UK, and the USA) had iOS phones (BinDhim et al. 2014a). In an observational study of user characteristics of another cessation app, SF28 (Ubhi et al. 2017), iOS and Android users did not differ significantly on the socio-demographic characteristic, but they differed on app usage and cessation history reported at baseline through the app. Specifically, in comparison to Android users, iOS users were more likely to had made a serious quit attempt in the past 12 months, to set their quit date for the day of registration, and to download the app to make a serious quit attempt, but were less likely to had used cessation pharmacotherapy before (Ubhi et al. 2017).

2.7. Chapter 2 Summary

There exist numerous approaches to the development and evaluation of DBCIs, including stop smoking apps, each associated with opportunities and limitations. Application of most of these into a single project would constitute a major programme

of research, requiring the engagement of multidisciplinary teams. This thesis comprised studies that drew on several of these methods and approaches, which also offered an opportunity to assess them in the context of creating and assessing smartphone apps supporting cessation and NRT use.

Chapter 3: The NRT2Quit app development

3.1. Chapter 3 overview

This chapter outlines the rationale for the NRT2Quit trial and associated studies described in Chapters 4 to 6, as well as the process of developing the NRT2Quit app, with a focus on app components supporting NRT adherence. Finally, it outlines NRT2Quit functionality.

3.2. Contributions

The initial trial protocol and funding application outlining the scope of the NRT2Quit app, as well as the plan for its evaluation through a randomised controlled trial (RCT), were prepared by Tobias Raupach (TR). I was responsible for all the steps and tasks related to app development and its subsequent evaluation through the RCT, as well as for planning and conducting any future studies. With regards to app development, my responsibilities included (a) planning out app development given the available resources and the timelines (e.g. participating pharmacies were scheduled to start recruitment for the trial within 4 months of me joining the project); (b) designing user journeys and algorithms for monitoring and feedback, and sketching wireframes for all screens in the app; (c) developing the content for the app, including the text with all advice, instructions, tutorials; (d) embedding trial procedures and data collection within the app, (e) planning and conducting research underlying the app development (e.g. conducting a rapid scoping literature review and consultations with the National Centre for Smoking Cessation and Treatment (NCSCT), completing the steps outlined in the Behaviour Change Wheel –a Guide to Intervention Development (BCWG) (Michie et al. 2014)), and organising usability testing of the app); (f) overseeing the work of two external IT companies in the UK and India, including: vetting the potential companies, negotiating the contracts, preparing briefs and documentation for the developers (i.e. preparing the ‘business analysis’ and detailed instructions on all aspects of the app that formed the basis for app development), regularly communicating with the programmers and designers (e.g. participating in weekly videoconferences as part of the ‘sprints’

devoted to creating individual app components; communication via email or project management software to set and approve milestones), supporting modifications to the app and fixing bugs through reading the code and preparing detailed instructions for changes for the developers, as well as conducting internal testing. All decisions and the final study write-up were consulted with TR, Prof Robert West (RW) and Dr Jamie Brown (JB). Dr Andy McEwen (AM) provided expert advice on treatment of tobacco dependence with NRT and feedback on the NRT2Quit app during its development.

3.3. Introduction

3.3.1. The rationale for the NRT2Quit app and the trial

Nicotine Replacement Therapy (NRT) includes several medically-licenced products that contain nicotine and can support quit attempts (e.g. a slow-acting patch and fast-acting gum, lozenges or sprays). NRT has been shown to be effective in high-quality RCTs when it was offered with some support from healthcare professionals (HCPs) (Stead et al. 2012). However, findings from large population-based studies have not found NRT to be effective among smokers who purchase NRT over-the-counter (OTC), and with no professional support (Kasza et al. 2013, Kotz et al. 2014b, Kotz et al. 2014a). One possible reason for the low effectiveness of OTC NRT is poor adherence to the medications, which could include using them at too low doses, terminating their use prematurely, or applying them incorrectly (Curry et al. 2003, Carpenter et al. 2011, Raupach et al. 2014, Beard et al. 2015, Stanley and Massey 2016, Apollonio and Glantz 2017, Hughes et al. 2017). Poor adherence has been commonly observed among NRT users (Amodei and Lamb 2008, Foulds et al. 2009, Raupach et al. 2014, Beard et al. 2015). There is some research to suggest that better adherence to cessation pharmacotherapy, including NRT, could lead to better cessation outcomes (Raupach et al. 2014, Ma et al. 2016, Cropsey et al. 2017, Schlam et al. 2018).

In principle, smartphone apps could support NRT adherence and optimal use, especially among smokers using OTC NRT (Kotz et al. 2009, Raupach et al. 2013, Pulverman and Yellowlees 2014). There already exist smartphone apps supporting medication use for a range of conditions (Morrissey et al. 2016, Santo et al. 2016, Ahmed et al. 2018). However, stop smoking apps created to date offer at best limited

advice on medication use (Abroms et al. 2011, Abroms et al. 2013, Bricker et al. 2014, Buller et al. 2014, Choi et al. 2014, Jacobs et al. 2014, Ubhi et al. 2015, Hoepfner et al. 2016, Ubhi et al. 2016b, Bricker et al. 2017, Cheng et al. 2017, Haskins et al. 2017, Iacoviello et al. 2017, Thornton et al. 2017, Ahmed et al. 2018, BinDhim et al. 2018). Furthermore, there is still little direct evidence to guide the development of interventions promoting more effective use of NRT, especially for smokers using OTC NRT (Hollands et al. 2015b, Pacek et al. 2017).

To address these gaps in research, we aimed to develop and evaluate NRT2Quit (*short for 'using NRT to quit smoking'*) – an app focused on improving adherence to NRT among adult smokers during quit attempts. The app was designed to be evaluated in a pragmatic RCT funded through the Pfizer GRAND competition⁵ (the trial is reported in detail in Chapter 4), which involved comparing a complete version of the app (intervention with a minimum credible intervention (control), which only offered very brief advice on NRT use and quitting.

3.3.2. Practical assumptions underlying NRT2Quit development

The development of the NRT2Quit app was informed by several assumptions identified at the outset of the project: (1) a bespoke app would be developed that (2) would address reasons for poor adherence to NRT among adult smokers motivated to quit, with a focus on OTC NRT and on intentional sources of non-adherence (e.g. negative attitudes) (Lehane and McCarthy 2007, Clifford et al. 2008); (3) the advice on NRT use would be supplemented by generic advice and support with quitting provided as part of digital cessation interventions developed previously by the team members (e.g. features to set a quit date and monitor progress) (Brown et al. 2014, Ubhi et al. 2015); (4) the recommendations offered would be based on best clinical practice applicable to the UK setting, with materials developed and curated by the NCSCT used as key sources of clinical best practice and information for the app content.

Additionally, given the low effectiveness of OTC NRT (Kotz et al. 2014b, Kotz et al. 2014a), it was important to evaluate NRT2Quit in a real-world OTC setting, requiring no involvement of researchers or healthcare professions (HCPs). Community

⁵ Global Research Awards for Nicotine Dependence Research, <http://grandawardsprogram.org/>

pharmacies were judged to be an appropriate setting to promote the study and reach smokers who have just purchased NRT. Therefore, (5) NRT2Quit would need to be a fully-automated enabling remote and online recruitment (Eysenbach and Group 2011). This would also help to increase generalisability of the findings and the scalability of the intervention in the future. Furthermore, due to limited resources and following consultations and market research, a decision was made (6) to develop an iOS app version in the first instance, followed by an Android version during future iterations, if this was warranted.

Finally, it was recognised that implementing the intervention to support NRT use in a smartphone app would require IT expertise (Roth et al. 2014, Blandford et al. 2018). Additionally, there were many uncertainties at the project initiation with regards to what would be feasible to deliver given the resources available. As a result, it was decided that NRT2Quit would be developed drawing on some elements of both the waterfall and agile process (described in Chapter 2.3.1). Thus, the developers would deliver on pre-specified general requirements for NRT2Quit, but the specific features would be finalised through an iterative process once the software development starts.

3.3.3. Theoretical underpinnings of NRT2Quit

Since NRT2Quit would constitute a complex intervention including novel components targeting NRT use, it was necessary to identify a theoretical framework that could guide its development. Interventions based on a theory, especially if well-selected, tend to result in better outcomes (Webb et al. 2010, Michie et al. 2018). The Behaviour Change Wheel (BCW; (Michie et al. 2011c)) was selected for this purpose, which was motivated by several reasons. First of all, the BCW is an integrative framework of behaviour change synthesising 19 existing frameworks (e.g. MINDSPACE and intervention mapping) (Michie et al. 2011c). The BCW is conceptually coherent, covers a comprehensive range of intervention types, and supports the systematic linking of interventions to models of behaviour (Tombor and Michie 2017).

Secondly, the BCW is underpinned by the broad and inclusive COM-B model of behaviour and factors influencing it (i.e. facilitators and barriers) (Michie et al. 2011c,

Michie et al. 2014). COM-B proposes that three high-level categories interact dynamically to produce any Behaviour: Capability (physical, e.g. skills and stamina, and psychological, e.g. knowledge, mental strength), Opportunity (physical, e.g. access, resources, and social, e.g. support, cultural norms, modelling), and Motivation (reflective, e.g. identity, and automatic, e.g. emotions and habits) (see Fig 3.1) (Michie et al. 2011c). COM-B has been suggested as a good basis for developing medication adherence interventions (Jackson et al. 2014), but has not yet been used for improving NRT use.

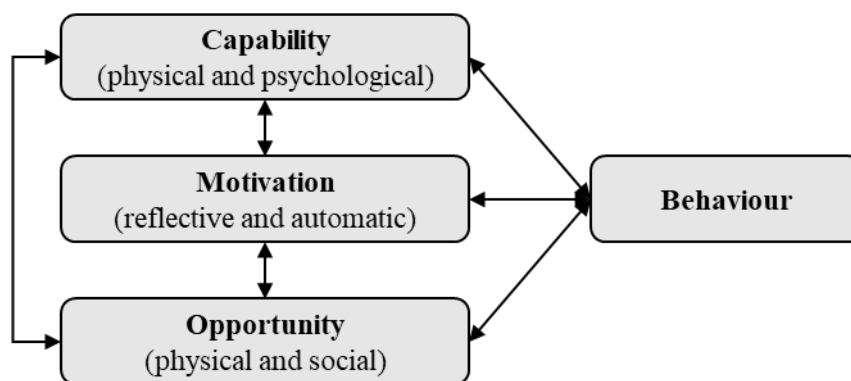


Figure 3.1. COM-B Model of Behaviour (adapted from Michie et al., 2011)

Some of the individual domains of the COM-B model can be elaborated on by the domains of the Theoretical Domains Framework (TDF), a synthesis of 33 theories and 128 constructs (Cane et al. 2012, Atkins et al. 2017). The TDF (version 2) consists of 14 domains, but it does not specify the relationship between these. Table 3.1 presents a mapping of the COM-B and TDF domains. Together, COM-B and TDF offer a detailed framework for behavioural analysis, which can help to identify relevant or novel intervention targets (Craig et al. 2008, Michie et al. 2014).

Table 3.1. Mapping of COM-B and TDF constructs (adapted from Atkins et al., 2017).

COM-B domains	TDF domains
B – Behaviour	-
Capability - Physical	Skills
Capability - Psychological	Knowledge
	Memory, attention and decision making
	Behaviour regulation
Opportunity -Physical	Environmental Context and Resources
Opportunity - Social	Social Influences
Motivation - Reflective	Beliefs about capabilities
	Beliefs about consequences
	Optimism
	Social/professional role and identity
	Goals
	Intentions
Motivation - Automatic	Habit
	Emotions
	Reinforcement

Both COM-B and TDF can guide the creation of data collection instruments for formative research (e.g. surveys, interview guides, data extraction forms) and subsequent data synthesis and analysis (e.g. coding frameworks or checklists) (Michie et al. 2014). Additionally, research underpinned by COM-B and TDF is highly context-specific, as both stress the role and unique qualities of the individuals engaging in the behaviour, as well as the environmental and social circumstances surrounding them and influencing the behaviour. Due to their versatility, both COM-B and TDF, individually or in combination, have been used to develop and evaluate a range of complex interventions, for example in sepsis management (Myers et al. 2016), use of gas stoves (Curtis et al. 2015), medication prescribing (French et al. 2012), and vaccination uptake (Rubinstein et al. 2015).

The third reason for using BCW to develop NRT2Quit is the existence of a methodology facilitating the application of BCW, which is described in the “*Behaviour Change Wheel – A Guide to Intervention Development*” (BCWG; (Michie et al. 2014). BCWG has been used in a range of settings, including in the development of apps supporting cessation among pregnant smokers (Tombor et al. 2016) and for increasing the uptake and attendance at stop smoking services (Fulton et al. 2016), as well as in

interventions to improve weight management among children (Curtis et al. 2015) and medication management in multimorbidity (Sinnott et al. 2015).

Finally, the BCWG also supports incorporating other theories relevant to the target behaviour, with COM-B and TDF acting as a scaffold to organise and synthesise the data. This was crucial for the development of NRT2Quit, since it required integrating information from a range sources, including clinical recommendations, theories relevant to NRT use (e.g. the distinction between intentional and non-intentional non-adherence (Lehane and McCarthy 2007, Clifford et al. 2008)), as well as literature on factors associated with NRT and medication use ((Etter and Perneger 2001, Bansal et al. 2004, Lowry et al. 2005, Mooney et al. 2006, Clifford et al. 2008, Shiffman et al. 2008a, Vogt et al. 2008, Yerger et al. 2008, Foulds et al. 2009, Carpenter et al. 2011, Ferguson et al. 2011, Beard et al. 2012, Kardas et al. 2013, Silla et al. 2014, Tsang et al. 2014, Pacek et al. 2017, Herbec et al. 2018b)).

3.4.4. Aims

This chapter reports on the methods and results of the two phases of NRT2Quit development, i.e. the theory-informed intervention development followed by its implementation in an app and software development.

3.5. Methods

3.5.1. Overview of the development of the NRT2Quit app

As was discussed in Chapter 2.3, it is useful to distinguish two phases in the creation of digital behaviour change interventions (DBCIs), including NRT2Quit (see Fig 3.2 for an outline of the core tasks in these two phases and sources of information that guided NRT2Quit development). Phase 1 involved intervention development (August-December 2014) that followed the steps outlined in the BCWG (Michie et al. 2014) and was supplemented by expert consultations with the NCSCT. Phase 2 focused on the implementation of the intervention in a smartphone app, which included software

development (December 2014-March 2015). During Phase 2, a control version of the NRT2Quit app (a minimum credible intervention) was also developed to be used in the subsequent RCT.

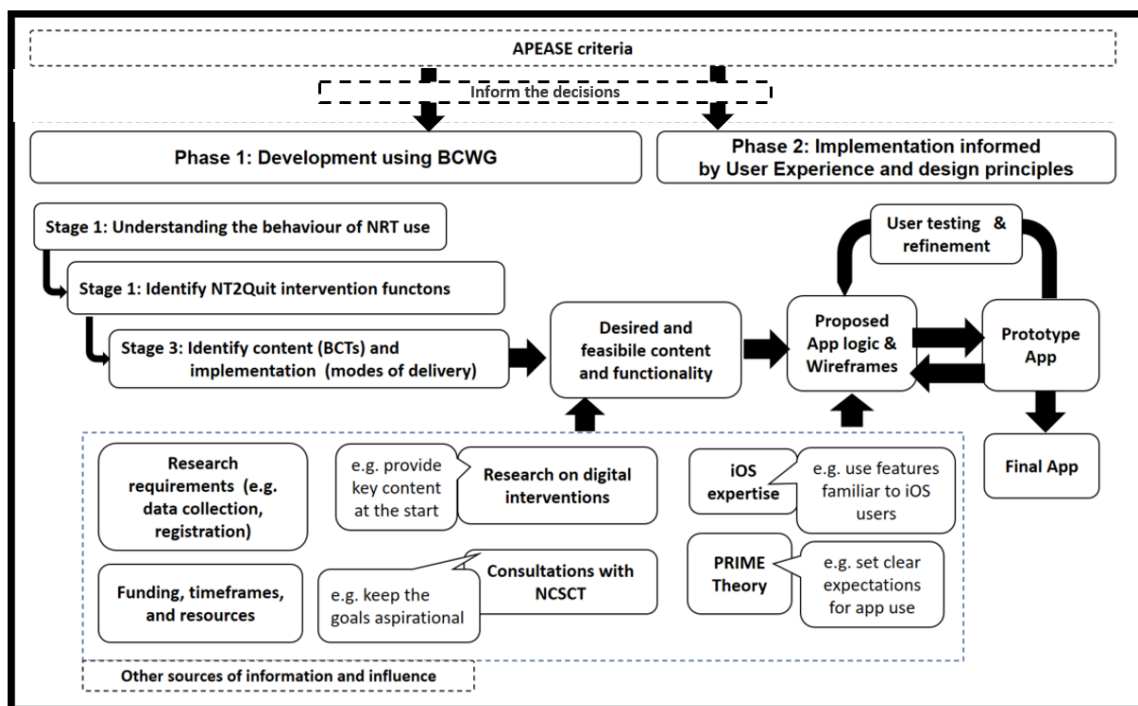


Figure 3.2. NRT2Quit development - overview of Phase 1 (intervention development) and Phase 2 (intervention implementation and software development)

Phase 1: Development of the NRT2Quit intervention

The NRT2Quit app was developed to support both NRT use and quitting smoking in general. The latter was delivered through BCTs identified in the existing digital cessation interventions developed earlier by our group (Brown et al. 2014, Herbec et al. 2014b, Ubhi et al. 2015). The process of developing the novel components for NRT2Quit to support adherence to NRT was based on the BCWG.

In short, the process of intervention development proposed by BCWG comprises eight steps that are grouped under three stages. The details of the methods, sources of information, and the results of each of the three Stages are outlined in Box 3.1. Stage 1 (steps 1-4) focused on a comprehensive analysis of the behaviour of interest using COM-B and TDF. The analysis was based on existing sources of information (Michie et

al. 2014). Stage 2 (steps 5 and 6) identified suitable intervention approaches. Stage 3 (steps 7 and 8) resulted in a selection of relevant behaviour change techniques (BCTs) and modes of delivery based on the results from the first two stages. As per BCWG, the selection of the modes of delivery was initiated at the end of Phase 1. However, it was completed through agile processes in Phase 2 as it involved software development and required consultations with the IT team.

Additionally, BCWG proposed to use the APEASE (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Safety and side effects, and Equity) criteria to identify the most appropriate interventions and components for the circumstances and resources available at hand (Michie et al. 2014, Tombor and Michie 2017). Due to a lack of standardised assessment methods, the APEASE criteria were assessed using our best judgment and understanding of the context (Tombor and Michie 2017).

Box 3.1. NRT2Quit intervention development - the methods, sources of information and results of Stages 1-3 (steps 1-8) guided by the BCWG (Michie et al, 2014).

Stage 1: Understand the behaviour (Steps 1-4)
Methods of Stage 1
Sources for the behavioural analysis were identified through a scoping search and included: <ul style="list-style-type: none"> a) patient leaflets provided by NRT manufacturers; b) training materials developed by the NCSCT, including video-based training on cessation medication use, and insights from consultations with AM (the NCSCT Director) – these were considered to be a benchmark for best clinical practice in the UK; c) findings from the research literature on NRT adherence identified for the original grant application by TR and supplemented by a scoping literature review conducted by me; d) theories and frameworks pertaining to medication use: the framework of intentional and unintentional non-adherence (Lehane and McCarthy 2007, Clifford et al. 2008), Medication Compliance and Persistence framework (Cramer et al. 2008), and the Necessity-Concerns Framework (Horne et al. 1999, Horne et al. 2013);

Box 3.1. (cont).

- e) advice on NRT use delivered through digital stop smoking interventions developed by the UCL Tobacco and Alcohol Research (UTARG) team: the web-based StopAdvisor (Brown et al. 2012, Michie et al. 2012a) as well as the SmokeFree28 (SF28) app (Ubhi et al. 2015). These interventions were informed by theory and evidence, and had undergone preliminary evaluation suggesting their acceptability, usability, and effectiveness.

Concepts and constructs (i.e. component parts in theories) related to NRT use and factors affecting use were extracted from these sources to populate a spreadsheet with COM-B and TDF domains (see Table 3.1). Additionally, the framework was extended by the Compliance and Persistence (Cramer et al. 2008) because it encouraged making a distinction between factors that could be relevant for NRT initiation and those relevant for continued medication use. APEASE criteria were applied to identify which barriers and facilitators could be addressed by an app-based intervention.

Results of Stage 1

The following specifications of the target behaviour were formulated in steps 1-3: '(a) use of the selected NRT product, or combination of products, (b) by smokers making a serious quit attempt, with the target behaviour needing to be practiced (c) everywhere (e.g. in public, and in private), and (d) across the day, every day, for at least 8 weeks, and additionally, (e) regardless of side effects and smoking status (i.e. despite relapsing or successfully abstaining from cigarettes)'. The analysis showed that OTC NRT use is a complex and dynamic behaviour, and the likely barriers to use were found across the COM-B and most TDF domains. Limited information was available for the domain opportunity.

The COM-B domains meeting the APEASE criteria for an app-based intervention were psychological capability (e.g. knowledge about NRT, its use, and side effects) and reflective motivation (e.g. fostering optimism and realistic expectations about NRT). It was determined that limited opportunities exist for an app to directly address physical capability (except for offering demonstrations of the behaviour), physical and social opportunity, and automatic motivation.

Stage 2 - Identification of intervention options (Steps 5) and policy categories (Step 6)**Methods of Stage 2**

During Step 5 intervention functions were identified based on the results from Stage 1. Step 6 (identification of policy categories) was judged to be unnecessary, as an app-based intervention was falling under a single policy category of 'Service Provision'.

Box 3.1. (cont.)**Results of Stage 2**

During Step 5 the following intervention functions were identified as relevant for NRT2Quit: Education (e.g. providing information about all relevant aspects of NRT and its use), Persuasion (i.e. use of motivational communications to encourage NRT use), and to a lesser extent, and depending on the resources available – Incentivisation (e.g. gamification of NRT use), Environment Restructuring and Enablement (e.g. reminders or pop-ups with supportive messages).

Stage 3 – Identification of content (i.e. BCTs, Step 7) and implementation options (Step 8)**Methods of Stage 3**

Step 7 involved identifying which of the 93 BCTs listed in the BCTTv1 Taxonomy (Michie et al. 2013) should be implemented as part of the new intervention based on the findings from Steps 1-6. The BCTs were selected using the mapping provided in BCWG that linked each of the BCTs to COM-B and TDF domains. Step 8 involved identifying potential modes of delivery of the selected BCTs within the NRT2Quit that were then consulted with the app developers during Phase 2 and assessed against the APEASE criteria. These included:

- Education: text, illustrations, multimedia (e.g. audio or video recordings);
- Persuasion: text, tailored recommendations and feedback, progress charts, multimedia;
- Enablement / Environment Restructuring: reminders, facilitated scheduling and treatment outlined, tools for self-monitoring and feedback;
- Other features: discussion forums, calendars, distracting games, audio-video features (e.g. instructional videos), gamification features.

Results of Stage 3

Step 7 resulted in the selection of 25 individual BCTs targeting NRT use to be delivered within NRT2Quit (see Appendix 3.1.).

Step 8 resulted in the selection of modes of delivery meeting the APEASE criteria. To ensure that NRT2Quit is easily downloadable and that the main BCTs are accessible from the start and available for the ‘power users’ to explore at their own pace (Herbec et al. 2014a), most of the information and advice within the app was presented as easily accessible text. A detailed description of the resulting functionality of NRT2Quit is presented in 3.6 below).

As a final step, the selected BCTs were mapped onto an 8-week-long intervention programme, and draft content or possible modes of delivery were prepared for each BCT. In the process, the BCTs judged to have the greatest potential for impact on NRT use (i.e. ‘the priority’ BCTs) were identified to ensure they would be delivered during the initial sessions or made easily accessible through the different app content, which was important in anticipation of the likely attrition from the app (Eysenbach 2005).

Phase 2: Software development - implementing the NRT2quit intervention in an iPhone app

In Phase 2 the BCTs identified in Phase 1 were implemented in an iOS app, and additionally, a control version of NRT2Quit was developed to be accessible within the same NRT2Quit platform. The process required additional sources of information and expertise (referred to as the ‘guiding principles’), as well as insights from usability testing (Zapata et al. 2015) described below. The guiding principles were identified in the early stages of software development, and are listed in Box 3.2. The guiding principles drew primarily on the IT expertise, user experience (UX) design for apps, wider research on digital cessation interventions to date, the PRIME Theory of Motivation (West 2007b), and the APEASE criteria (Roth et al. 2014, Blandford et al. 2018).

Box 3.2. Guiding principles informing NRT2Quit development (part 1)

Source	The guiding principles	Implications for NRT2Quit
<p>APEASE criteria (Michie et al, 2014)</p>	<p>Considered for the first iteration:</p> <ul style="list-style-type: none"> • Practicability, Safety and side effects, Equity, Affordability <p>The following would be relevant for future iterations once evaluation was completed:</p> <ul style="list-style-type: none"> • Effectiveness and cost-effectiveness, Acceptability 	<ul style="list-style-type: none"> • The advice on NRT use provided within NRT2Quit should be in line with NCSCT guidelines • The app should not include elements that could be barriers to access and use • The app will be offered for free
<p>Best clinical practice (NCSCT)</p>	<ul style="list-style-type: none"> • NRT use can be complex and is often tailored to individual smokers’ needs by the advisor; • Assume little/no prior knowledge of NRT even if used before; • Manage expectations (curb counter-productive optimism with regards to NRT effectiveness); • Emphasise safety of NRT; • Give smokers responsibility and ownership over NRT use (support their decision-making); • Emphasise best practice and evidence-base (e.g. encouraging sticking to the chosen NRT and the quit date set); • Keep the goals aspirational; • Reward any progress; • Smoking is a chronic disease; complete cessation may require several attempts; • Providing advice on NRT selection and use should be tailored to individual circumstances, needs and experiences, and may require adjustments. 	<ul style="list-style-type: none"> • Reward any use of NRT; • Encourage use of additional NRT; • Use every opportunity within the app to address common misconceptions about NRT and reinforce the message; • Provide an opportunity to change the parameters of the quit attempt and NRT used; • Enable smokers who relapse to reschedule their quit date; • Simple decision trees offer some degree of personalisation (<i>note</i>: the necessarily sophisticated and dynamic personalisation was judged as too complex to implement, and would require different technology, e.g. natural language processing and machine learning, which were beyond the scope of this thesis.
<p>PRIME Theory (West et al. 2007b)</p>	<ul style="list-style-type: none"> • Address motivation (e.g. support the development of relevant identity, set clear mental rules, address unhelpful beliefs, create expectations of reward, positive but realistic information framing); • Promote engagement (e.g. establish rapport with the users, set clear expectations for app use); • Maximise self-regulatory capacity and skills (e.g. help to develop a routine of NRT use). 	<ul style="list-style-type: none"> • Offer clear expectations for how to use the app and individual features; • Suggest to create an identity of a ‘non-smoker’ who quits with NRT to benefit him/herself (and reinforce it across the app); • Create and reinforce mental rules about NRT use, e.g. recommend users to “use enough NRT and across the day”; • Create and reinforce mental rules about ‘not a puff rule’; • Use language that is encouraging and empathetic.

Box 3.2. (cont.) Guiding principles informing NRT2Quit development

Source	• The guiding principles	• Implications for NRT2Quit
Research on DBCIs	<ul style="list-style-type: none"> • High attrition (many users expected to disengage already after the first few logins); • Limited exposure to most intervention components among those who disengage, especially in tunnelled interventions; • Keen, ‘power users’ may remain engaged with the app or want to explore rich content; • Users expect novelty on each log-in; • Users expect personalised support. 	<ul style="list-style-type: none"> • Make the content always accessible for users to explore freely; • Key BCTs should be reinforced from the start and during the first login (including immediately after the registration); • New content to be present on each visit; • Information to be tailored to the dependence level, the smoking status, and NRT use.
Research governance and ethics	<ul style="list-style-type: none"> • In the first instance NRT2Quit will be offered only to trial participants; • The trial participants will be smokers who already purchased NRT to quit; • The app is not suitable for smokers who had not purchased NRT already, or who are not planning to quit with NRT. 	<ul style="list-style-type: none"> • App discoverability on app stores should be limited to prevent ineligible users from downloading it (e.g. optimisation of the NRT2Quit page on the iTunes app to promote the app was not needed).
Added during Phase 2 and in consultation with the IT team		
User experience and design principles	<ul style="list-style-type: none"> • Limit burden on the user; • Use iOS solutions and features that are recommended for developers to enhance user experience and take advantage of familiarity; • Provide flexibility in use and access; • Allow users to ‘change’ or ‘cancel’ actions and decisions (a forgiving system); • Limit the size of the app to limit barriers to download and retention; • Limit reminders and notifications as they may be considered intrusive; • Users may access the app for brief interactions and in busy environments, without headphones. 	<ul style="list-style-type: none"> • Only limited content and features are ‘mandatory’ to access through a tunnelled interface; • Where possible, existing iOS solutions and interface are used; • Users can access most of the features and content at any moment; • Users can change or cancel changes in a range of settings (e.g. reminders, wake up times) and quit attempt parameters; • The text was used instead of videos or audio-recordings.
Feedback from usability testing at UCL	<ul style="list-style-type: none"> • Provide explanation and justification for the study, tasks and data collection; • Offer easily accessible instructions about intervention features; • Offer all the information at hand and easily searchable; • Some icons and text should be bigger. 	<ul style="list-style-type: none"> • Onboarding to include clarification and justification of tasks and data collection; • Instructions about specific app features are always accessible; • Most information can be categorised under headings (as FAQ); • Text size should be increased.

Phase 2 involved several stages, which are listed in Box 3.3. As a first step, documentation was prepared for the IT team that outlined the requirements, assumptions, and the intervention overview, together with the proposed modes of delivery of the different BCTs. The guiding principles in Box 3.2 were considered in the process. The documentation included a list of research-related requirements for the app (e.g. a registration tunnel, baseline assessment, randomisation). Additionally, it was accompanied by PowerPoint slides presenting the wireframes (i.e. annotated designs of each of the planned screen in the app, including possible content, features, navigation buttons, decision rules, and data collection requirements), a proposed ‘map’ of the app and its navigation (i.e. how the individual screens connected to each other), and user journeys (i.e. anticipated pathways, or representations of possible scenarios for engagement with the individual app components and their consequences).

Next, the documentation was revised following consultations with the UTARG team, AM, the IT team. Once the agreement was reached on the shape of the version of NRT2Quit that would be used in the planned RCT, the software development initiated. The latter was organised around regular sprints during which I worked closely with the designers and the programmers preparing the individual features, testing them internally, and adapting them in light of any challenges that emerged.

Finally, during the usability testing session (≤ 20 min long), naïve users ($n=8$) recruited from among colleagues who were iPhone-users were asked to engage with a close-to-final version of NRT2Quit, and to complete a series of core tasks (e.g. registering, selecting and updating the quit date and NRT used, finding information about a selected NRT; see Appendix 3.2 for an instruction sheet used during these sessions) (Nielsen 2012, Zapata et al. 2015). This method allows identifying key barriers and usability issues already among five participants (Nielsen 2012). The sessions were not audio-recorded, but participants’ comments and any issues arising were noted down and discussed with the developers. Minor issues were rectified by the addition of instructions or other small modifications to navigation, but no large changes to NRT2Quit were possible at this stage (e.g. suggestions to add multimedia or imagery).

Box 3.3. The steps in Phase 2 involving implementing NRT2Quit onto an iPhone app

Phase 2 – Steps in implementing NRT2Quit onto iOS app (October 2014-March 2015).

1. The guiding principles for NRT2Quit development were identified. These are listed in Box 3.2.
2. Core research tasks (e.g. registration, randomisation) were identified to be embedded within the app.
3. Surveys and a list of data items to be saved through the app were created.
4. Documentation outlining the research-related requirements as well as the planned app functionality was created for consultation with the IT team.
The documentation included:
 - 4.1. A list of functional and technical requirements for the app;
 - 4.2. Annotated wireframes that outlined functionality, decision rules, content (text and graphics), and data collection for each screen in the app;
 - 4.3. A ‘map’ of the app and user journeys that linked the individual screens and functionality into a coherent 8-week intervention;
 - 4.4. Algorithms and decision rules for individual features (e.g. daily diary and feedback on NRT use);
5. Feedback on the planned intervention components and content was obtained from the UTARG and NCSCT;
6. Software development commenced;
7. App content (e.g. text, instructions, graphics) was finalised;
8. Internal app testing was conducted alongside app development;
9. Usability testing with naïve iPhone users informed small modifications;
10. App profile on iTunes was created together with additional documentation to accompany the app on the iTunes store (e.g. End User Licence Agreements; EULA; and other meta-data, e.g. keywords);
11. The project website was created;
12. The final version of NRT2Quit was published on iTunes.

3.5.2. Development of the control version of NRT2Quit

The control version of NRT2Quit was developed together with the intervention version. The process involved identifying which of the NRT2Quit components (i.e. features and content) would together constitute a minimum credible intervention (MCI) (Michie et al. 2017) that offered brief advice on quitting and NRT use. The process was conducted through discussions with TR, JB and RW.

3.6. Results of app development

3.6.1. NRT2Quit Platform

The NRT2Quit intervention and control app versions were embedded within a single NRT2Quit platform developed for iPhone (iOS 8.0+). Both app versions could be used offline, except for the features allowing to update the quit date or information on NRT used that required an internet connection to ensure that the information would be saved on the server. During offline use, data were saved locally and synchronised with the server during subsequent online use. Several features were embedded within the NRT2Quit platform to support conducting the trial: (1) a registration tunnel, (2) features for 1:1 randomization, (3) information about the study and contact details to the team, and (4) the date for the follow-up marked in the calendar within the app.

Both app versions offered support for up to two weeks before the quit date and eight weeks post-quit date. Appendix 3.3. lists the functionality and the BCTs implemented in the two app versions, and Appendix 3.4 outlines the architecture and user journeys through the two apps.

3.6.1.1. NRT2Quit – the intervention (complete) version.

Figure 3.3 presents the screenshots of the intervention (complete) app version. Additional screenshots of the intervention app are presented in the Appendix 3.5. The app was designed for daily use, which was encouraged through daily reminders and new daily tips. However, in recognition of the existence of ‘power-users’ who might want to explore all the app content at will (Herbec et al. 2014a), as well as in anticipation of the

attrition from the app (Eysenbach 2005), most of the app content was accessible immediately following the registration. Additionally, the app offered feedback and advice on NRT use that were minimally tailored to tobacco dependence (those who were smoking 11-19 cigarettes per day (CPD) and smoked the first cigarette within the first 5 minutes of wakening, or all those smoking ≥ 20 CPD were classified as heavy smokers; everyone else was classified as moderate smokers).

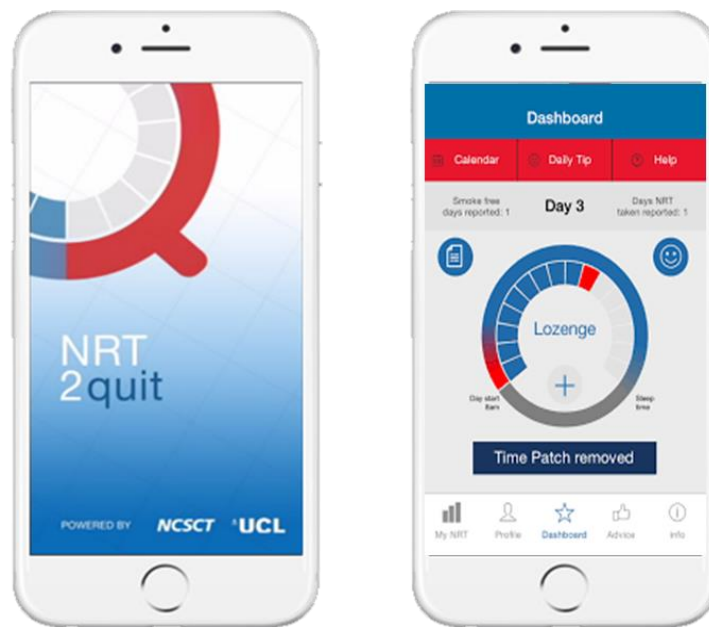


Figure 3.3. Screenshots of the landing screen and the dashboard in the intervention version of NRT2Quit app (displaying the ‘NRT Dial’).

NRT2Quit had four core components. First, (1) it delivered 25 BCTs (listed in Appendix 3.1) that offered comprehensive advice on each of the NRT products and its use, including features and information addressing potential reasons for non-adherence. These BCTs were delivered through (1.1) advice on NRT use embedded within the daily tips and help sections, which were tailored to the dependence level; (1.2) a comprehensive guide with advice on the selected NRT or combination NRT (the topics covered were: effectiveness, safety, use, common misconceptions, and side effects and managing side effects); (1.3) interactive questions-and-feedback sessions on smoking status and NRT used that addressed the reasons for poor adherence (e.g. relapse, successful cessation, concerns about NRT harms or side effects, experiencing withdrawal symptoms); (1.4) an interactive monitoring tool on the dashboard (referred

to as the ‘NRT Dial’ – see Appendix 3.6 for more information), which offered feedback on the amount of NRT used that was tailored to the time of the day (accounting for the wake up time that individual users inputted) and the type of NRT used; (1.5) marks on the calendar that reminded users about buying more NRT.

Secondly, it offered (2) 27 BCTs (listed in Appendix 3.3) supporting planning and carrying out a serious quit attempt. These BCTs were delivered through: (2.1) features for choosing a quit date within two weeks of app download (with options to change it) and an agreement to commit to quitting; (2.2) daily pre-quit and post-quit daily tips that aimed to boost motivation and self-regulatory skills; (2.3) a comprehensive guide with advice on preparing for the quit date, managing cravings and withdrawals, as well as on the range of other cessation medications available; (2.4) encouragement to develop an identity of a non-smoker who uses NRT as an integral part of a successful quit attempt; and (2.5) daily diary to record smoking status and NRT use.

The app also included (3) additional features: (3.1) a calendar that displays the quit date, (3.2) daily reminders to use the app (these could be disabled); (3.3) information about the study, the rationale for focusing on supporting adherence to NRT, and details about the team and their expertise; (3.4) tutorials and ‘help’ sections that guided the users through app’s core functionality and the NRT Dial.

3.6.1.2. NRT2Quit – the control (minimum credible) version.

Choosing the right control conditions for the evaluation of apps remains challenging (Michie and West 2016). It was decided that the most appropriate and realistic comparison for NRT2Quit would be a bespoke, minimum credible intervention (MCI) version of the app (Michie and West 2016). Such a version would be similar to the intervention app in many respects (e.g. the registration flow and app design) but would provide only limited yet believable support. The rationale for using an MCI is discussed in Chapter 2.5.2.

The control version of the app provided only minimal support with quitting and NRT use: (1) features for choosing a quit date in the next two weeks (with possible to change it); (2) very brief advice on how to use the selected NRT based on the information presented in the patient leaflets; (3) brief advice on quitting and managing

nicotine withdrawal, (4) progress monitoring (days to and since the quit date); and (5) a calendar that displayed the quit date and the 8-week questionnaire. It also included (6) brief information about the study and the app but without providing detailed information about the study rationale or teams' expertise. Users could (7) change the quit date and the NRT used.

3.6.1.3. NRT2Quit name and icon

A final step in the app development was selecting the app logo and name. The name 'NRT2Quit' was agreed through internal discussion. It was recognised that this name might not be immediately suggestive of the app functionality. Several other app names were considered, e.g. Stop Smoking with Nicotine or Be Smokefree, which offered a potentially better fit and these would be recommended for app optimisation. However, there were two advantages of using the name NRT2Quit. First, the app was created to be evaluated in an RCT in the first instance, and the app would be promoted primarily through participating pharmacies and information leaflets. Therefore, any limitations arising from using the name 'NRT2Quit' were expected to be offset by the recruitment campaign. Secondly, we wanted to limit the number of app downloads among potentially ineligible participants, namely smokers who search app stores for quitting apps without having bought NRT, as the app would have little relevance to them.

3.7. Discussion

NRT2Quit was developed to be a fully automated, standalone intervention for iPhones designed to aid cessation by offering easily-accessible advice, reassurance and encouragement to use NRT during a quit attempt. The app was developed systematically using theory and was guided by best clinical practice, research on digital interventions, as well as insights from usability testing and design principles. The behavioural analysis identified 25 BCTs relevant to addressing reasons for NRT non-adherence and suboptimal use that could also be implemented in the app given the resources available and in line with the APEASE criteria, such as monitoring of the behaviour, feedback on the outcomes of behaviour, and information about

consequences. Additionally, the app delivered 27 BCTs supporting quitting smoking in general.

The behavioural analysis guided by the BCWG has shown that NRT use is a complex behaviour with barriers to use present across all COM-B domains. Of these, several barriers within capability and motivation were judged to be feasible targets to address through a smartphone app. Although within the general BCT taxonomy V1 (Michie et al. 2013) there is one technique dedicated to medication use (i.e. 11.1 Pharmacological support), this current project identified as many as 25 BCTs relevant to NRT use that could be delivered in an app but also other interventions involving NRT provision. In comparison, a review (Morrissey et al. 2016) of apps for medication adherence available in Google Play and iTunes app stores found that they tended to include fewer than three BCTs on average each, and in total delivered only up to 12 out of the possible 93 BCTs (Michie et al. 2013). The BCTs most commonly used in those other apps were action planning, prompts or cues, self-monitoring and feedback on behaviour (Morrissey et al. 2016). In addition to these, NRT2Quit offered BCTs from other categories, including goals and planning, comparison of behaviour, social support, shaping knowledge, natural consequences, identify and self-belief.

However, some of the identified barriers to NRT use, such as limited physical skills or limited social and physical opportunity, are unlikely to be satisfactorily addressed through an app. Moreover, creating a system of advice that would be sufficiently personalised and responsive to the changing circumstances (e.g. changes to the NRT products used) and smokers' experiences with NRT use would require implementing much more sophisticated technological solutions than the simple decision trees implemented in NRT2Quit.

The BCWG offered a very valuable methodology to consider the problem of NRT non-adherence systematically and to organise and synthesise data from the different sources available. The use of additional theories and frameworks relevant to medication use allowed to expand on the COM-B and TDF frameworks. Specifically, the Compliance and Persistence framework (Cramer et al., 2008) has helped to consider the BCTs that should be present during initiation and continuation of NRT use, while the research on the Necessity-Concerns Frameworks (Horne et al. 2013) offered a helpful elaboration on the cognitive and motivational domains of the COM-B model.

However, the BCWG was not able to inform the mode of delivery of the selected components, neither regarding how to present the individual BCTs, nor how to combine them into an app-based programme. Until now there is still very little direct and empirical evidence to guide such decisions, also as the work on the BCT taxonomy and the possible mechanism of actions and modes of delivery continues (Michie et al. 2018). As a result, during NRT2Quit development, these decisions had to be made during the implementation phase and software development, were sometimes pragmatic, and informed by the consultations with the developers and NCSCT, where possible.

Similarly, it was only during the implementation stage and usability testing when additional necessary components and content were identified, such as the additional instructions for participants. Furthermore, certain modes of delivery that were potentially attractive, e.g. videos or other multimedia, were judged to be potential barriers to app download and retention, especially among smokers with data and storage limits. Similarly, audio-video content could help convey useful information, but its use would likely require privacy (or at least use of headphones) as well as extended periods to explore (relatively longer than reading text-based advice). Therefore, the final version of the app was offering the main BCTs in the form of text-based advice that was organised into easily accessible sections, but which were likely less engaging and attractive than multimedia.

3.7.1. Strengths and limitations

NRT2Quit was developed using a systematic and theory-based method outlined in the BCWG, was based on published evidence and clinical recommendations, and drew on several theories of behaviour and medication use that were judged to be relevant to NRT use. However, the process suffered from several notable limitations. First of all, the literature and materials used for the behavioural analysis were selected through a scoping review only. Therefore, it is possible that not all of the relevant publications and theories were considered in the analysis. Furthermore, as will be argued in the introduction to Chapter 4, the research on NRT use has been limited to assessing the motivational and cognitive factors. Nevertheless, the analysis of NCSCT resources had helped to conduct a broader behavioural analysis that also covered issues falling within physical skills and opportunity domain. Secondly, it was decided *a priori* that the

resulting intervention will be delivered through an app, which determined the decisions based on the APEASE criteria, and which also biased the behavioural analysis and selection of BCTs in line with what could be offered within an app.

Finally, except for usability testing among only a few users, the app development did not involve consultations with the end-users, as would be recommended by person-centred approaches and good practice on app development (Yardley et al. 2015, Blandford et al. 2018). This was because neither end-user engagement nor interview research were part of the original grant proposal, and were not feasible given the project timelines and resources.

3.7.2. Future directions

The newly developed NRT2Quit app should undergo a systematic evaluation to assess its effectiveness and acceptability among smokers. Moreover, the behavioural analysis reported in this chapter would have been strengthened if it also involved collecting and analysing primary data on each of COM-B domain from the smokers experienced with using NRT (Michie et al. 2011c). To address these limitations, and in line with the iterative intervention development (Michie et al. 2017, Wu et al. 2017), a separate COM-B-informed interview and think-aloud study about NRT2Quit were planned as part of this thesis (see Chapters 5 and 6).

Finally, the process of NRT2Quit development also showed that much more research is needed to systematically identify the best methods to deliver through apps the individual BTCs supporting NRT use. Furthermore, looking forward, it will be important to identify ways in which such an intervention could be further optimised using technological advances, e.g. machine learning, to offer appropriately tailored advice. Indeed, with better technology and greater resources it should be possible to deliver additional BCTs to those implemented in NRT2Quit, and possibly also with a better effect.

3.8. Conclusion

The BCWG provided a very useful scaffolding supporting a systematic

behavioural analysis that relied on the integration of information from diverse sources, including patient leaflets, consultations and resources from NCSCT, as well as published theories and evidence. The resulting NRT2Quit was highly complex in terms of functionality and the number of BCTs included. The app was developed together with its control version (a minimum credible intervention), and could be evaluated through a remote pragmatic RCT.

Chapter 4: The NRT2Quit trial

4.1. Chapter 4 overview

This chapter reports the methods and findings from a randomised control trial (RCT) of the NRT2Quit app.

4.2. Contributions

The first version of the trial protocol was prepared by Prof Tobias Raupach (TR). I was responsible for all tasks related to setting up and conducting this trial. This included: (1) revising the initial trial protocol (e.g. changing the plan for baseline and follow-up data collection) and securing approval for the amendments from the UCL Ethics Research Committee and data protection registration; (2) pre-registering the trial on ISRCTN registry; (3) preparing the recruitment materials, study information brochures and trial website, and recruiting and managing communication with participating pharmacies (including visiting the pharmacies); (4) overseeing recruitment and data collection; (5) planning data analysis, as well as cleaning and analysing the trial data; (6) writing up the findings. All final decisions regarding the trial protocol, trial progress, and data analysis were agreed in consultation with TR, Dr Jamie Brown (JB) and Prof Robert West (RW). Members of the UCL Tobacco and Alcohol Research Group (UTRG) provided feedback on the final protocol and the write-up.

4.3. Introduction

Chapter 1 (1.9.1., 1.10.3) has outlined numerous challenges associated with nicotine replacement therapy (NRT) use and potential reasons for the limited real-world effectiveness of over-the-counter (OTC) NRT, including poor adherence. Research suggests that improving NRT use could improve cessation success (Raupach et al. 2014, Ma et al. 2016, Cropsey et al. 2017, Schlam et al. 2018). Smartphone-based interventions could offer a new way to deliver relevant support with OTC NRT use, but research in this field remains limited.

The behavioural analysis reported in Chapter 3 has identified several candidate intervention targets for improving NRT use, especially the limited capability and motivation of smokers to optimise its use. These findings, together with additional sources of information, such as research on digital cessation interventions to date, theories, and best clinical practice, were used to design a new app for iPhones, called NRT2Quit. In its complete form, NRT2Quit delivered 25 behaviour change techniques (BCTs) addressing NRT use, and 27 BCTs addressing smoking cessation in general (see Chapter 3.6).

It was anticipated that NRT2Quit would support cessation efforts among smokers who were using NRT as part of their quit attempts, with a focus on those who purchased OTC NRT. However, this had to be ascertained through a randomised controlled design.

4.3.1. Aims

This study was conducted to evaluate the short-term effectiveness of NRT2Quit in comparison with a control version of the app - a minimum credible intervention (MCI). It was hypothesised that in comparison with the control app version, the intervention app would lead to greater (1) biochemically-verified 4-week abstinence assessed at 8-week follow; (2) self-reported use of NRT, (4) app usage, and (5) satisfaction with the app.

4.4. Methods

4.4.1. Design

The study was a pragmatic two-arm parallel, double-blind, RCT with 8-week follow-up. Randomisation (1:1 ratio) to the intervention and control arms was based on a random numbers function embedded within the app source code. The study was approved by the UCL Research Ethics Committee (ID: 5398/001) and was pre-registered on ISRCTN registry (ISRCTN33423896). The reporting of the trial follows the CONSORT (Altman et al. 2001) and TIDieR guidelines (Hoffmann et al. 2014).

4.4.1.1. Changes to the protocol.

After recruitment initiated, three changes to the protocol were made, which was primarily motivated by very slow recruitment into the trial. First, the 7-month follow-up was suspended as it was judged an inappropriate use of resources to follow-up such a small sample. Secondly, the trial was terminated prematurely after 18 months as it was not feasible to recruit the target sample. Finally, eligibility criteria were changed. Specifically, they initially specified that smokers had to purchase at least one OTC NRT product, as it was assumed that those purchasing it on prescription (Rx) would already receive some support with cessation and medication use. Among our sample of otherwise eligible participants, almost a third obtained Rx NRT. However, Rx users did not report accessing more support from healthcare professionals (HCPs) with NRT use than OTC users did (OTC only: 30.0%, Rx only: 21.4%, and those using both OTC and RX: 13.3%, $p=.60$). Therefore, it was decided that participants using only Rx NRT would be included in the trial, but excluded in sensitivity analyses.

4.4.2. Participants

4.4.2.1. Participant recruitment

Recruitment lasted between 23rd March 2015 and 15th September 2016 and was conducted remotely with no involvement of the researchers. Participants were recruited through self-identification and self-selection. Recruitment materials were delivered to around 300 UK community pharmacies, mostly through their central managerial offices, with instructions to display and distribute the leaflets among smokers who purchase NRT (see Appendix 4.1 for the recruitment materials). The materials directed potential participants to the study website with a detailed study information sheet, information about data processing, the End User Licence Agreement (EULA), and links to download the app for free. The app could also be found through online searches and on iTunes. Participants provided informed consent before participating.

4.4.2.2. Eligibility criteria

To participate, participants had to own an iPhone and download NRT2Quit on

their device. Eligibility for the trial was assessed based on the information provided during the registration within the app. The inclusion criteria were: (a) being UK-based, (b) aged ≥ 18 years, (c) smoking daily at least ≥ 10 cigarettes/day, (d) use of at least one NRT product, (e) downloading the app to quit, (f) completing the registration process, including providing plausible and complete contact details and (g) providing consent to participate that also implied no contraindications for NRT use.

4.4.2.3. Sample size

Based on an *a priori* power calculation (with $\alpha=0.05$, two-tailed), the target sample size needed was $n=1186$ to have 80% power to detect an expected effect size of $OR=1.7$, or 5% difference in self-reported abstinence rates at 8-week follow-up (8% in the control and 13% in the intervention arms; attrition from the study was expected to be as high as 50% from each group (Eysenbach 2005) hence the low cessation rates expected for the intention-to-treat, ITT, analysis). While small, this effect size would be potentially cost-effective (West 2007a). Due to very slow recruitment, the trial was terminated with only 41 eligible participants recruited.

4.4.2.4. Note on the recruitment of pharmacies supporting study promotion

The community pharmacies supporting recruitment into the NRT2Quit trial were identified and contacted in one of two ways. First of all, nation-wide pharmacy chains (initially ASDA, followed by Well Pharmacy - former Co-Op pharmacies, and Superdrug) were approached through their managerial and communications teams in order to identify stores which would participate in the recruitment campaign and to establish best ways to engage the individual pharmacies. ASDA's support was secured before app development commenced. The recruitment campaigns could be run only with the prior agreement and oversight from the management teams, and hence communication with these pharmacies was only through official, internal communications channels. Dates for the recruitment were selected so that they would not collide with busy festive seasons, such as Christmas and New Year's Eve, or other important store events (e.g. refurbishments). Finally, recruitment materials, including leaflets (ASDA and Superdrug) and electronic posters near the tills (Well Pharmacy),

were created by myself or designers and approved by the pharmacy management teams. Secondly, independent pharmacies were approached via email or Twitter, and local pharmacies around Bloomsbury in London were opportunistically visited by myself to discuss the study and recruitment directly with the pharmacy staff.

The study was initially promoted using posters and leaflets distributed across 250 ASDA pharmacies in the UK (250 leaflets were posted to each pharmacy; March-June 2015). This was supplemented by leaflets distributed in several local independent pharmacies around Bloomsbury in London, by on-screen advertisements next to the tills in around 20 Well Pharmacies (Autumn 2015), and by leaflets distributed in around 20 Superdrug pharmacies throughout London (Spring 2016).

Due to the busy pharmacy environment and lack of resources, it was not possible to organise training about the study and its procedures with the pharmacy staff. However, each pharmacy received printed short instructions about the study and recruitment. These explained the study and the app and instructed the pharmacy staff to display the leaflets close to the counters, to provide a leaflet to everyone purchasing an NRT product, and to encourage these customers to join the study and download the app.

The lack of direct communication with the pharmacy staff was suboptimal, but at the trial onset this was considered sufficient for several reasons: (a) the pharmacy staff had a relatively limited role of directing potential participants to the recruitment materials, and did not need to conduct any research-related tasks, such as eligibility screening; (b) the pharmacy environment and workflows were busy, and it was often not possible to arrange for a discussion of the study with the individual pharmacies, and (c) it was judged impractical and too resource-consuming to establish more formal contact with the pharmacies, especially given the lack of budget to reimburse pharmacy staff for supporting recruitment. Finally, (d) it was anticipated that even with a low-intensity recruitment campaign and low interest in the study, a sufficient number of pharmacy customers who obtain a leaflet would enrol into the study (given the number of leaflets, a conversion rate of 2% would suffice, i.e. 1,200 out of 63,000 leaflets).

However, already within a week of launching the recruitment campaign through ASDA pharmacies, it became clear that the recruitment was much slower than anticipated. I visited several of the London-based ASDA stores to identify barriers to recruitment. The visits resulted in several observations. First of all, each pharmacy was

organised differently, and displayed the leaflets in different areas, e.g. near the cashier, pinned to boards, or placed on tables with other informational and promotional materials. Some pharmacies had no leaflets on display at the time (some did not remember receiving the box or did not unpack it, and others reported distributing all the leaflets already). Given the number of other leaflets and materials made available to pharmacy customers, the recruitment leaflets for NRT2Quit were not very visible. Furthermore, some pharmacies were already running stop smoking services or campaigns. In this context, our study and app might have been perceived as potential competition for these programmes.

Secondly, and more importantly, ASDA pharmacies were often part of larger ASDA supermarkets, with NRT products sold both in the pharmacy and in the main supermarket section. The former was dedicated to preparing and dispensing Rx medications while the customers shopped, while in the latter NRT was displayed together with other OTC medications and cosmetics. Separate teams managed the pharmacy and supermarket floors, and our recruitment materials could not be placed beyond the pharmacy sections. Meanwhile, the general section tended to have a greater selection of NRT products, sometimes at lower prices.

Finally, the pharmacy assistants engaging directly with the customers did not receive information about the study and tended to have limited knowledge of what NRT was, or whether e-cigarettes were a type of NRT. Some were also confused as to whether the name of our app, i.e. NRT2Quit, was referring to a brand of NRT that they did not sell.

Taken together, it was clear from these observations that recruitment through community pharmacies using the ‘passive’ methods (i.e. leaflets) would not recruit sufficient numbers of participants for the NRT2Quit trial.

4.4.3. NRT2Quit intervention and control arms

Chapter 3 reports in detail on the development and functionality of the intervention and control versions of NRT2Quit. Neither of the app version was modified during the trial.

4.4.4. Procedures

Appendix 4.2 presents the participant flow through the RCT embedded within the app and other procedures, and Appendix 4.3. summarised the trial procedures and measurements. Following app download, potential participants entered a registration tunnel that included a summary of the study information sheet and links to the study website, and required the users to provide informed consent, contact details and baseline data, as well as to enter data on the NRT purchased, and to set the quit date. After registration participants were automatically randomised to the intervention or control versions of the app and assigned a unique ID. Participants received an email confirming registration with a link to the study website and contact details to the researchers. The registration and contact details were checked manually for completeness. Duplicate registrations were excluded.

The follow-up took place at eight weeks after registration (18th May 2015-22th November 2016). It was assumed that many participants would delete the app before the follow-up date, and therefore the follow-up data were collected through an online survey in anticipation of the participants deleting the app. The links to the survey were distributed through personalised e-mails sent using the Opinio software at UCL (up to 3 reminders across ten days, scheduled for different times on each of the day) (Brown et al. 2014). Participants failing to complete the survey were contacted over the telephone (up to three calls across a week, at different times of the day (Brendryen and Kraft 2008)) to assess their smoking status only. Participants self-reporting prolonged abstinence were posted a saliva kit with instructions, a £20 high street gift voucher as reimbursement, and a freepost envelope addressed to the laboratory and asked to post the samples as soon as possible (Brown et al. 2014). See Appendix 4.4 for the letter that was posted with the saliva kit.

Early in August 2016 it was decided that the trial will be terminated due to the slow recruitment that could not be rectified. Bayes factors (see section 4.5.6 on data analysis) were calculated on the self-reported cessation outcome on 18th August 2016 (after 39 eligible participants were recruited), but no hypothesis testing was performed. Before NRT2Quit was removed from the iTunes store on 15th September 2016, two additional participants meeting eligibility criteria joined the study and were included in

the analysis reported here. All current users could still use the app. All study procedures, including the follow-up for all participants, were conducted blind to study arm allocation.

4.4.5. Measurements

All surveys were designed to be as short as possible to limit the burden on participants and thus limit the risk of attrition and missing data.

Baseline assessment

The baseline questionnaire assessed socio-demographic characteristics (age, gender, having post-16 years of age education vs. not), smoking and quitting history (the Heaviness of Smoking Index (Etter et al. 1999); when the last quit attempt was made, and past use of cessation aids), and reasons for joining the study (to quit smoking/other). Participants also provided information about the NRT type purchased (NRT patch/fast acting NRT/combination), how they obtained NRT (OTC/Rx/both); and whether they received any support with NRT use from HCPs (yes/no) (see Appendix 4.5).

Primary outcome

Appendix 4.6 lists the follow-up questionnaire. The primary outcome was self-reported 4-week prolonged abstinence assessed at 8-week follow-up, verified by saliva cotinine levels of <15ng/mL (West et al. 2005) or, among participants reporting NRT or e-cigarette use: anabasine levels of <1ng/mL (Benowitz et al. 2002, Brown et al. 2014). Participants lost to follow-up were assumed to have resumed smoking, as per the intention-to-treat (ITT).

At the time of trial registration, there was limited data to inform the salivary anabasine cut-off values. The pre-registered cut-off for the salivary anabasine was decided in consultation with the processing lab in 2014. After having conducted more research since, the lab recommended in 2018 a lower cut-off value for salivary anabasine (<0.2ng/mL). The trial protocol was not amended, but the results for the

lower cut-off are reported in the footnote of Table 4.2.

Secondary outcomes

Secondary outcomes were: (1) the follow-up parameters: follow-up rate, the re-contact channel (online survey/phone), and the proportion of saliva samples returned. The online survey at 8-week follow-up assessed (see Appendix 4.6.): (2) the total number of cigarettes smoked in the past 4 weeks (none/ $<5/\geq 5$); (3) adherence to NRT: (i) use of NRT on the follow-up day (yes/no), (ii) the number of weeks when NRT was used ($<5/\geq 5$ weeks), (iii) the number of days in those weeks NRT was used (every day/not every day); (4) use of other cessation support, e.g. other medications, behavioural support, or self-help support (yes/no); (5) satisfaction: how helpful the NRT2Quit app was for (i) quitting smoking and (ii) using NRT (1=not at all, 5=extremely helpful), (iii) whether the participant would recommend the app to others wanting to quit (yes/no). Additionally, (6) data on app usage was collected: (i) number of logins, and (ii) the number of days users logged in on. Due to the structure of the app database, data on time spent using the app, or on accessing individual app features were not available.

4.5.6. Data Analysis

The primary outcome was analysed using Fishers' exact test. Unadjusted logistic regressions were conducted for the dichotomised cessation outcomes, and odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. In exploratory sensitivity analyses participants who were reporting using only Rx NRT (n=14), or for whom that data were missing (n=3), were excluded. All other analyses were pre-planned.

Bayes Factors were calculated for the smoking outcomes as they can distinguish between the likelihood of both the null and alternative hypotheses, and assess whether the data provide an insensitive test of the hypotheses (Dienes 2008, Dienes 2014, Brown et al. 2016, West 2016). Bayes Factors were calculated using an online calculator that is available for free⁶. We used a uniform H1 distribution with a possible expected effect

⁶ http://www.lifesci.sussex.ac.uk/home/Zoltan_Dienes/inference/Bayes.htm

size between OR=1 and OR=3 versus an H0 of OR=1. In sensitivity analyses, we used a conservative H1 with a half-normal distribution with the mean of the log OR of 0, and the standard deviation corresponding to expected effect sizes of OR=1.2, OR=1.7, and OR=2.5 (Brown et al. 2016 , Naughton et al. 2017). This distribution means that plausible values have been represented between zero and twice the effect size, with smaller values more likely.

Descriptive statistics are presented for baseline and all secondary outcomes. Categorical variables were compared using Fisher's exact test, chi-square test, and Linear-by-Linear association for ordered categories, and continuous variables using the independent t-test or Mann-Whitney U-test for data that were not normally distributed. Data on app usage were not normally distributed, but both medians (IQR) and means (SDs) are reported to enable comparison with other published studies. All tests were 2-sided, and alpha was set to 5%.

4.5. Results

4.5.1. Participants

In total 41 participants met eligibility criteria for the study, of which 16 (39.0%) were randomised to the intervention app. Figure 4.1 shows the flow of participants, and Table 4.1 presents the baseline characteristics. About half of the participants were female, had post-16 years of age education, and made an attempt to quit in the past 12 months. Almost all participants used cessation support before, most commonly NRT (41.5%) and e-cigarettes (24.4%). At enrolment, 43.9% of participants reported they were using a fast-acting NRT product on its own, and 26.8% were using combined NRT. A quarter of participants obtained advice from HCPs on NRT use.

Figure 4.1: Flowchart of participants in the NRT2Quit trial.

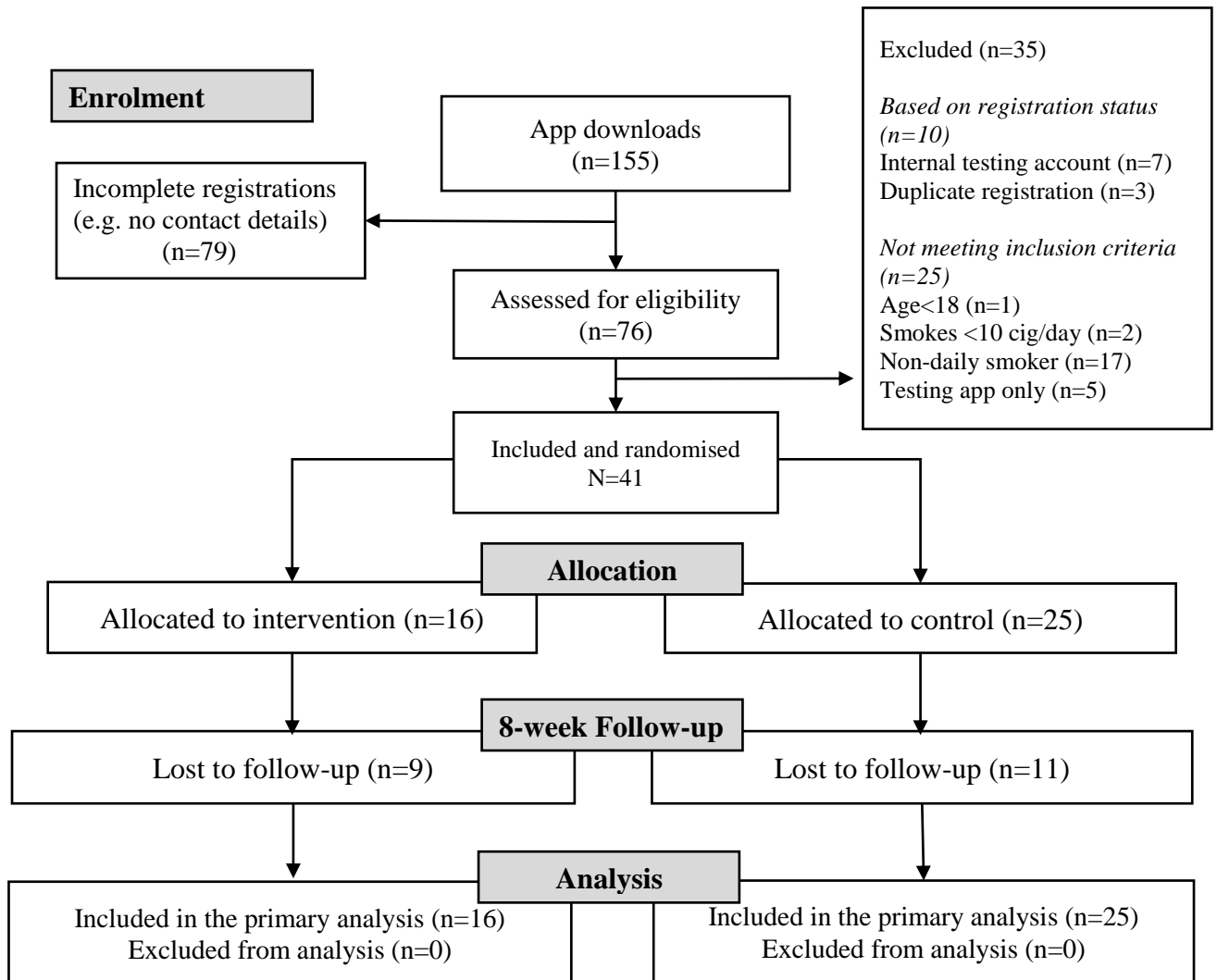


Table 4.1. Baseline characteristics of the NRT2Quit trial participants.

	Total (n=41)	Intervention (n=16)	Control (n=25)
Female % (N)	51.2 (21)	37.5 (6)	60.0 (15)
Age (years) Mean (SD)	33.4 (10.02)	32.1 (9.07)	34.3 (10.67)
Has post-16 yrs qualification % (N)	51.2 (21)	56.3 (9)	48.0 (12)
CPD¹ Mean (SD)	18.7 (6.54)	17.9 (5.39)	19.2 (7.24)
Smokes within 5min of waking up % (N)	39.0 (16)	37.5 (6)	40.0 (10)
HSI, Mean (SD)	3.2 (1.32)	3.3 (1.24)	3.2 (1.39)
When made a last quit attempt % (N)			
past 12 months	48.8 (20)	68.8 (11)	36.0 (9)
>12 months ago	39.0 (16)	18.8 (3)	52.0 (13)
Never	12.2 (5)	12.5 (2)	12.0 (3)
How learned about the app			
Pharmacy	56.1 (23)	31.3 (5)	72.0 (18)
App store or google search	26.8 (11)	37.5 (6)	20.0 (5)
Other	17.1 (7)	31.3 (5)	8.0 (2)
Used any cessation aids in the past[#] % (N)			
No aids	7.3 (3)	12.5 (2)	4.0 (1)
NRT	41.5 (17)	62.5 (10)	28.0 (7)
Other medications	12.2 (5)	0.0 (0)	20.0 (5)
Stop smoking services	9.8 (4)	16.0 (4)	0.0 (0)
Apps	2.4 (1)	0.0 (0)	4.0 (1)
E-cigarettes	24.4 (10)	18.8 (3)	28.0 (7)
Other	2.4 (1)	2.4 (1)	0.0 (0)
Type of NRT used at baseline			
Patch only	29.3 (12)	37.5 (6)	24.0 (6)
Fast acting NRT only	43.9 (18)	37.5 (6)	48.0 (12)
Combination of patch and fast acting NRT	26.8 (11)	25.0 (4)	28.0 (7)
Reasons for selecting NRT^a			
Used it before	40.0 (16)	50.0 (8)	33.3 (8)
Recommendations from a HCPs	15.0 (6)	18.8 (3)	12.5 (3)
Other, incl. wanting to try something new	45.0 (18)	31.3 (5)	54.2 (13)
Obtained advice from HCPs on NRT use^b	20.5 (8)	20.0 (3)	20.8 (5)
Method of obtaining NRT^b			
OTC only	25.6 (10)	20.0 (3)	29.2 (7)
Rx only	35.9 (14)	33.3 (5)	37.5 (9)
OTC and Rx	38.5 (15)	46.7 (7)	33.3 (8)

CPD = cigarettes per day; HSI = the Heaviness of Smoking Index (Etter et al, 1999); NRT = nicotine replacement therapy; [#]participants could select multiple answers, ^aavailable for 40 participants; ^bavailable for 39 participants ; OTC = over the counter; Rx = on prescription

4.5.2. Follow-up

At 8-week follow-up, 51.2% of participants were successfully contacted (43.8% among the intervention and 56.0% among the control arm, see Table 4.2). Only 12 (29.3%) of the participants completed the online follow-up survey that assessed additional secondary outcomes. The rates were similar across the study arms.

Table 4.2. Follow-up rates and channels in the NRT2Quit trial.

	Total (n=41)	Intervention (n=16)	Control (n=25)	P^a
Follow-up status		% (N)		
Successfully contacted at 8 weeks	51.2 (21)	43.8 (7)	56.0 (14)	0.53
Follow-up channel				
Survey	29.3 (12)	31.3 (5)	28.0 (7)	0.50 ^b
Phone	22.0 (9)	12.5 (2)	28.0 (7)	
Not contacted	48.8 (20)	56.3 (9)	44.0 (11)	
Completed the survey on secondary outcomes	29.3 (12)	31.3 (5)	28.0 (7)	1.00 ^b
Returned saliva samples when invited	85.7 (6/7)	100.0 (4/4)	66.7 (2/3)	0.43

^aFisher's exact test for 2x2, and chi-square for other categorical variables; ^bdue to small sample size, a considerable proportion of cells in chi-square analyses had expected count of <5)

4.5.3. Cessation outcomes

Table 4.3 presents cessation outcomes assessed at the 8-week follow-up. In the ITT analysis, abstinence was biochemically verified for 14.6% of trial participants (25.0% among the intervention and 8.0% among the control, p=0.19). The results changed only minimally when the <0.2ng/mL cut-off for salivary anabasine was used. Self-reported abstinence was reported by 17.1% of participants (25.0% vs. 12.0%, p=0.40). The Bayes factors calculated for biochemically-verified and self-reported abstinence suggested the data were insensitive to distinguishing between the null and experimental hypotheses. The results did not change when the analysis was limited to participants who bought at least one of their NRT OTC (not reported here).

Table 4.3. Cessation outcomes in the NRT2Quit trial (smoking status in past four weeks assessed at 8-week follow-up).

	Total (n=41)	Intervention (n=16)	Control (n=25)	<i>p</i> *	OR (95% CI)	<i>p</i> *	Bayes factor ^a uniform (OR of 1 to 3)	Bayes factor ^a half normal (OR=1.2, 1.7, 2.5)
Primary cessation outcome (verified)		% (n)						
Smoking status ITT¹								
Not smoking	14.6 (6)	25.0 (4)	8.0 (2)	0.19	3.83 (0.61-24.02)	0.15	1.92	1.24, 1.70, 1.99
Assumed to be smoking	85.4 (35)	75.0 (12)	92.0 (23)		-		-	-
Secondary outcome (self-reported)		% (n)						
Smoking status ITT								
Not smoking	17.1 (7)	25.0 (4)	12.0 (3)	0.40	2.44 (0.47-12.78)	0.29	1.52	1.18, 1.41, 1.43
Assumed to be smoking	82.9 (34)	75.0 (12)	88.0 (22)		-		-	-
Smoking status ITT								
Not smoking	17.1 (7)	25.0 (4)	12.0 (3)	0.12	-	-	-	-
Smoking <5 cigarettes	2.4 (1)	6.3 (1)	0.0 (0)		-	-	-	-
Smoking ≥5 cigarettes	31.7 (13)	12.5 (2)	44.0 (11)		-	-	-	-
Not contacted/assumed to be smoking	48.8 (20)	56.3 (9)	44.0 (11)		-	-	-	-

¹Two subjects self-reporting not smoking had salivary cotinine >100ng/mL and anabasine levels=0.2ng/mL. When using a lower cut-off value for salivary anabasine level suggested recently by the processing lab (<0.2ng/mL), 18.8% of intervention and 4.0% of control participants met criteria for biochemical verification, OR=5.54 (95% CI: 0.52-58.76). *for 2x2 analysis the p-value reported is for Fisher's Exact Test; otherwise for Pearson Chi-square; ITT=Intention to Treat ^a Bayes factor <1/3 suggests support for the null hypothesis, Bayes factor >3 suggest support for the experimental hypothesis, and intermediate values suggest the data are insensitive (Dienes 2008, Dienes 2014) (Beard et al. 2016a) (Brown et al. 2016).

Table 4.4. Secondary outcomes in the NRT2Quit trial: app use, NRT use and satisfaction.

	Total (n=41)	Intervention (n=16)	Control (n=25)	P^a
App usage after initial registration*				
Logins, Median (IQR)	1.0 (28.0)	2.5 (12.0)	0 (2.0)	0.01
Mean (SD)	5.1 (11.17)	10.2 (15.82)	1.8 (4.75)	0.05 ^b
Logins, % (N)				
0 logins	41.5 (7)	25.0 (4)	52.0 (13)	0.01^c
1 login	12.2 (5)	6.3 (1)	16.0 (4)	
2-5 logins	31.7 (13)	3.7 (6)	28.0 (7)	
≥ 6 logins	14.6 (6)	31.3 (5)	4.0 (1)	
Days logged in, Median (IQR)	1.0 (10.0)	1.5 (5.0)	0.0 (1.0)	0.03
Mean (SD)	2.7 (5.98)	5.1 (8.35)	1.2 (3.18)	0.10 ^b
Days logged in % (N) **				
0 days	41.5 (17)	25.0 (4)	52.0 (13)	0.02^c
1 day	29.3 (12)	25.0 (4)	32.0 (8)	
2-7 days	19.5 (8)	31.3 (5)	12.0 (3)	
≥ 8 days	9.8 (4)	18.8 (3)	4.0 (1)	
Survey responses***				
	(n=12)	(n=5)	(n=7)	
NRT use and other cessation behaviour				
		% (N)		
Made a serious QA since registering	91.7 (11)	100.0 (5)	85.7 (6)	1.00
Used additional cessation support	83.3 (10)	60.0 (3)	100.0 (7)	0.15
Used NRT in past 8 weeks	83.3 (10)	80.0 (4)	85.7 (6)	1.00
Used NRT on the day of follow-up	58.3 (7)	100.0 (5)	28.6 (2)	0.03
Used NRT for ≥ 5 weeks	66.7 (8)	100.0 (5)	42.9 (3)	0.08
Used NRT every day in weeks when NRT used	58.3 (7)	40.0 (2)	71.4 (5)	0.56
App satisfaction				
App helpful for quitting (1-5)[#], Median (IQR)	3.0 (1.0)	3.0 (1.0)	2.0 (2.0)	0.07
Mean (SD)	2.6 (.90)	3.2 (.45)	2.14 (.90)	0.04^b
App helpful for NRT use (1-5)[#], Median (IQR)	3.0 (3.0)	4.0 (1.0)	2.0 (2.0)	0.02
Mean (SD)	2.7 (1.15)	3.6 (.55)	2.0 (1.00)	0.01
Recommend to others % (N)	58.3 (7)	100.0 (5)	28.6 (2)	0.01

*app usage includes data from any new sessions after registration was completed and excludes the time of registration and initial app exploration following the registration; data on usage and logins may be an underestimation as app use during offline use would not synchronise with the study database if the participants did not access the app online on any future occasion; **not consecutive days; ***data assessed via online survey among 12 respondents; [#]1=not at all, 5=extremely. ^aFisher's exact test for 2x2, and chi-square for other categorical variables; ^bunequal variance; ^cLinear-by-Linear association; QA: quit attempt; IQR: interquartile range.

4.5.4. NRT use

Among participants who completed the online survey (n=12), adherence rates were relatively high. The differences between study arms were not statistically significant except for having used NRT on the survey day (100% vs 28.6%, p=0.03, see Table 4.4).

4.5.5. App usage

App usage (see Table 4.4) was low and positively skewed in both conditions, but there was an indication that the intervention participants engaged more (e.g. a median number of logins: 2.5 vs 0, p=0.01). The usage data are possibly an underestimation, however, as offline use might not have been saved and other technical issues might have prevented data synchronisation with the server.

4.5.6. Satisfaction

Among the 12 participants who completed the survey (see Table 4.4), the intervention participants gave higher median ratings of the app as being helpful with NRT use (p=0.02). Additionally, all intervention participants stated they would recommend the app to others, compared with 28.6% among the control participants (p=0.01).

4.6. Discussion

4.6.1. General summary

Recruitment through the community pharmacies into the NRT2Quit trial proved infeasible. Among the recruited participants only a sub-sample completed all follow-up questions, which further limited app evaluation. Among the recruited sample, the intervention app version had somewhat greater self-reported (25.0% vs 12.0%) and biochemically-verified short-term quit rates (25.0% vs 8.0%), but the differences were not significant when assessed using traditional statics (p-values). Bayes factors

suggested ‘anecdotal’ evidence that NRT2Quit could aid cessation, but showed that the data were insensitive to distinguish between experimental and null hypotheses (Naughton et al. 2017). Among this self-selected sample, the intervention participants reported greater engagement and satisfaction with the app, and possibly longer duration of NRT use. These findings would warrant conducting an adequately powered study, but establishing a feasible recruitment channel in the real world will be a major challenge.

The cessation rates reported in this study were similar to those found in other research, but few studies conducted biochemical verification of abstinence (Bricker et al. 2014, Bricker et al. 2017, BinDhim et al. 2018). Although the trial seems to bring some support for the hypothesis that NRT2Quit could aid cessation, the results should be interpreted with caution in light of the many methodological limitations. Nevertheless, the findings are encouraging, especially as the control app included several evidence-based BCTs, including goal setting and monitoring (West et al. 2010, Lorencatto et al. 2012). However, the design of the current study did not allow to determine what could be driving the effect, if it was real. Due to the small sample, it was also not possible to explore predictors of cessation.

Attrition from the study was high, and engagement with the app was low, although the mean number of logins was comparable to those found in other digital stop smoking interventions (Bricker et al. 2014, Brown et al. 2014, Taylor et al. 2017). The lack of contact with the researchers at the enrolment and the lack of incentives for completing the follow-up survey (except the reimbursement for providing the saliva samples) could explain the slow recruitment and poor follow-up (Bricker et al. 2014). However, NRT2Quit offered access to the core content immediately following the registration, and it is possible that participants accessed the relevant advice already during their first visit, which might have been sufficient to optimise NRT use.

4.6.2. Low recruitment rate

We managed to recruit less than 4% of the target sample despite securing access to more than 300 pharmacies across the UK. Relying on recruitment via printed materials distributed in community pharmacies, but with no researcher or HCPs

engagement, is likely to be unsuccessful.

There were also other potential reasons for the low recruitment. The trial took place during a phase marked by a decline in NRT use and an increase in popularity of electronic cigarettes, which reduced further an already small pool of potential participants (Beard et al. 2016b). Secondly, only an iOS version of the app was developed, thus excluding users of Android smartphones from the trial. However, it is unlikely that offering an Android version of the app would sufficiently improve recruitment. As has been reviewed in Chapter 2.6.2, iOS and Android users differ on a range of characteristics and app use, and iOS users are more likely to download and use health apps and engage with more content (BuildFire 2017, Ubhi et al. 2017). iOS users also tend to be better off financially (Schonfeld 2011, Shaw et al. 2016, BuildFire 2017) and thus may have more disposable income to buy OTC NRT. On the other hand, given that lower socio-economic status is associated with higher smoking rates, creating an Android version of NRT2Quit in the future should be considered.

4.6.3. Study strengths and limitations

Contrary to several other studies of cessation apps (Ubhi et al. 2015, BinDhim et al. 2018), this study collected contact details through the app and followed-up participants outside of the app. It also involved biochemical validation of abstinence, which had a good response rate. The study also resulted in important insights into the challenges of recruitment. Finally, the study had greater ecological validity in comparison to the earlier studies as it did not involve incentives, reimbursement for engagement, nor contact with the HCPs or the researchers (Bricker et al. 2014, Buller et al. 2014, Bricker et al. 2017).

However, the study had important limitations. The follow-up rates were moderate, and lower than in the other studies of DBCIs for smoking (Brendryen and Kraft 2008, Bricker et al. 2014). Moreover, the response to the online survey was even lower, which limited the availability of data on NRT use and satisfaction. We were also unable to assess adherence to NRT in sufficient detail given the attrition and complexity of NRT use (e.g. as discussed in Chapter 2.5.5). Only limited data on app use were available. Additionally, the burden of joining the current trial was higher than that associated with

accessing other quitting apps available on the market. It is very likely that the recruited participants, as well as those who responded to the follow-up, were more motivated than the general population of smokers. While this should not have impacted the main results (as motivation would have been similar in the control and intervention arms), the findings should be interpreted with caution, and their generalisability is limited. Finally, if the app did improve quitting, we could not establish if this was accomplished through the support on NRT use and better NRT adherence, or through having access to more comprehensive cessation support in general.

4.6.4. Future directions

The findings suggest that further development and evaluation of NRT2Quit may be worthwhile. More research is needed to establish effective recruitment strategies for such apps. Additionally, evaluation of NRT2Quit as part of face-to-face support could help establish if the app could augment cessation and medication use in this context as well. Assessing the app as part of cessation services may also result in better uptake. Moreover, recruiting participants into this online and remote trial required concealing the differences between the two app versions that prevented promoting the features and advice offered within the intervention app. It is possible that actively promoting the benefits of the intervention version of NRT2Quit, or offering only this version, could also lead to better uptake. Thus, assessing NRT2Quit in a study with a waitlist control or an observational study, may be a possible future direction. However, future studies would need to involve updating the app designs and navigation to reflect the changing trends in the app ecosystem (see Chapter 2.6).

4.7. Conclusion

In a limited evaluation disrupted by extremely poor recruitment, there was preliminary, inconclusive evidence that NRT2Quit has a promising effect on short-term quit rates, medication use, app use, and satisfaction. These results would need to be confirmed in definitive studies. Future research will need to identify more effective recruitment strategies.

Chapter 5: COM-B-informed qualitative interview study on NRT use

5.1. Chapter 5 Overview

This chapter reports findings from a theory-informed qualitative study with smokers and ex-smokers who used nicotine replacement therapy (NRT) to quit in the past. The study explored their experiences with medication use and with the support they received.

5.2. Contributions

I initiated and designed this study, developed the interview guide and data collection instruments, secured ethical approval and data protection registration, oversaw recruitment, conducted the interviews, analysed the data, and wrote up the findings. Prof Robert West (RW) provided feedback on the interview guide. Dr Ildiko Tombor (IT) contributed to second-coding of the interviews and internal validation of the coding framework. IT, Dr Lion Shahab (LS), and RW provided feedback on the manuscript prepared for publication based on the findings.

5.3. Dissemination

A version of this chapter was published in a peer-reviewed journal:

Herbec, A., Tombor, I., Shahab, L., & West, R. (2018) “If I’d known...” – a theory-informed systematic analysis of missed opportunities in optimising use of nicotine replacement therapy and accessing relevant support: A qualitative study. *Int J Behav Med*. DOI: 10.1007/s12529-018-9735-y. Available as: Open Access (distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>)).

5.4. Introduction

As has been discussed in Chapter 1.10.2, there is a disconnect between the effectiveness of NRT found in clinical trials and the effectiveness observed when NRT is purchased over the counter (OTC) and used without professional support (Stead et al. 2012, Kotz et al. 2014b, Kotz et al. 2014a, Anthenelli et al. 2016). A possible reason for this is the suboptimal use of NRT. Insofar as NRT is effective at improving cessation, it is reasonable to expect that improving NRT use could increase quit attempt success (Raupach et al. 2014). Understanding the experiences, needs and preferences of smokers regarding NRT use and support with NRT use could help inform effective and acceptable interventions.

Chapter 3 reports the results of a behavioural analysis of NRT use that was informed by COM-B and the Theoretical Domains Framework (TDF) (Michie et al. 2014), and which drew on information from the published literature, best clinical practice, and theories relevant to NRT use. The results of the analysis contributed to the development of the NRT2Quit app. However, in the process no research was conducted with the end-users to identify their needs and other possible factors that could be affecting NRT use.

Furthermore, although a wide range of factors were shown to affect adherence to different medications, including financial resources and support received (Michie et al. 2011c, Michie et al. 2012d, Jackson et al. 2014), much of the research and interventions on NRT use to date focused on cognitive and attitudinal factors in NRT use (Etter and Perneger 2001, Bansal et al. 2004, Mooney et al. 2006, Shiffman et al. 2008a, Vogt et al. 2008, Yerger et al. 2008, Foulds et al. 2009, Carpenter et al. 2011, Ferguson et al. 2011, Beard et al. 2012, Kardas et al. 2013, Silla et al. 2014, Tsang et al. 2014). It is likely, however, that additional factors play a role in NRT use, including environmental and contextual factors, which have received much less scholarly attention.

The findings from the NRT2Quit trial reported in Chapter 4 brought very limited support for its effectiveness and showed that recruiting smokers into such trials may be very challenging. Several potential reasons for the poor recruitment to the randomised controlled trial (RCT) were identified, including low visibility of the recruitment materials, difficulty to reach potential participants, and insufficient engagement of the

pharmacy staff. However, it is also possible that additional, individual-level factors impacted on recruitment, such as smokers' cognitions, motivations, as well as needs and preferences with regards to NRT use and support with NRT use.

In order to develop more relevant and acceptable versions of NRT2Quit or other interventions, as well as to plan more effective recruitment campaigns, there is a need for a more comprehensive assessment of NRT use and factors affecting it. For example, very little is known about why smokers hold negative cognitions, how they select and initiate NRT use, and what kind of support with NRT use they find useful and attractive (Pacek et al. 2017). Such information would be particularly important for future digital behaviour change interventions (DBCI) for NRT use and their promotion.

5.4.1. Aims

This exploratory study used a qualitative approach informed by the COM-B and the TDF (Cane et al. 2012, Michie et al. 2014) to conduct a comprehensive analysis of the possible factors contributing to the suboptimal NRT use by UK-based smokers (with focus on OTC NRT), including factors falling within capability and opportunity that had received little attention to date. The findings could inform future interventions for optimising NRT use. The research questions were:

1. What are smokers' experiences and behaviours in relation to NRT use, from initiation to termination?
2. What are the capability, opportunity and motivational factors that impact on NRT use?
3. What support with NRT use do smokers find acceptable and beneficial?

5.5. Methods

5.5.1. Design

The study involved in-depth semi-structured individual face-to-face interviews that were supplemented by a think-aloud procedure about NRT2Quit (the app was described in detail in Chapter 3). The present chapter reports information required by COREQ guidelines for reporting qualitative studies (Tong et al. 2007). The UCL Research Ethics Committee approved the study (6212/002) and participants provided informed consent before participating. During the same session, data were collected for a related study that is reported in Chapter 6.

5.5.2. Participant recruitment

Convenience sampling was used, with participants recruited from the general population of Greater London through online advertisements, mailing lists, posters around UCL, and word of mouth. Recruitment materials invited participants to an interview study as part of a project that aimed to develop aids and tools to support NRT use while quitting, including smartphone apps. To be eligible, participants had to (1) be 18 years or older, (2) have used any OTC NRT products in the past 5 years as part of quit attempts (this timeframe was selected to address the challenge of slow recruitment due to the decreasing pool of potential participants who use NRT as part of quit attempts (Beard et al. 2016b)), (3) be a current or recent daily smoker (past 3 years), or currently trying to quit, (4) own a smartphone and be interested in using apps, (5) be fluent in English, and have good or corrected-to-normal vision.

5.5.3. Procedure and interviews

Due to the progression of the wider programme of research, including the RCT of NRT2Quit and the challenges with recruitment, the interviews were conducted in three phases (two in December 2014, nine in the summer of 2016, and five in the summer of 2017). In this period in the UK there had been no substantial change to the guidelines on NRT, but e-cigarette use had been on the rise while NRT use had been declining (Beard et al. 2016b), and additionally funding cuts to the NHS might have affected prescribing of NRT (ASH 2018). The 2014 interviews prioritised usability testing of the NRT2Quit

app to inform final steps of the app development. However, the emergence during the first two interviews of surprising to me and important themes related to NRT use, engagement with NRT support, and the context of NRT use motivated pausing and re-scheduling these interviews, as well as making small modifications to the interview guide.

Starting from 2016 the interviews focused on exploring participants' experiences with NRT use, the support with NRT use they accessed, and how the latter could be improved and delivered through an app. At the end of the interview, participants explored NRT2Quit during a think-aloud procedure (see Chapter 6). The final five interviews were conducted after the first round of data analysis as it was judged necessary to conduct more interviews for data saturation to be reached (Carlsen and Glenton 2011, Birt et al. 2016). Participants were reimbursed with vouchers of £20 in 2014 and, due to extending the duration of the modified interviews, £30 in 2016-2017.

Participants completed a questionnaire on their history of smoking and quitting, use of NRT, self-assessed knowledge of NRT, support with NRT use accessed to date, and satisfaction with the available support. The questionnaire was prepared using wording from other studies and was discussed with other team members, but was not piloted. The questionnaire was used to characterise the interviewed sample and to supplement the qualitative data collection by obtaining standardised data that would be more easily comparable across participants on their knowledge and satisfaction with support on NRT use.

The interviews lasted 50-90 minutes. The interviews followed a semi-structured guide (see Appendix 5.2) and were divided into two parts. The first part involved an in-depth exploration of participants' accounts in the absence of any prompts. It was guided by the COM-B model and TDF and focused on (i) experiences with NRT use from initiation to termination, (ii) knowledge, skills and views pertaining to NRT and its use, (iii) experiences with, and views on the available support with NRT use, and (iv) preferences for support with NRT use, including digital support. The second part used NRT2Quit as a prompt and involved think-aloud methodology (Charters 2003, Wu et al. 2017) to elicit views on (v) advice and recommendations on NRT use provided in the app and on (vi) app features and suggestions for app improvement. Data pertaining to NRT2Quit and expectations for features, content, and other qualities in apps supporting NRT use were analysed separately and are reported in Chapter 6.

Participants' responses guided the interview progression. Impromptu questions invited elaboration (e.g. "could you please clarify this...?"). During the interview, after participants described their accounts, or when raised questions or concerns, the guidelines around NRT use were clarified, particularly around safety, regimen of use, and combination NRT. The NRT2Quit app was the only prompt used. The interviews were audio-recorded and transcribed intelligently *verbatim* by a professional company, who signed confidentiality agreements. Participants' data was labelled with codes to protect their identity.

The participants were informed that I worked on creating new stop smoking aids, including NRT2Quit. Participants were encouraged to share all the thoughts and ideas they were comfortable with and to be honest as their suggestions could inform future programmes supporting quitting and medication use created by our group.

5.5.4. Data analysis

Descriptive statistics were used to report the data from the questionnaire. Data from the interview transcripts were analysed in NVivo 12 using principles of Framework Analysis (FA) (Ritchie and Lewis 2003), which has been commonly used in applied health research (Beard et al. 2012, Gale et al. 2013, Herbec et al. 2014a, Parkinson et al. 2015). FA supports a transparent and systematic analysis of large volumes of qualitative data, and is particularly suitable in projects with a well-defined participant sample and pre-determined themes, while also enabling emergence of novel themes (Ritchie and Lewis 2003, Srivastava and Thomson 2010, Beard et al. 2012, Herbec et al. 2014a, Parkinson et al. 2015).

FA involves: (i) familiarisation through reading and re-reading of transcripts, (ii) identification of recurrent themes and subthemes using pre-defined and emerging codes, (iii) development and refinement of a thematic framework through systematic indexing of transcripts, and (iv) development of descriptive accounts and creation of explanatory frameworks. All data were analysed together, regardless of the context in which they emerged. Since the current study was primarily exploratory, all participants' statements were treated as potentially important, and a realist epistemological perspective was adopted (Madill et al. 2000).

I conducted the first round of coding. The analysis was both deductive, whereby data were classified using a coding framework informed by the interview guide and the COM-B and TDF domains (the mapping is shown in Table 3.1 (Atkins et al. 2017) (Michie et al. 2014), as well as inductive, allowing for novel findings to emerge. If relevant, data were coded to multiple codes and COM-B and TDF domains (Atkins et al. 2017).

The final coding framework was agreed through several rounds of iterations and internal validation (Birt et al. 2016) conducted by myself and IT, who was experienced in the use of COM-B and TDF and qualitative research. Additional codes were devised for data falling outside of the COM-B framework, e.g. data related to participants' reactions to facts and guidelines on NRT (also reported in this chapter). Together with IT we used constant comparison (Madill et al. 2000) and deviant case analysis (Mays and Pope 2000) to ensure internal validity, which meant that usual or surprising cases were identified, discussed, and coded to themes after there was a consensus.

5.5.5. Interviewer characteristics and positionality

These are reported in Chapter 1.14.

5.6. Results

5.6.1. Participants

Participant characteristics, experiences, and views on NRT and support with NRT use are presented in Tables 5.1 and 5.2. Sixteen adults from Greater London (mean age=34.9, SD=10.3) were interviewed, of whom 13 (81.3%) were women, 13 (81.3%) worked in non-manual occupation, 13 (81.3%) had post-16 years of age education, and 11 (68.8%) were current smokers.

The majority (81.3%) of the participants had tried at least two different NRT products in the past, most commonly the patch or gum (93.8%). Only three (18.8%) had tried combination NRT, i.e. a patch with another product. Most (68.8%) participants received some advice on NRT use from different healthcare professionals (HCPs, e.g.

pharmacy staff or General Practitioners, GPs). However, satisfaction with the available support tended to be moderate (mean rating: 2.5, SD=.8 on a scale 1=not at all, 5=completely).

Table 5.1. Characteristics of the participants, their access to support with NRT use in the past, and their satisfaction with the support available.

ID	Sex	Age range	Smoking status during the interview	Cig /day	Tried to quit last year	Accessed any support on NRT use from HCPs	Satisfaction with the support on NRT use (1=not at all, 5=completely)
P1	f	18-34	quit	1-5+	yes	yes	2
P2	f	18-34	daily	5	-	-	2
P3	f	18-34	daily	15	yes	yes	3
P4	f	18-34	daily	5-10	yes	yes	2
P5	m	35-70	quit	unk	-	yes	2
P6	m	18-34	daily	8-10	yes	yes	4
P7	f	35-70	nondaily	10-12	yes	yes	2
P8	f	35-70	daily	20	yes	yes	3
P9	f	18-34	daily	25	yes	yes	1
P10	f	35-70	daily	6-7	yes	yes	3
P11	f	35-70	daily	5-10	yes	-	3
P12	m	35-70	quit	9	yes	-	3
P13	f	35-70	nondaily	20	yes	-	3
P14	f	35-70	nondaily	3	-	-	1
P15	f	18-34	quit	20	yes	yes	3
P16	f	18-34	daily	10-15	yes	yes	3

f=female; m=male; HCP=healthcare professional, unk=unknown; NRT=nicotine replacement therapy.

Table 5.2. Participants' use of NRT in the past and self-rated knowledge about the NRT and its use.

ID	Patch	Gum or lozenges	Sprays or inhalators	Combination NRT	Ratings of knowledge on NRT, regimen and application techniques (1=none, 5=very good)		
					NRT	regimen	technique
P1	-	yes	yes	-	3	2	2
P2	yes	yes	-	-	2	2	2
P3	yes	yes	yes	yes	4	3	4
P4	-	yes	-	-	3	3	3
P5	yes	yes	yes	yes	2	2	3
P6	yes	yes	yes	-	4	4	4
P7	yes	yes	yes	yes	3	2	2
P8	yes	yes	yes	-	2	2	3
P9	yes	yes	yes	-	2	3	2
P10	yes	yes	-	-	4	3	3
P11	yes	yes	yes	-	4	5	4
P12	-	yes	yes	-	4	3	4
P13	yes	yes	yes	-	3	2	2
P14	-	yes	-	-	2	2	2
P15	yes	yes	yes	-	3	2	2
P16	yes	-	-	-	2	5	1

5.6.2. Overview of the qualitative findings

As initially planned, the first round of analysis resulted in a single COM-B- and TDF-informed thematic framework that captured all the interview data relevant to the behaviour of NRT use. However, during the data analysis I realised that two separate but inter-related behaviours were emerging from the data requiring separate analyses. This was confirmed through further iterations of the coding framework and internal discussions with IT. The first behaviour (B1) was ‘using NRT per se’, and the second behaviour (B2) was ‘engaging with support and resources on NRT use’. As a consequence, the data were re-analysed using separate, parallel thematic frameworks informed by COM-B and TDF. Box 5.1 reports higher-order themes and sub-themes for each of these behaviours. A summary of findings related to each of the two behaviours and COM-B domains, together with illustrative quotes, is reported below.

Additionally, each of the coding frameworks included a meta-theme and associated sub-themes related to ‘*Missed Opportunities*’. These were instances or circumstances identified and agreed through discussions with IT as preventing smokers from taking a full advantage of the available resources or to otherwise optimise the two target behaviours. These missed opportunities included challenges, barriers, or shortcomings, also in light of best clinical practice, and thus could constitute relevant targets for future interventions. These missed opportunities are reported in Box 5.2 for each of the two behaviours. Finally, findings are also reported for a separate theme capturing participants’ reactions to the guidelines and recommendations for NRT use discussed during the interview.

Box 5.1. Thematic frameworks informed by COM-B and TDF for two behaviours: using nicotine replacement therapy (NRT) per se (B1) and engaging with information and support on NRT use (B2) (from (Herbec et al. 2018c))

Using NRT per se (B1)	Engaging with information and support with NRT use (B2)
<p>1. B1: Using NRT per se – from imitation to termination</p> <p>1.1. Product selection and initiation of NRT use</p> <p>1.1.1. Formal health care channels</p> <ul style="list-style-type: none"> - GP recommendations or prescription - Recommendations in pharmacies - Stop smoking programmes - Samples from healthcare professionals <p>1.1.2. Informal channels</p> <ul style="list-style-type: none"> - Word of mouth - Internet, TV and other advertisements - Samples from acquaintances <p>1.2. Selection criteria for NRT type</p> <p>1.2.1. Convenience</p> <p>1.2.2. Level of addiction and NRT strength</p> <p>1.2.3. Prior experience</p> <p>1.2.4. Cost, flavour and other criteria</p> <p>1.2.5. Spontaneous and unguided selection</p> <p>1.3. Experience of purchasing NRT</p> <p>1.4. Past NRT use</p> <p>1.4.1. Using individual NRT</p> <p>1.4.2. Using multiple NRT products</p> <p>1.4.3. Adhering to guidelines and recommendations</p> <p>1.4.4. Experiencing side-effects</p> <p>1.4. Termination of NRT use</p>	<p>13. B2: Engaging with information and support on NRT use</p> <p>13.1. Using NRT without any support</p> <p>13.2. Reliance on one’s experience and understanding of addiction</p> <p>13.3. Engaging with patient information leaflets</p> <p>13.3.1. Reading the leaflet</p> <p>13.3.2. Selective reading</p> <p>13.3.3. Ignoring the leaflet</p> <p>13.4. Engaging with healthcare professionals</p> <p>13.4.1. GPs</p> <p>13.4.2. Cessation advisers</p> <p>13.4.3. Pharmacists and pharmacy staff</p> <p>13.5. Accessing informal sources of support and information</p> <p>13.5.1. Friends and family</p> <p>13.5.2. Internet</p> <p>13.5.3. TV and other ads</p> <p>13.6. Engaging with display and packaging of NRT</p>
Capability: Physical	
<p>2. Physical skills in taking NRT</p> <p>2.1. Techniques and application methods</p> <p>2.2. Practice and experimentation with NRT use</p>	Not identified as a theme
Capability: Psychological	
<p>3. Knowledge related to NRT use</p> <p>3.1. Factual knowledge about NRT</p> <p>3.1.1. Types of NRT</p> <p>3.1.2. Combination NRT</p> <p>3.1.3. Mechanisms of action and ingredients</p> <p>3.1.4. Effectiveness</p> <p>3.1.5. Safety and side-effects</p> <p>3.2. Procedural knowledge about NRT use</p> <p>3.2.1. Techniques and application methods</p> <p>3.2.2. Regimen of NRT use</p> <p>3.3. Misconceptions and factual errors</p>	<p>14. Knowledge of sources of information and support with NRT use</p>
<p>4. Memory and attention to take NRT</p> <p>4.1. Remembering about NRT use</p> <p>4.2. Competing tasks and attention to NRT</p>	<p>15. Memory and attention for information and support on NRT use</p> <p>15.1. Focus on potential harm and side-effects</p> <p>15.2. Limited attention and recollection of advice</p>
<p>5. Behaviour regulation in NRT use</p> <p>5.1. Mental stamina to endure negative sensations</p> <p>5.2. Monitoring and scheduling NRT use</p> <p>5.3. Planning and preparing for obtaining NRT</p>	Not identified as a theme

Box 5.1 (cont.) Thematic frameworks informed by COM-B and TDF for two behaviours: using nicotine replacement therapy (NRT) per se (B1) and engaging with information and support on NRT use (B2) from (Herbec et al. 2018c)

Using NRT per se (B1)	Engaging with information and support with NRT use (B2)
Opportunity: Physical	
<p>6. Physical opportunity for NRT use</p> <p>6.1. Views on NRT products in general</p> <p>6.1.1. Range of NRT products</p> <p>6.1.2. NRT product design</p> <p>6.1.3. NRT cost and availability</p> <p>6.2. Views on individual NRT products</p> <p>6.3. NRT regimen</p> <p>6.3.1. Dose recommendations</p> <p>6.3.2. Combination NRT</p> <p>6.3.3. Cognitive complexity of NRT regimen</p> <p>6.3.4. Impracticality, convenience and high effort</p> <p>6.4. Views on medications and pharmaceutical companies</p>	<p>16. Physical opportunity for engagement with information and support</p> <p>16.1. Pharmacy setting</p> <p>16.2. Display and packaging of NRT</p> <p>16.3. Views and preferences on current printed resources on NRT use</p> <p>16.3.1. Accessibility of guidelines</p> <p>16.3.2. Patient leaflets</p> <p>16.3.3. Other written resources</p> <p>16.4. Digital support with NRT use</p> <p>16.4.1. Online resources</p> <p>16.4.2. Smartphone apps</p>
Opportunity: Social	
<p>7. Social opportunity and perceived norms impacting on NRT use</p> <p>7.1. Role models in relation to NRT use</p> <p>7.2. Use of NRT products in public</p>	<p>17. Social opportunity</p> <p>17.1. Not being offered support from healthcare professionals</p> <p>17.2. Views and preference regarding face-to-face support</p> <p>17.2.1. Accessibility of support</p> <p>17.2.2. Satisfaction with past support</p> <p>17.2.3. Signposting</p> <p>17.2.4. Support in the pharmacy</p> <p>17.2.5. Anonymous support</p> <p>17.3. Peer testimonials and demonstrations</p>
Motivation: Reflexive	
<p>8. Beliefs about capabilities to use NRT</p>	<p>Not identified as a theme</p>
<p>9. Beliefs about consequences of using NRT and other medications</p> <p>9.1. NRT effectiveness</p> <p>9.2. NRT safety concerns</p> <p>9.2.1. NRT and addiction</p> <p>9.2.2. Overdosing and dual use with cigarettes</p> <p>9.2.3. Side-effects</p> <p>9.2.4. Other concerns</p> <p>9.3. Views on smoking and quitting that could impact on NRT use</p> <p>9.3.1. Quitting requires commitment and willpower</p> <p>9.3.2. Smoking as a habit and learned gestures</p>	<p>18. Beliefs about consequences of engaging with information and support on NRT use</p> <p>18.1. Value of accessing support</p> <p>18.1.1. Face-to-face support</p> <p>18.1.2. Self-help resources</p> <p>18.1.3. Reliance on one's experience and knowledge</p> <p>18.2. Burden of commitment to face-to-face support</p> <p>18.3. Right timing and frame of commitment to quitting needed</p>
<p>10. Identity related to NRT use</p>	<p>Not identified as a theme</p>
Motivation Automatic	
<p>11. Emotions: anxiety related to NRT use</p>	<p>19. Emotions: shame and embarrassment to engage with support</p>
<p>12. Routines and habits in NRT use</p> <p>20. Reaction to NRT facts and recommendations</p> <p>20.1. Shock and surprise</p> <p>20.2. "aha" moment – re-assessing one's prior knowledge and experiences with NRT</p> <p>20.3. Feeling encouraged</p> <p>20.4. Ambivalence</p>	

GP= General Practitioner

Box 5.2. The key challenges for the behaviour and the missed opportunities in capability, opportunity and motivation in using NRT per se (B1) and in engaging with information and support with NRT use (B2) (adapted from (Herbec et al. 2018c))

Missed opportunities in using NRT per se (B1)	Missed opportunities in engaging with information and support with NRT use (B2)
Key challenges	
<ul style="list-style-type: none"> • Inadequate process of NRT selection • Suboptimal use of NRT 	<ul style="list-style-type: none"> • Poor engagement with resources and face-to-face support on NRT use • Over-reliance on prior experience and informal sources of information
Capability	
<ul style="list-style-type: none"> • Limited knowledge of recommended application techniques • Limited knowledge of regimen of individual and combination NRT • Incorrect application of NRT • Misconceptions and factual errors that negatively impact on NRT use • Poor behaviour regulation: limited planning, scheduling, monitoring and stocking • Low acceptability and limited endurance of unpleasant sensations and side effects 	<ul style="list-style-type: none"> • Low awareness of the intricacies of NRT use that require additional support • Low awareness of guidelines and techniques that could help optimise NRT use • Preoccupation with information on potential harm, rather than on optimisation of use
Opportunity	
<ul style="list-style-type: none"> • High NRT cost • Unattractive and impractical product design • Complex and burdensome NRT regimen • Lack of appropriate role models for NRT use 	<ul style="list-style-type: none"> • Limited access to and exposure to comprehensive guidelines on NRT use • Unattractive patient leaflets • Deficient advice and support offered by healthcare professionals • Busy pharmacy environment • Overwhelming and uninformative NRT product display
Motivation	
<ul style="list-style-type: none"> • Low motivation to optimise use • Limited expectations and uncertainty of benefit from NRT use • Concerns over safety and side-effects • Negative beliefs and emotions, including anxiety when using NRT • Negative identity of NRT users, associating use with greater addiction or desperation • Unhelpful beliefs about smoking, addiction, quitting, and medications 	<ul style="list-style-type: none"> • Limited expectations to benefit from resources and support on NRT use • Embarrassment to seek face-to-face support • Low acceptability of face-to-face support and anticipated commitment

5.6.3. Summary of findings

B1: Behaviour of ‘using NRT per se’

Participants obtained NRT in a range of contexts in the past, primarily buying it OTC, but some obtained their NRT through cessation programmes or were offered samples from friends or HCPs. Frequently they received no guidelines on use.

“[the adviser] gave me just a couple of packets of gum [and] the mints, just to try, but I never went beyond [...] But because she didn’t give it to me in [a normal package] then I didn’t get [instructions].” (P1)

Although some participants knew about the wide range of NRT and believed that individual products could suit different preferences and circumstances, only few participants mentioned systematically selecting their NRT products. They tended to choose NRT spontaneously and drew on their prior experience, information in the advertisements, or word of mouth. Strength of NRT and perceived convenience of the NRT were important selection criteria.

“I just grabbed the strongest one [inhalator] that they had out there because I smoked a lot.” (P15)

Most participants experienced side effects, and few reported benefitting from NRT. This were common reasons for terminating NRT use prematurely. Suboptimal experiences with NRT undermined efforts at establishing a routine for medication use. The irregularity, in turn, also contributed to forgetting and poor adherence. Additionally, negative prior experience tended to discourage future use of NRT products.

“I just thought “Oh if the gum is rubbish, everything else will be rubbish”, so I won’t try anything else.” (P14)

B1: Capability to use NRT

Participants had some confidence in their knowledge about using NRT, which was also reflected in their ratings reported in Table 5.2. However, their actual knowledge was limited and was often based on information obtained in the distant past.

“[combination NRT] goes against what I read twenty, you know, [...] many, ten [years ago].” (P13)

As a result, participants often held misconceptions about different aspects of NRT products and their use, including the mechanisms of action, effectiveness, safety, and guidelines for use (especially about combination NRT and techniques to use or apply the individual medications).

“[NRT patch placed on torso] is going directly into your bloodstream and [...] it's near to the vital organs I suppose, so I felt more, had a more problem with that, yeah.” (P5)

Participants' accounts of NRT use in the past also suggested that many of them lacked the procedural knowledge and skills to correctly use these products. Practising and experimenting with different ways to use NRT (e.g. chewing the gum differently) to improve effectiveness or to minimise side-effects were very uncommon. This was also the case with participants who accessed specialist cessation support before.

“I chewed it as a normal gum [...] I had no idea [there was a special technique for gum use], no wonder I thought it was gross.” (P14)

“Yeah, the inhaler, the little white one I used to try and smoke it like it was a cigarette.” (P3)

Prioritising and remembering to take NRT regularly was rare, especially amidst busy daily routines. Some participants realised they would need to set up routines or reminders (e.g. use apps) to use NRT regularly. Participants rarely discussed efforts to ensure adequate supply of NRT, scheduling, or monitoring its use. Indeed, participants tended to use fast-acting NRT (e.g. gums, sprays) when experiencing cravings or in situations when they would normally have a cigarette, rather than at scheduled or regular times before a craving develops.

“it was just when I was having an immediate craving, I would have a gum then. I think after eating as well, that's a good time and it was fine but it was like it was just never enough.” (P3)

Participants also had difficulties persisting with NRT use when experiencing side-effects or other unpleasant sensations

„I just saw it [gum] in Boots or Superdrug and thought I'd give it a go because the patches weren't working and I just thought it tasted disgusting so I just, you know, that was, it was one time I tried it [...] I kind of just wrote it off.” (P2)

B1: Opportunity to use NRT

Some participants were happy about the range of NRT available, but many thought the products were expensive. The design of some NTR products was judged unattractive, and participants felt uncomfortable or even embarrassed to use some of them in public.

“[using inhalator among friends made me feel] Like a bit of an idiot really. [...] it looks a bit like a tampon holder or something” (P1).

Additionally, the recommended regimen for NRT use, including combination NRT, was considered complex, inconvenient, effortful, and potentially harmful. Participants also complained about NRT products making daily routines more difficult. Some accounts suggested that inconvenience may be a key barrier to NRT use, and other forms of nicotine delivery would be welcome.

„I just think [taking NRT] five to ten times a day is a lot. [...] People's going to forget when they get busy.” (P6)

“that was annoying as well, being told not trying get it [patch] wet and trying to position myself in the shower for it, it didn't work.” (P9)

“[NRT should be] something portable, easier to remember, and cheaper than tobacco as well.” (P11)

Moreover, interviewees also lacked positive role models and access to success stories of NRT use that could encourage and guide them. They expressed interest in hearing such stories.

“I think it would be nice to have the information on a website that I could find or go to a forum and read about people's experiences with it.” (P2)

“I would have tried it if I'd had the, I guess the reading material and the advice and proven that it had helped somebody else I would have done it but I didn't have any of that, so I just left it all.” (P14)

Finally, some participants held unfavourable beliefs on medications in general that also extended to perceptions of NRT use. These participants preferred to try to quit unaided.

B1: Motivation to use NRT

Participants expressed self-confidence in the correct use of NRT in the past, and demonstrated motivation to initiate NRT use, often purchasing it OTC. However, they were not necessarily motivated to continue using it or to optimise use. Only few participants found using NRT helpful, and many were unsure or had low expectations to benefit from NRT in general. Safety concerns were particularly common, especially around over-dosing, which seemed to trigger anxiety among some participants.

“I just thought it was not working at all and I still wanted to smoke so I just threw it away.” (P14)

“So that was one of the other things that made me nervous a bit of this gum because I thought “oh gosh, what if I become addicted to the gum [...] I was worried that I was going to [...] give myself nicotine poisoning.” (P4)

Certain beliefs about smoking and quitting were also related to lower motivation to use NRT. These were, in particular, the perception of smoking as a habit or set of learned gestures, and of quitting as an individual journey that requires a personalised approach or primarily willpower to succeed.

“each one [quitting method] is more suited like to other people, like some are more suited for the patch, or the gum, or whatever, or just willpower.” (P6)

Participants also held negative perceptions and identity of an NRT user, especially if combination NRT was used. They associated using NRT with greater addiction to cigarettes, a sign of ‘still’ being a smoker or someone who is desperate to quit, and a source of embarrassment, rather than as a positive and health-oriented behaviour.

“it [nicotine] keeps on reminding you that you are a smoker...” (P12)

“...administering, delivering nicotine, I thought that’s what real addicts have” (P4)

[Researcher: what convinced you to actually go for the patch?] “Well desperation, like to give up.” (P6)

“obviously you didn't see it [the patch] when it was covered up but when it wasn't covered up and there were hot days, like recently I've felt horrible, I felt a bit embarrassed almost” (P9).

B2: Behaviour of ‘engaging with information and support with NRT use’

Many participants reported no information seeking, used NRT without any support or advice, or engaged only with informal information sources (e.g. discussions with friends).

“On Amazon I just looked at reviews and it had like four point some rating out of five so people said it was helping them so I mean that’s why I tried it, give it a shot.” (P12)

Additionally, participants tended not to read patient leaflets, while those purchasing OTC NRT through pharmacies or shops did not browse through the products displayed on the shelves. Decisions regarding NRT selection and use were often based on participants’ understanding of their addiction to cigarettes, information presented on TV, online or other advertisements, word of mouth, and prior experience with NRT products.

“the lozenges I kind of knew what [the leaflet] was going to say [...] you can work that one out [...] I did read the gum advice and I did read the patches advice at some point, [...] anything else I haven’t because I kind of know how it works” (P13)

Participants who were offered some assistance with NRT use by pharmacy staff at the time of purchase tended to decline it. Only few participants were actively seeking advice on NRT and its use from their doctors or other HCPs.

“No, I didn't [get advice from a pharmacist], when they'd say 'do you know what, like have you used it', I'd say 'yes', because I don't like, because I always feel like you're going to just end up getting advice and then feel guilt-tripped into it!” (P15)

B2: Capability to engage with information and support with NRT use

Participants tended not to be aware of the intricacies of NRT use and the existence of more comprehensive and updated guidelines relating to NRT use, which in turn did not promote information seeking.

“I did not actively go for a technique, search for a technique but that’s because I didn’t know there was a technique.” (P12)

They also often mentioned difficulties remembering the advice provided by HCPs. Participants who sought information or advice on NRT and, for example, read the patient leaflets, tended to focus on the side-effects and potential harms from overdosing or dual use of NRT and cigarettes, rather than on how to optimise NRT use.

“I only read the side-effects [on the leaflet]” (P16)

“We all, a lot of our questions to begin with was what happens if we smoke a cigarette and we’re wearing a patch? Or use the inhalator than have a cigarette.” (P8)

B2: Opportunity to engage with information and support with NRT use

Participants’ accounts suggested they had few opportunities to engage with relevant support with NRT use, e.g. they often described not being offered advice during NRT purchase. However, some participants were accepting that pharmacy staff does not offer additional advice at the till. Additionally, face-to-face appointments dedicated to quitting were viewed as scarce and difficult to schedule, while the pharmacy environment was seen as too busy to engage in a comfortable conversation.

“I just used to take it up to the counter and that’s fine, no one ever said “We have these options” or “Have you tried this programme or there’s...?” No, nothing like that.” (P14)

“if it was pharmacy based a lot of people think, you know, I’ve got queue, got to talk, got to get questions and wouldn’t bother.” (P10).

However, after having discussed NRT use during the interviews, some participants expressed dissatisfaction with the level and quality of support available to them. In the hindsight some felt it might have negatively influenced their NRT use.

“I was in a [cessation] group this year [...] I promise you, it [combination NRT] was definitely not [mentioned]. No way were any of us told, honestly, that if you take two together, no.” (P8)

“You feel like a failure when you’ve like relapsed so if you actually had more information about how to take things properly maybe it would have better chances.” (P3)

Additionally, the busy and unorganised displays of NRT products in pharmacies and other stores seemed to be overwhelming to smokers and discouraged browsing.

“I only bought what I had initially which was the one with the green tab which is what I remembered but when I went there was like lots of stuff. I was like wow, it’s a big range [...] it’s really quite shocking.” (P10)

Finally, some participants expressed mistrust towards medication manufacturers and the advice provided by them in the patient leaflets.

“I don’t believe for a minute that [pharmaceutical companies] have optimised the information [patient leaflets] for customers.” (P13)

Many participants expressed the need for having accessible, relevant, and comprehensive advice on NRT use. Some suggested that a broader information campaign would be needed to inform smokers about any updates to the recommendations. Many felt that advice on NRT should be present already during product advertisement, provided together with the product, or during purchase, as otherwise they may not seek additional information.

“Then there are dozens of other things that you need to prioritise [...] so if there is a technique I think it should be communicated in a very small amount of time and when the other person’s attention, whether it’s at doing an advertisement or at the point of sale.” (P12)

Some had preferences for accessing advice in the form of testimonials from smokers who used NRT, while others expected to receive advice from HCPs.

“I think if someone had said to me, “Do you know about this, you know, this leaflet of information or the support that you could get from your doctor or even an app”, I would have used it.” (P14)

Finally, participants had little experience with digital cessation aids, including apps, but most had used some smartphone apps before. Nevertheless, some participants

were interested in the idea of having digital support with NRT, especially if there was scarcity of other, readily available or acceptable support.

B2: Motivation to engage with information and support with NRT use

Most participants had low motivation to seek information or support with NRT use. On one hand, some participants viewed NRT as simple products, had high perceived self-efficacy for their use, and did not expect that medication use could be improved.

“No, I just thought that I could just do it, I just thought it was just straightforward.” (P7)

On the other hand, many participants had low awareness of the existence of relevant support and guidelines, and its potential value. Sometimes this made it also difficult for participants to appraise during the interview the support they had received in the past or to suggest improvements to it, including in relation to the NRT2Quit app or other DBCIs. Moreover, some felt that generic guidelines are not beneficial to individuals, and hence accessing such information would not be effective.

“In the end you actually write those instructions for yourself, because it has to be tailor-made for you, because what they put on the instructions is a generic, but not one shoe fits all.” (P7)

Finally, participants anticipated that face-to-face support would require too much commitment or could bring about negative emotions, such as feeling embarrassed for seeking help or having others witness their failure at quitting unassisted.

“People are more intimidated like when it's like a doctor or a pharmacist because, again, you just feel like you know, you have to... and then you feel like you have to commit to it properly because someone's helped you. [...]” (P15)

“I was just too embarrassed, so I just went in and grabbed some gum and thought “I’ll try this” and I didn’t even really look into it.” (P14)

Reactions to NRT facts and recommendations

During both the interview and exploration of the NRT2Quit app, some participants were surprised about the different recommendations on NRT use, particularly, the suggested methods of using individual NRT products or combination NRT. Others experienced ‘aha’ moments, or moments of realisation, as they re-appraised their knowledge and prior experience with NRT or with accessing existing sources of information and support. Discussing these issues during the interview encouraged some participants to try out more effective ways of using NRT in the future.

“... even from finding out a little bit more information about the fact that some NRTs I haven’t been taking them properly and there’s like different ways to use them from what I was thinking, I think that’s already made me feel a bit more positive! (P3)”

5.7. Discussion

This study identified two inter-related behaviours that could be contributing jointly to the optimal use of NRT: using NRT per se, and engaging with information and support with NRT use. The findings suggest that some smokers select or obtain their NRT products in suboptimal circumstances that may preclude them from benefitting from the right medication type. This includes using these products inadequately, including terminating use already after few uses in some cases. Additionally, smokers tend not to seek support with NRT use, rely on informal sources of information instead, and focus on the information on potential harms as opposed to seeking advice on optimal use. Finally, given the limited experience with support on NRT use and limited knowledge of optimal use, participants offered only limited direct suggestions on the type of support that could be developed or which they would find beneficial.

Applying the theoretical framework informed by the COM-B model and TDF revealed potential intervention targets that had not been identified previously. The findings corroborated, but also elaborated on, the insights from the behavioural analysis of NRT use reported in Chapter 3, particularly within the COM-B domains of social and physical opportunity. Furthermore, the identified barriers with accessing traditional support with NRT use would likely also extend to the smartphone-based support, which

in turn helps to explain the poor enrolment into the NRT2Quit trial that was reported in Chapter 4.

The study identified a range of missed opportunities directly related to using NRT, which could be addressed by future interventions, including smartphone-based support. Echoing previous research, the findings revealed limitations in the reflective motivation and psychological capability, such as misconceptions regarding NRT, its effectiveness and safety, as well as the benefits of combination NRT, all of which are likely to negatively impact NRT use (Etter and Perneger 2001, Bansal et al. 2004, Mooney et al. 2006, Shiffman et al. 2008a, Vogt et al. 2008, Yerger et al. 2008, Foulds et al. 2009, Carpenter et al. 2011, Ferguson et al. 2011, Beard et al. 2012, Kardas et al. 2013, Silla et al. 2014, Tsang et al. 2014, Pacek et al. 2017). Additionally, the findings suggest that smokers are dissatisfied with the design of NRT products and the overly complex regimen (e.g. frequency and duration of use).

Moreover, important shortcomings in physical skills and procedural knowledge on NRT use emerged commonly, which may be contributing to avoidable side-effects and low NRT effectiveness. Additionally, the lack of role models for NRT use, and perceived low acceptability of using NRT in public, may constitute further important, but still under-researched barriers to optimal NRT use. Interventions addressing these barriers may benefit from incorporating behaviour change techniques (BCTs) that support Shaping Knowledge (individual BCTs: 4.1-4.4) and Comparison of Behaviour (BCTs: 6.1-6.3) (Michie et al. 2013). Using testimonials of smokers and ex-smokers with experience of NRT use may be also welcomed by smokers. Although the first iteration of NRT2Quit did not include such components, they could be implemented in apps in the future.

Numerous guidelines and best practice on NRT use exist. However, this study shows that smokers face barriers in capability, motivation and opportunity to engage with the relevant support. Among the identified missed opportunities were: low awareness of intricacies of NRT use and available advice and support, low expectations to benefit from such support, and pre-occupation with information on potential harm, instead of on advice on how to use the medications correctly. Moreover, the advice provided to smokers may not be comprehensive and up-to-date, even when HCPs offer it.

Prior research found that patient information leaflets for different medications often fail to meet the needs of patients (Hamrosi et al. 2014). In this study participants also engaged poorly with leaflets on NRT and did not perceive them as relevant. Therefore, future printed material may need to be redesigned to attract smokers' attention and highlight the information on optimal use. Finally, the busy pharmacy environment and poorly organised NRT displays may also contribute to limited help- and information-seeking among smokers. These findings are in line with research showing numerous barriers faced by the pharmacy staff, including lack of training, resources and space, to deliver cessation programmes to smokers (Sohanpal et al. 2016).

Taken together, this study elucidated numerous under-researched contributors to the limited knowledge, negative attitudes, and suboptimal use of NRT found in the numerous earlier studies (e.g. (Etter and Perneger 2001, Foulds et al. 2009, Silla et al. 2014)), and highlights the need for more accessible, attractive and comprehensive support for smokers wanting to use NRT. Some of the potentially supportive resources could be delivered through apps, but many would require non-app-based interventions. These findings can be used to design new interventions.

5.7.1. Strengths and Limitations

This was a qualitative study among a relatively small and self-selected sample of adult smokers living in Greater London, and therefore the findings may have limited generalisability. However, the sample size was sufficiently large for an exploratory interview study (Braun and Clarke 2013) and saturation was reached (Francis et al. 2010, Malterud et al. 2015). Nevertheless, the current sample was predominantly female, had post-16 years of age education, worked in non-manual employment, owned a smartphone, and had the motivation and possibility to purchase OTC NRT in the past. Thus, the issues and challenges identified in this study are likely to be even more prominent among smokers with lower socio-economic status or those who have limited opportunity or motivation to initiate NRT use.

Furthermore, the study explored participants' prior experiences with NRT use, some of which had taken place even several years prior to the interviews. Therefore, the participants' accounts could have been affected by recall bias. Nonetheless, even the distant experiences with NRT still shaped the participants' current views on these

medications, and possibly affected whether or not, and how, these participants would use them in the future.

5.7.2. Implications for future research

This study suggests several avenues for research. First, many of the missed opportunities identified in this study have received limited attention to date and should be explored further. For example, future studies could assess the prevalence of the factors identified in this study as contributing to suboptimal NRT use and engagement with the different support on NRT use among smokers in the UK and other countries. Secondly, the discussion about the guidelines on NRT use, which was conducted using NRT2Quit as a prompt, revealed useful insights. This methodology could be improved in future studies by using additional standardised prompts, e.g. patient leaflets or other printed guidelines, and photos of the different NRT displays.

Moreover, the findings point to the potential value of developing and evaluating the effectiveness and acceptability of new forms of communication about NRT and its use. These could include creating new materials to accompany brief advice as well as more complex interventions and information campaigns delivered in pharmacies. Such interventions might also offset some of the shortcomings in the advice offered by the HCPs who are recommending or selling NRT. Another area for research is creating and assessing new displays of the NRT products.

Finally, given the findings from the NRT2Quit trial described in Chapter 4, namely the low effectiveness and uptake of the NRT2Quit app, it still remains to be established how to best leverage the technology to better support optimal use of NRT and disseminate it among smokers.

5.7.3. Implications for clinical practice

Drawing on the research on NRT to date and the findings from this study, there is a high chance that smokers provided with NRT OTC, or on prescription but without appropriate skill training and advice, will use it incorrectly. The incorrect use of NRT is likely to cause side effects and lower effectiveness, and the overall negative experience with these medication could also discourage future use of that and other NRT products.

One of the encouraging findings from this study was that participants tended to be positively surprised by the best clinical practice recommendations on NRT use and were encouraged to use the medications better in the future. This has been observed in previous research as well (Ferguson et al. 2011). Nevertheless, this study suggests that smokers may be reluctant to directly engage with the information and support on NRT use if it is presented in traditional forms, such as printed materials, or delivered in the busy pharmacy setting. Future interventions therefore need to emphasise novelty and relevance of the advice to catch smokers' attention and engage them. Smokers may be receptive to accessing such information through other smokers' testimonials and multimedia supporting skills training. Nevertheless, as the insights from the NRT2Quit trial (reported in Chapter 4) show, it will also be important for any interventions to include an active promotion or signposting by HCPs or researchers, rather than relying on passively distributed leaflets.

Finally, addressing suboptimal NRT use that is caused by negative distant experiences and limited knowledge may require a broader information campaign that draws on principles of making every contact count (Percival 2014). Such an intervention should run across multiple channels and engage smokers at different points of contact, including during product advertisement, but also through packaging, display, and at points of sale.

5.8. Conclusion

The use of nicotine replacement therapy by some smokers, especially when purchased over-the-counter, but even with healthcare professionals' support, is characterised by missed opportunities in terms of capability, motivation and opportunity. These missed opportunities negatively affect both NRT use and accessing support for NRT use by smokers. Interventions to optimise NRT use will need to address all of these obstacles.

Chapter 6: Think-aloud study about the NRT2Quit app

6.1. Chapter 6 Overview

This chapter reports findings from a think-aloud study of the NRT2Quit app, which was conducted as part of a qualitative interview study discussed in Chapter 5.

6.2. Contributions

I designed the study and the data collection instruments, including the interview guide, conducted participant recruitment and collected the data, conducted the analysis, oversaw second coding of the data (including recruiting and training a research assistant, Rhea Kohli (RK) to support the analysis), as well as written up the findings.

6.3. Introduction

Smartphone-based interventions are a new potential medium to deliver support with NRT use, but little is known about what smokers would find attractive in such programmes. As per person-centred approach, better understanding the needs and preferences of smokers and engaging them in the iterative intervention development could help to create more attractive and impactful versions of NRT2Quit and other interventions (Yardley et al. 2015, Murray et al. 2016, Michie et al. 2017).

The NRT2Quit app described in Chapter 3 was based on theory, best clinical practice, research on Digital Behaviour Change Interventions (DBCIs) for quitting smoking, and user experience (UX) design. The pragmatic RCT of NRT2Quit described in Chapter 4 found very limited evidence that among the small sample recruited NRT2Quit could increase cessation, medication use and engagement in comparison to the control version of the app. Furthermore, recruitment into the trial was very challenging. NRT2Quit was developed with no input from the potential end-users, which was an important limitation, and which might have contributed to the poor trial outcomes.

Several potential reasons for the poor recruitment into the NRT2Quit trial were identified. Some of these emerged during the trial, such as the suboptimal organisation of the pharmacies for recruitment. Additionally, findings from the interview study reported in Chapter 5 suggest that at least some smokers who use NRT may not be seeking support or information on how to use it, which could also provide some explanation for the unexpectedly poor recruitment into the trial.

However, another possible reason for the lack of interest in joining the NRT2Quit trial could be low attractiveness and acceptability of such an intervention among the potential end-users. Still very little is known about the preferences and views of smokers regarding app-based support for NRT use. Identifying and implementing in apps what smokers would find beneficial, acceptable, and desirable might improve engagement with such interventions, which could then also translate into better outcomes (Yardley et al. 2015, Murray et al. 2016, Perski et al. 2017b).

Think-aloud procedures have been used as part of person-centred development and evaluation of DBCIs, other complex interventions and services (Charters 2003). During the think-aloud procedure participants are presented with tasks or prompts (e.g. an actual or a prototype app) and are asked to interact with them and to verbalise their views, thoughts, impressions, suggestions, and concerns regarding all aspects of the programmes. The emerging data can be analysed using qualitative methods (Charters 2003). The method allows to capture participants' impressions and views about the different features, content and user journeys within one or more DBCIs (Perski et al. 2017b), as well as to identify elements that may negatively impact on usability and satisfaction.

The present study involved a think-aloud procedure about the NRT2Quit app as well as semi-structured interviews. The data collection for it took place during the second part of the interview session reported in Chapter 5. There were two main reasons for embedding the think-aloud procedure on NRT2Quit within the broader interview about NRT use. First, the data from the other part of the interview helped to contextualise the emerging views and suggestions for the NRT2Quit app and other digital support for NRT use. Secondly, the wider interview guide explored more general preferences and needs for smartphone-based support with NRT use, and these insights would also be valuable for the development of future app-based interventions.

6.3.1. Study aims

The present mixed-methods qualitative study had two converging aims. First, it aimed to explore views, preferences and needs regarding smartphone-based support for NRT use among adult smokers and ex-smokers who had experience with trying to quit smoking using any NRT products. The NRT2Quit app was used as a prompt to elicit views about specific functionality and content of such apps. Secondly, it aimed to identify ways in which NRT2Quit could be improved in the future.

6.4. Methods

6.4.1. Design

This was an exploratory study using a mixed-methods qualitative approach, combining think-aloud methodology about the NRT2Quit app with semi-structured interviews about the desired functionality in smartphone-based programmes for quitting with NRT. The data for the present study were collected during the same qualitative study reported in Chapter 5, and thus the individual interviews were conducted between December 2014 and August 2017. The information presented is in line with the COREQ guidelines for reporting qualitative studies (Tong et al. 2007).

6.4.2. Participant recruitment, participant characteristics, and study procedures

Chapter 5 reports a detailed description of participant recruitment (section 5.5.2), study procedures (5.5.3) and participant characteristics (section 5.6.1 Table 5.1).

In short, adult smokers and ex-smokers from Greater London were invited to participate in a qualitative study that aimed to explore their experiences with using stop smoking medications (focus on NRT) and their suggestions for support with medication use (with focus on smartphone-based support). Participants took part in individual interviews lasting 60-90minutes that were audio-recorded and transcribed. The interviews were divided into two parts. First, participants were asked about their experiences with using NRT and accessing relevant support while trying to quit, as well as about their views and preferences for digital and other support for NRT use. Next, participants were invited to explore freely the NRT2Quit app and to share their views as per the think-aloud procedure.

6.4.3. Changes to the protocol

Two changes to the data collection for the present study were made between 2014 and 2016-2017. First, as discussed in Chapter 5, due to the emergence of important themes pertaining to the medication use and engagement with support with medication use, the duration of the interviews was extended by about 20 minutes, and the focus of the interviews had shifted to explore these two areas in more detail first. As a result, less time was devoted to the think-aloud procedure about NRT2Quit.

Secondly, during a traditional think-aloud procedure, the researcher has a relatively limited role as an observer (Charters 2003, Perski et al. 2017b, Wu et al. 2017). However, the insights from the first two interviews suggested that a modification to this procedure was required to collect relevant insights about the app. Specifically, certain app features (particularly the dashboard, i.e. the NRT Dial) were not intuitive to participants. Additionally, given the limited time, participants were not able to familiarise themselves with the instructions available within the app, and some of them did not actively seek such instructions. Moreover, due to the often limited knowledge about NRT and its use, including on NRT regimen (as reported in Chapter 5), participants seem to struggle to comment on the relevance and usability of specific functionality and advice within the app. As a result, clarifications and explanations of the functionality and a rationale for them were offered whenever participants voiced concerns or questions or seemed 'lost' when exploring the app.

6.4.4. Data analysis

Data were analysed in NVivo 12 using framework described in Chapter 5.5.4 (Ritchie and Lewis 2003, Beard and West 2012, Herbec et al. 2014a, Parkinson et al. 2015). First of all, all transcripts were re-read again, and the data relevant to smartphone-based support with NRT use and the NRT2Quit app was identified from each transcript, coded to an overarching code 'NRT app' and highlighted in a blue colour to facilitated further analysis. This data was not separated from the other interview data to allow interpreting the emerging accounts in context.

Secondly, a sample of five interviews was selected to develop the first version of the coding framework. In the process, the transcripts were read and re-read again with a

focus on the highlighted sections, and the emerging themes were grouped under a hierarchical thematic framework. The themes were both deductive (based on the functionality of NRT2Quit and themes emerging from a study conducted earlier about a web-based intervention supporting quitting smoking in pregnancy (Herbec et al. 2014a) and inductive to allow novel insights. Next, this first emerging coding framework was applied to the remaining 11 transcripts and refined as needed. Finally, the coding framework was validated by a second, trained, researcher (an undergraduate student of psychology), who applied the framework to four interview transcripts. Any emerging discrepancies in coding were resolved through a discussion. Finally, descriptive accounts were drafted.

6.3.5. Interviewer characteristics and positionality

These are reported in Chapter 1.14.

6.5. Results

6.5.1. Overview of findings

The analysis revealed seven overarching themes (See Box 6.1). These themes, together with sub-themes and illustrative quotes, are described below. As has been reported in Chapter 5, the interviewed sample often had negative experiences with NRT use in the past (e.g. low benefit and satisfaction, or side-effects), as well as limited experiences with accessing support and information on NRT use. These experiences seemed to have also contributed to participants' low expectations or limited suggestions for how an app such as NRT2Quit could assist them with medication use. Moreover, when discussing current or potential features in NRT2Quit or similar programmes, participants tended to draw on their experiences with other DBCIs rather than with traditional support with medication use or quitting smoking.

Box 6.1. Main themes and subthemes emerging from the study on NRT2Quit and digital support with NRT use.

Theme 1: General views and preferences on NRT2Quit and apps supporting quitting

Theme 1.1: Relevance and usefulness of NRT2Quit and similar programmes

Theme 1.2: Expectations for comprehensive cessation support

Theme 2: Features supporting NRT use

Theme 2.1: Reminders to use the app and NRT products

Theme 2.2: Advice on NRT and its use

Theme 2.3: Monitoring of NRT use

Theme 2.4: Feedback on NRT used

Theme 3: Features supporting quitting

Theme 3.1: Craving monitoring and management

Theme 3.2: Quit plan and a quit date and general cessation advice

Theme 3.3: Advice on developing non-smoker identity

Theme 3.4: Progress monitoring and feedback

Theme 4.4: Encouraging and non-judgemental support with relapse

Theme 4: ‘Appness’ – general app qualities

Theme 4.1: Personalised support

Theme 4.2: Customizability of app features

Theme 4.3: Ad libitum use, app interactivity, and forgiving interface

Theme 4.5: Gamification and rewarding interactions

Theme 4.6: Credibility

Theme 5: Auxiliary support

Theme 5.1: Support from healthcare professionals

Theme 5.2: Peer support

Theme 6. App visual design and promotion

Theme 6.1: App promotion and distribution

Theme 6.2: Suggestive app design, icon and name

Theme 7. Experience and identity of app users

Theme 7.1: Identity of an app user

Theme 7.2: Experienced ‘appers’

6.5.2. Summary of the identified themes

Theme 1: General views and preferences on NRT2Quit and apps supporting quitting

Theme 1.1: Relevance and usefulness of NRT2Quit and similar programmes

Participants differed in their evaluation of the NRT2Quit app and their general views on using smartphone-based programmes as aids for NRT use while quitting smoking. Some participants, especially those with limited knowledge of NRT or

negative views on the medications, those believing that willpower is vital for quitting successfully, and those with limited experiences or negative views on apps in general, tended to be ambivalent or sceptical about such interventions and their value.

“[NRT2Quit] has advice about the NRT but [...] I’ve not successfully really used NRT [...] I don’t in my head know quite how, how much it will satisfy my cravings [...] for a lot of people [...] they may have similar feelings to me [...]” (P4)

“It is good, like I’m seeing stuff that I wouldn’t think of [in the advice on NRT], but a lot of it is unnecessary. [like] vivid dreams, like I said, that’s cool, the role of NRT, the safety [...] they are useful, but do you really need them? As long as you give up, who cares?” (P6)

Other participants, especially those who used different health apps before, often held more favourable views on NRT2Quit and similar apps, mainly due to the convenience and unique functionality that smartphone-based support offers. They also praised the comprehensive set of features and advice.

„I’m well aware that there is a lot of support out there from, you know, hospitals and GPs and things but you have to make an appointment and you have to travel to get there or you have to speak to the pharmacist when you buy the product whereas if you’re online or if you’re on the app, [...] I could [...] get the information that I know I want and I know I need but at a time that’s convenient to me.” (P2)

“It’s not bad actually. Advice. Your profile, when you started, your target dates and then looking at it in a... Is it going to be a pie chart? Oh, telling you what you’re using. Oh, so it’s what you’re... About your NRT that you’re actually having. Interesting!” (P10)

After familiarising themselves with the app content, participants felt that the main role and potential benefit of NRT2Quit were to help raise users’ awareness of the recommended, and often higher than expected, daily dosage of NRT.

“If the results and the research suggests that you have to take shedloads of it [NRT], to help you stop smoking, then maybe it’s [NRT2Quit] helpful to people [...] it’s just about getting that information across to people.” (P13)

Theme 1.2: Expectations for comprehensive cessation support

Many participants were dissatisfied by the app’s narrow focus on medication use.

Many participants expressed a strong preference for apps delivering more comprehensive support with quitting in general (see Theme 3 below).

“[NRT2Quit] has advice about the NRT but [it also should have information on] how to kick your cravings maybe..” (P4)

“...this is all about NRT rather than what people want to achieve, which is stopping smoking. So I’m not, personally I don’t think I would be interested in it.” (P13)

Theme 2: Features supporting NRT use

Theme 2.1: Reminders to use the app and NRT products

While some participants viewed reminders and notifications as intrusive and nagging, others believed these features could be useful if they reminded them of relevant functionality or provided advice or tips within the notification text itself (see Themes 4.1-4.2.). Nevertheless, when asked about their views on what a hypothetical app for NRT use should do, most participants immediately suggested reminders to use medications as its primary function.

“Do, app-wise, what would the app do then, would it, 'cos the easiest thing is to remind people to take their stuff isn't it?” (P5)

“Well, [taking NRT] it’s every hour you said. [...] So why do I need an app for that? [...] Not unless it prompts you.” (P6)

Some participants also expected more sophisticated reminders, including the use of suggestive noises, or tailoring the reminders to one’s pattern of cravings.

„I just wouldn’t remember [to take NRT on a schedule] because a craving is what reminds you [...] unless you set a reminder or something [...] Unless, maybe an application can help in that make a set a pattern [...] based on [...] when you get cravings...” (P12)

“I mean I think stuff with recall's great, I think an app that makes a [spraying noise] noise [to remind about nicotine spray] I think it'll be great, if there could just be some kind of alarm” (P9)

Theme 2.2: Advice on NRT and its use

Participants were also interested to read information about the individual NRT

products, their use, and the mechanism of action. However, often this was only mentioned after the participants learned for the first time about the different guidelines and recommendations on NRT and its use.

„Yeah, maybe a bit more information about exactly how the gum was helping me, I knew it was helping me to quit, but I didn't know kind of what was in the gum, [it] could have a section saying “Use medications to do this, this is what they contain, this is”, you know, and list even maybe the side-effects” (P14)

„I think with the patches I definitely want some kind of advice about how to use it, so all of the stuff that the pharmacist would probably tell you when you buy it, having that conversation but have it stored in the app somehow so people can get to it when they want to.” (P2)

After exploring NRT2Quit, many participants considered the advice on medication use within the app to be comprehensive, and some interviewees were positively surprised and even encouraged about the information provided. Nevertheless, many expressed particular interest in the information about possible side-effects (which was also reflective of the preoccupation with possible harms in other sources with information about NRT – see theme B2: Capability to engage with information and support with NRT use in Chapter 5).

„[section] “What to expect” is also really good because I was never, I think, I wasn't told what to expect or what I should feel or anything like that so I think that's very good to have all of this down. I think you're very open about all the information that you put exactly, it's really good, all the side-effects and the dreams and things like that, that's good.” (P14)

Participants rarely expressed a need for information on how to use medications, but those that realised they might have used NRT incorrectly in the past were welcoming any additional resources on this issue, including videos or other visual aids:

„if I'd seen a video of someone having the gum and explaining that it's working and you know, warning me that it's not a great taste but it's doing all of this, that would have, I might have, you know, pursued [with] it” (P2)

Theme 2.3: Monitoring of NRT use

The central feature of NRT2Quit was the ‘NRT Dial’ on the dashboard that

allowed participants to record NRT use across the day, and also offered feedback (Figure 3.3 and Appendix 3.6). On the first use, participants were often confused by its role and functionality. This was somewhat resolved with verbal clarifications offered or when participants carefully read the Help section accessible from the dashboard.

„now I know how it [NRT2Quit dashboard] works yeah it’s a good design.” (P11)

Others were of an opinion, however, that by being too focused on NRT use, NRT2Quit could belittle efforts at trying to quit unaided:

“I might want some, some recognition [...] if I haven’t used [NRT when quitting successfully], because I think for me it was very much about getting the whole habit out of my system rather than just replacing one habit with another habit. [...] maybe [other smokers] don’t want to use [NRT] all the time” (P1)

Additionally, many participants did not see value in the monitoring of the amount of NRT used, and viewed the need for frequent reporting on NRT within the app as burdensome.

“I would probably feel over time that sixteen times a day remembering to log in and press it would be annoying but if I knew from the outset that actually just it was fine just to sort of at 4 o’clock in the afternoon just suddenly just count how many pieces of gum I’ve had and upload it all in one go, that would be a lot more feasible and a lot less involved.” (P4)

Theme 2.4: Feedback on NRT used

Participants were interested in feedback on the amount of NRT used and saw this as the main value of the NRT Dial. However, in line with their general preoccupation with harms from NRT (see Chapter 5), many seemed primarily interested in learning when they are taking too much of the NRT and when they should start taking less of it to prevent overdosing or to limit the nicotine intake.

“that’s good, see because if I had something like that that would have told me I was eating too much gum or that, yeah, I like that, it’s telling you that you’ve used more than you’re allowed.” (P14)

“I guess it’s [NRT2Quit dashboard] just if you want to know whether you’ve used too much at any one point, okay.” (P2)

Participants were often also surprised and even concerned that the app allows or encourages them to use doses of NRT that were higher and more frequent than they expected.

“I suppose it’s good for showing you that you can [use more NRT] still, especially because as I said, you know, I was worried that I was having, that it was going to double-up on my, what I was having. ...so what happens if you get to the end, if you tap them all? Does it say you’ve had too much? Okay. It won’t show on the dial.” (P4)

Some participants also preferred a more dynamically tailored feedback on NRT, e.g. one that is accounting for the patterns of smoking and cravings to determine if the medications have the desired effect.

“I mean that [a chart] would be helpful, because if you’re using a certain strength of product then you could see maybe measured against your cravings, you could work out [...] whether that’s the right drug for you” (P11)

„you need to look at how much of the gum you’re using to get away from smoking and how you’re smoking and over time you’ll be able to see the patterns” (P10)

Theme 3: Features supporting quitting

Theme 3.1: Craving monitoring and management

Features supporting management of cravings for cigarettes were among the most desired components in a stop smoking app, including one focused on medication use. Participants expressed a desire for features promoting distraction, advice on how to resist cigarettes, as well as tools for mood regulation and stress management.

“I’ve got an app, I’ve downloaded it, I just listen to rain, if I can’t sleep I just listen to rain, if I get anxious I listen to rain, I fall asleep. Put some music, opera, different genres on here and let people listen to it to distract them from smoking” (P9).

They often mentioned a ‘panic button’ as a desired feature that could take them directly to the relevant support, and some also expected to receive support that is tailored to the context when the craving occurs.

“Yeah, just, kind of like, like a panic button thing, you know, sort of like 'OK, I'm about to smoke, [...] but as an absolute last resort I'm just letting you know I'm going to do it' and like there to be like a recording of some sort that would just be like 'OK, cool, that's fine, you're going to do it, you know, it's OK, that's your choice, you're free to do that, but just like relax and give it three minutes” (P15)

„You could always have a sort of fun thing to click on when you need a cigarette and you're really like a panic button, [...] make it like really clear like a danger button or like, you know, 'when you're feeling bad click here” (P5)

Theme 3.2: Quit plan and a quit date and general cessation advice

Participants were interested in having a quit plan within the app, but many preferred to cut down rather than to quit abruptly.

“[on the app] “I'm going to stop in,” and then I can enter that, and then maybe have an optional countdown, so maybe in the weeks leading up to it it reminds me two weeks, so it's nice and gentle,..” (P11).

There also voiced mixed views about setting a quit date, especially in the near future, as many felt it can be too constraining and even stressful.

“I haven't [looked at stop smoking apps] because I haven't picked my day and I didn't wanna put pressure on myself.” (P11)

“[when using apps] there's no pressure [but] if you have to give a date to the advisor sometimes you've got to make sure that actually you're not just pulling any date, you're not saying any date just because you need to say a date, you know, it's a bit, there's no mental side of it, I don't know, great [that NRT2Quit gives you flexibility], wow, OK!” (P5)

Some participants had also different views on what ‘a quit date’ is (e.g. whether it means stopping smoking, or stopping using NRT as well).

“...But is that, that's a bit naïve is it not to imagine that suddenly you'll [stop smoking on the quit date] ...? [...] So when I think of a quit day I think of that as the day when I no longer need NRT and no longer want to smoke.” (P4)

Theme 3.3: Developing non-smoker identity

Some participants noted and read out-loud the frequent suggestions and advice within NRT2Quit related to developing a non-smoker identity as part of quitting (e.g. suggestions to start to think about oneself as a non-smoker), which was met with very mixed views – some found it as an appealing technique, but others seemed put off by it.

„But all the information is great and all the things that you’ve got down, like the “Think as a non-smoker” and things like that, that’s really good.”
(P14)

“Yeah, your journey to becoming a non-smoker, I don’t think, that sounds a bit cheesy to me.” (P2)

Theme 3.4: Progress monitoring and feedback

In general, participants were interested in different progress reports, charts, calendars and other features that tracked the process as well as highlighted the benefits of quitting, particularly for health gains and money savings, and especially if these could be quantified.

“...if there was some like really impressive statistics about giving up smoking, yeah, that “oh wow it is really good” and like working out how much money you would save over a year and, I don’t know, yeah I’d need to be impressed by some stats or something about giving up smoking.”
(P3)

“if you’ve managed it [to resist a craving], it can maybe keep a rolling tally of how many cigarettes you’ve not smoked and then you could either convert that roughly into how much money you’ve saved, or even health.”
(P4)

However, participants differed in their interest in, and acceptability of, features requiring them to input data into the app, including as part of progress monitoring. For example, some expected the progress to be calculated automatically and presented to the users on app launch, while others expected diary-like features enabling more detailed documenting of experiences and feelings during quitting or receiving reminders about progress monitoring and feedback.

“It’s got to have a diary, people have got to express, we’ve got to express, there’s got to be a part where you can have a diary and then diary that interacts with you like Siri.” (P9)

“it’s like a diet, you know, you don’t want to say “Yes, I’ve had salads two days in a row”, you know that doesn’t sound fun [laughter]. [...] I wouldn’t want to be recording my progress on it. [...] I think the app checking on you is dare I say it, a bit disingenuous because it doesn’t feel like a person [...] no one is checking on you” (P2)

“I certainly wouldn’t want someone to be, you know, checking in every week, “How are you doing?” Or have to report to an app saying, you know, “Seven days without smoking or eight days”, [...] I wouldn’t want to have to update progress [...] I certainly don’t want to get a 30 day alert that I’ve stopped smoking, you know.” (P2)

Theme 4.4: Encouraging and non-judgemental support with relapse

Participants expected an quitting app to offer non-judgmental, friendly, and encouraging support with quitting, and to be forgiving of slips and lapses into smoking.

„you know “you can do this and don’t worry if you slip up” and I think that’s the important thing, sort of making sure that people know that even if they slip up this app is still on their side [...] rather than just thinking “oh well I’ll never quit” and giving up on giving up.” (P4)

Theme 4: ‘Appness’ – general app qualities

Theme 4.1: Personalised support

Many participants expected apps to offer a high level of tailoring or personalisation to their profile, which could increase the relevance and acceptability of the programme. Personalisation was expected to apply to the content, advice and recommendations for quitting and medication use. Participants also suggested different levels of personalisation, from personalisation based on user profile (e.g. age) to dynamic tailoring to factors that affect the momentary experience of cravings.

„... you ask a couple of questions about your smoking style and your smoking habits and then that could kind of tell you which product might be best to help you stop smoking, I think that’s something that an app could do that a website would struggle with.” (P2)

“[maybe..] initially when you first start using [the app], it asks you questions, and based on your responses [...] you can have like a personalised plan” (P11)

Theme 4.2: Customizability of app features

Possibility to customise different settings and features within the app were also valued by participants, especially with regards to scheduling the delivery of specific advice and reminders and setting the parameters for the quit attempt.

„but is it worth sort of asking the user when, how and when they want their support? So do they want kind of updates during the day rather than a whole set, because if all the text is static [...] people might be doing something and they're “oh this is too long”, “ (P4)

„... you should be able to tailor it yourself, so if you really need a lot of reminders you could adjust it yourself, or if you don't need that many maybe just change once, change it to once or twice a day [...] I like that you can go back to see other tips or just close them if you're not really in the mood for tips.” (P11)

“I just think like personal goals, like making it more personalised to the individual so they like have some kind of like ownership over the app kind of thing, own personal goals.” (P3)

Customisability was seen as an important method to give ownership and control of the process of quitting and NRT use to the user.

“I think you've got to let people think that they're still, they're in control and this is their choice [e.g. reminders] and this is something that they've chosen to help them and not something that's going to nag them.” (P4)

“not everyone wants eight week support so it's good to have option, you don't want to be forcing them so if you're texting and they've contacted you for support that's good because then they feel like they're in control of them stopping. I think when people think that they've been to stop they don't like it. [...] Yeah, got to self-manage it.” (P10)

Theme 4.3: Ad libitum use, app interactiveness, and forgiving interface

In general, participants preferred the app to provide information that is easily browsable and searchable, and to be able to use the app and its features *ad libitum*. However, participants differed in their preferences for the level of app interactiveness. Thus, while some participants were interested in being only passive recipients of the information and automated feedback from progress monitoring, others expected features enabling a two-way interaction, e.g. where they could enter information to shape the content or get feedback, or to communicate with someone (related to Theme 5:

Auxiliary support).

„Yeah. I like the way it's all laid out so it's not just 'boof', information, so you can pick and choose what you want to see, what to expect.” (P11)
“I think it would very much be pushing information to me [...]” (P2)

„Two way [interaction between the app and users], yeah, definitely because everything's interactive now.” (P13)

Participants also anticipated making mistakes with entering information and interacting with the app, e.g. about the NRT they used, and expected that the app would allow them to correct these.

“... 'cos sometimes we make mistakes, you know, sometimes you drop the phone or you hit on it or a child's playing with it and it's gone all the way happy and it's not, so I think if anything should be there should be a minus in case you make that mistake” (P9)

Theme 4.5: Gamification and rewarding interactions

Some participants expressed views that apps should be engaging, rewarding and fun – something that makes them stand out from other interactions, programmes and resources already available for quitting smoking. For example, providing gamification of the quit progress was believed to boost motivation and engagement with the programme.

“But I think, 'cos this [registration tunnel of NRT2Quit] is not really an app, this is more like a questionnaire that you're answering questions, I mean an app is like a fun sort of, but like a, it has pictures and maps and, you know, and does, it's active” (P5)

“Is that going to be achievement markers? I think that's really good because as I say when, with the Stoptober they were the things that I did find helpful. [...]” (P4)

Theme 4.6: Credibility

Few participants commented on the credibility of the app suggested by its different elements (e.g. logo, content), which was appreciated:

“Based on, yeah, makes it sound professional that the support and information is based on stop smoking services, by National Centre for Smoking Cessation and Training, makes it sound professional.” (P3)

Theme 5: Auxiliary support

Theme 5.1: Support from healthcare professionals

Many participants expected and preferred an app to work independently of any other support. Others, however, expected the app to act as an extension of support initiated by healthcare professionals or other experts known to them.

“No, no, it [an app] has to come with something, it has to, [...] I'll just look at it and go 'this can't help me', but when you've got professionals involved you can't log onto that app until you get a code from them and that will give them the access as well to monitor from the, from the, from the computer.” (P9)

“if a person was checking [the data entered in the app], you know, you've never spoken to this person because you've been using the app so that would feel a bit weird too.” (P2)

Another valued feature within an app was offering directions to external support, e.g. pharmacies.

“I think a map of pharmacies, what's the nearest pharmacy would be excellent, 'cos some people, when you say 'oh shit, I've lost it at home, let me just have a fag', 'no, just stay on track', a different locations for nearest pharmacy who have got that product.” (P9)

Theme 5.2: Peer support

Others valued peer-to-peer support, e.g. a discussion forum to exchange ideas and support one another, as well as testimonials of others, e.g. on quitting and medication use.

„Yeah, and even if there was maybe a forum or something where you could chat to other smokers who are struggling if you're kind of, that would be good.” (P14)

“But yeah maybe some inspirational quotations from ex-smokers.” (P11)

“ if I’d seen a video of someone having the gum and explaining that it’s working and you know, warning me that it’s not a great taste but it’s doing all of this, that would have, I might have, you know, pursued it and gone through it” (P2)

Theme 6. App visual design and promotion

Theme 6.1. App promotion and distribution

Some participants discussed their preferred way of learning about the app and obtaining it. Some suggested it should be promoted through leaflets attached to, or provided with, the nicotine products or information provided directly on the product packaging. Others believed they would be more likely to download the app if it healthcare professionals recommended it.

“..even if I went to buy a product and on the product it had the name of the app, and if it said, “You can download this,” so even if it’s not that explicit yeah, I’d probably try it, yeah.”(P11)

“I think if my GP had told me that I would have been like “Yeah, cool, I’m going to quit in two weeks and stuff, I’ll give it a go”. I think if someone over the counter when I was buying a patch had told me that I’d have said “No, I don’t have time”, so yeah, I think who it comes from is quite important for me” (P2).

Theme 6.2: Suggestive app design, icon and name

Some participants were very attentive to the different visual aspects of the app and its icon, and often suggested improvements, particularly to the use of different colours and choosing icons that are immediately suggesting of quitting smoking:

“The only thing that I would change is the theme, that’s all, the colours, not red, not red, red is almost like a, any colour but red” (P9)

“...forgive me, but I don’t know if I like the actual icon. [...] Because I can’t, it’s not very familiar, what is it? [...]it could have been just a cigarette with a cross in it, no smoking.” (P7)

The name ‘NRT2Quit’ was not immediately appealing to many of the participants, often due to being difficult to pronounce, because participants had limited familiarity with NRT standing for nicotine products, and also because it was not

reminding them of quitting.

„It's a bit, [pauses] doesn't roll off the tongue, it's a bit technical.” (P11)

„Yeah, if that was on a list of app names, I don't think I'd... I wouldn't know what it was for.” (P14)

Theme 7. Experience and identity of app users

Theme 7.1: Identity of an app user

When discussing and justifying suggestions for apps some participants tended to draw on their observations and understanding of behaviour, needs and preferences of other smartphone users. From those accounts a shared identity of an app user was emerging, namely one of a person who is busy, impatient, with short attention span, and who seeks engaging, rewarding and effortless experiences with apps.

“we need something that's quick, accessible and, and very informative and straight to the point, yeah, I think people get bored after they see a page [...] it's got to have personalisation, people have got to feel unique, not the same” (P9)

„... all the information there's brilliant but if I think about my friends who smoke, they're not gonna read all of it, yeah it would just be, you know because they're used to just catching Pokémon [laughs].” (P11)

“...people like, you know, they're playing games on their phone, they look at stuff, social media era now.” (P10)

“whether you turn off your notifications or not your phone's gonna vibrate [...] I wouldn't worry about that too much [...] because people always look at the phone, it doesn't matter what it vibrates for, you look at your phone.” (P9)

Theme 7.2: Experienced 'appers'

Some participants had prior experiences with different smartphone apps, although few used health apps, and even fewer cessation apps. These participants were familiar the different functionality and designs used in apps, and they often drew on their experiences with these other programmes when suggesting and discussing preferences for apps supporting NRT use and cessation.

“you know what's good on apps, have therapeutic music on there” (P9).

“Yeah, I would engage with that because it's like my Cambridge Weight Plan. [...] it comes up with, you know those old-fashioned ribbons [...] and it's got 'well done' in massive writing [...] I love that, it's brilliant, it really is good. So I think it's the same thing with this [app for NRT use]” (P9).

„Do you have like any, any kind of like, you know, like mindfulness, meditation things on there or anything? [...] I always find it really relaxing to have like those little things, like the, you know how on the Headspace app” (P15)

“iQuit or, or QuitTime or something like that. [...] Yeah, I think that was one of my favourite things about the app, sort of like 'this has now left your bloodstream, this has now gone'” (P1)

Below is an example of one participant explaining while demonstrating on their phone the desired functionality and design for apps based on other apps they use:

“[this one non-health app I have] it's quite intrusive and labour-intensive, whereas my favourite app in terms of design is nice and bright, you can chart your progress [...] which I really like, and then you can choose [...] there's just four options, [...] but you can tailor it to what you want, and you can set reminders [...] and then you do your own challenge [...] it's only up and down, [...] it's just what I would call clean, but I haven't got any health apps that are like that, [laughs] I've just got yoga ones and relaxation noises. So something like that is what I would like because it's not 'fiddle, fiddle, fiddle', it's just 'that, that, that, that', so something like that.” (P11)

6.6.3. Reflections on the data collection in the present study

As per the think-aloud protocol, participants were encouraged to engage with the app naturally, rather than to explore it in a pre-determined and standardised manner. Moreover, NRT2Quit was a complex app, but given the limited time, it was not possible to discuss every screen and section of the app. As a result, the interviews tended to differ from each other as the discussion often revolved around specific advice or feature in the app that participants engaged with (e.g. tip for a specific day), or one version of feedback to a survey they completed. Moreover, none of the participants started exploring the app by reading the tutorials or help sections; instead, they relied on insights gained from experimenting with the app or asking for clarification.

“Basically I didn't read the instructions. [...] Sorry, it's a problem.”. (P5)

During the sessions, participants also often only skimmed through the content, reading out loud selected phrases and sentences in order to provide some, often brief, feedback.

“[participant reading out from the app] ‘My reminders. We would like to send you a friendly daily reminder about NRT and about new sessions and content, you can change them later’. Yeah, that’s good.” (P3).

Moreover, although participants were relatively familiar with the advice and the type of support offered to smokers wanting to quit, they were less familiar with the advice and support available for NRT use. As a consequence, and contrary to the initial expectations, participants rarely mentioned forms of support that they found helpful with the medication use and which could be implemented in digital forms in the future. They often also had few suggestions on how to support NRT use, and tended to question the relevance of specific functionality and advice within the app. Only one participant mentioned thinking about a possible app and its functionality before coming to the interview and came prepared with some suggestions.

6.7. Discussion

This study assessed the preferences and perceived needs of smokers and ex-smokers who had used NRT in the past with regards to smartphone-based support with quitting and NRT use. The NRT2Quit app was used as a prompt to collect the information. The study provided insights on features that smokers find potentially desirable and acceptable in such apps and identified several areas where the NRT2Quit app could be improved in the future.

In general, participants had few suggestions for features within the app that could be supporting NRT use, most commonly reminders to use the medications. This was likely due to their limited experience with engaging with relevant support with medication use in the past, as reported in Chapter 5. More often participants were voicing preferences for a range of features that they had encountered and liked in other stop smoking or health-related apps (e.g. specific diary-like features). Interestingly, participants often also justified their preferences by drawing on their observations of how others and themselves engage with smartphones and apps. From these accounts, a shared identity of app users was emerging, which was characterised by short attention

span, limited patience, low threshold for boredom, as well as preferences for rewarding and low burden interactions.

While there were considerable differences in preferences for apps supporting NRT use, there was generally a consensus on a number of features and qualities. Participants tended to prefer apps that provide comprehensive support with quitting, rather than to focus entirely on NRT use, and which include reminders to use medications, general information about smoking and quitting, information about individual NRT products, relevant feedback on NRT used, testimonials of smokers and ex-smokers (including video-based instructions on medication use), and support with craving management. Participants also expected such apps to have high relevance through offering personalisation of content, customisability of settings and reminders, and flexibility to change parameters of a quit attempt. There were also expectations for an *ad libitum* app use, an engaging and forgiving interface, the advice being delivered through visual means and short texts.

However, there was little consensus among participants for a number of specific features and app qualities, including: provision of peer support (e.g. forum), engagement of HCPs, use of notifications and reminders to use the app, features supporting monitoring of medication use, as well as the level of interactivity within the app and the expected level of engagement and data input on the part of the users (e.g. use of diaries). This suggests that future versions of NRT2Quit may need to account for these differences in preferences and offer certain features only as optional content.

These findings are in line with the previously published research on the preferences of smokers towards web-based cessation interventions (Herbec et al. 2014a) as well as smartphone-based support (Hartzler et al. 2016, McClure et al. 2017, Perski et al. 2017a). Additionally, echoing findings reported in Chapter 5, participants demonstrated some pre-occupation and particular interest in the content (e.g. advice) and features (e.g. monitoring and feedback) that offer information about harms, side-effects and possible risk of overdosing from the reported amount of NRT used.

Finally, participants expressed preferences for a customisable and flexible quit plan, including one that allows for cutting down, and showed little acceptability for setting a quit date and committing to quitting soon after downloading an app. Findings from an observational study of the SF28 app (Ubhi et al. 2015, Ubhi et al. 2017) found that the majority of users who download it set the quit date to the day of downloading

the app. This is perhaps not surprising, as users who seek and download apps may be more motivated and ready to quit in the near future than smokers who are currently not using such apps or trying to quit, but who are taking part in a study such as this one. Alternatively, it is also possible that those who download such apps choose the quit date to ‘today’ in order to explore app functionality before committing to quitting on a future date. Nevertheless, the implications are that research with smokers, who are at different stages of quitting during data collection, may result in different recommendations for app development.

6.7.1. Strength and limitations

The present study was conducted together with the interview study reported in Chapter 5, and the findings from the two can improve our understanding of the preference and needs of the smokers regarding smartphone-based support with NRT use, the context in which these views are emerging, and also the challenges of implementing and disseminating support with NRT use through apps.

Nevertheless, the present study suffered from several limitations that are inherent to qualitative research conducted among a small and self-selected sample, including limited generalisability of findings. Additionally, some of the participants were former smokers, and it is likely that to them the interventions such as NTR2Quit or similar hypothetical programmes had lower relevance and appeal. Secondly, participants were aware that me, as the interviewer, was involved in the development of NRT2Quit, and although they were encouraged to be honest and critical, it is possible that due to demand characteristics and a desire to please or not to offend the researcher they were refraining from offering too much criticism.

Finally, the study relied on first impressions from NRT2Quit during a limited interaction in a lab setting. Some research suggests that interaction with apps as part of usability studies in the lab and ecological settings results in similar observations and can identify similar issues (Anne Kaikkonen et al. 2005). Nevertheless, the findings may not reflect how smokers wanting to quit and who purchased NRT would use this or similar apps after downloading them from an app store in the absence of the researcher, which requires more research.

6.7.2. Implications and future directions

The present study shows that the resulting NRT2Quit app included many features and content that were valued by this study's participants. However, it also showed that the app and its clinical content could be improved in several ways, particularly from the perspective of user experience design, user journey, copy text editing, as well as visual designs (including app branding, its name and any icons used). The implications of these findings for app development are discussed in Chapter 12.

Furthermore, the advice offered within NRT2Quit was based on best clinical practice, which was valued by many participants. However, the recommendations regarding the regimen of NRT use (i.e. duration, frequency and amount) were often not acceptable to participants. Instead, they often questioned the appropriateness and safety of the advice on NRT use. This suggests that providing such recommendations through an app and without additional support or endorsement from HCPs may not have the intended effect on behaviour among some smokers. Finally, e-cigarettes were rarely mentioned by the participants, possibly because they were informed that the study focuses on NRT products. Nevertheless, NRT2Quit was developed when e-cigarettes were only gaining popularity, and when there was still a lack of clinical recommendations on their use. Given the popularity of e-cigarettes in the UK, including their endorsement and promotion by Cancer Research UK and the NCSCT, it is reasonable to anticipate that future iteration of NRT2Quit should include sections on e-cigarettes on par with that on the different NRT products.

6.8. Conclusion

The NRT2Quit app was found to be acceptable and potentially valuable as a cessation aid among some smokers and ex-smokers with experience with NRT use. However, the study identified a number of features and app qualities that should be improved and developed further using a person-centred approach. This included developing features that support quitting in general, most notably craving management tools, as well as the provision of highly personalised and customisable quit plan and feedback on NRT use.

Chapter 7: The BupaQuit app development and functionality

7.1. Chapter 7 Overview

This chapter outlines the rationale for the BupaQuit project that is described in Chapters 7-10, as well as reports on the development and functionality of the BupaQuit app.

7.2. Contributions

I co-designed the trial with Robert West (RW), as well as worked closely with the Bupa IT team (Alex Matei, AM) to co-design the BupaQuit app. The major decisions about the app development and functionality were consulted with RW, Harveen Kaur Ubhi (HKU) and Jamie Brown (JB) at UCL.

7.3. Introduction

7.3.1. The rationale for BupaQuit project and app development

As has been reviewed in Chapter 1.2, abstinence from cigarettes can trigger a series of withdrawal symptoms, including cigarette craving. The latter can be defined as the experience of strong motivation (desire, need or urge) to smoke, and it is predictive of relapse (Killen and Fortmann 1997, Zhou et al. 2009). Several techniques have a potential to reduce momentary cravings, including distraction, imagining pleasant experiences (May et al. 2010), relaxation (Ussher et al. 2009), physical exercise, muscle tensing (Scerbo et al. 2010, Ussher et al. 2012a, Haasova et al. 2013) and yogic breathing (Shahab et al. 2013b). Stop smoking interventions that include behaviour change techniques (BCTs) (Abraham and Michie 2008, Michie et al. 2011b) that reduce, or improve coping, with cravings appear to improve success rates (Michie et al. 2011b). Some of these techniques could be implemented in smartphone apps, thus potentially supporting quitting.

DBCIs, including smartphone apps, have been suggested by researchers and

smokers to be a useful medium to deliver support with managing of cigarette cravings, also because apps can support both cognitive and behavioural distraction (Ploderer et al. 2014, Hartzler et al. 2016, McClure et al. 2017). Participants in the think-aloud study about the NRT2Quit app also expressed interest in craving management in apps (e.g. a ‘panic button’ that triggers support when users want to smoke a cigarette, see Chapter 6). There are important advantages of using apps for craving management. For example, they can deliver diverse multimedia content aiding distraction (e.g. video and audio content or games), and guide users through other activities beyond the app (e.g. exercises). Additionally, apps can be designed to function both online and offline thus facilitating access to such aids.

To date several studies have evaluated DBCIs that aimed to support smokers with the management of urges to smoke, including websites and SMS texting (O'Connell et al. 1998, Rodgers et al. 2005, Whittaker et al. 2008, Ploderer et al. 2014). Several stop smoking apps that offer support with cravings have been developed and are available to smokers on the app stores (Healthline 2018)(Fischer 2018). However, research on their impact remains limited.

A pilot study of one such app called DistractMe assessed the patterns and reasons for app use during the first six weeks of a quit attempt among Australian smokers (Ploderer et al. 2014). In that study participants used four coping techniques and engagement patterns with DistractMe to prevent cravings and their effects: avoidance of triggers, displacement (e.g. gardening to cope with the cravings), preparation (e.g. planning for quitting), and fortification (e.g. accessing motivational tips). Additionally, these smokers used two techniques of coping with cravings when they emerged: confrontation (e.g. actively resisting cravings) and diversion (e.g. engaging with suggested content online)(Ploderer et al. 2014). These findings show that at least some smokers are interested to engage app-based support with cravings.

The wider BupaQuit project aimed first to develop (reported in this chapter) and then to evaluate a new, bespoke stop smoking app that offered general advice on quitting smoking, but also delivered CMTs to smokers, who were undergoing a serious quit attempt. The new app was sponsored by a healthcare company Bupa and was called ‘BupaQuit’.

7.3.2. Theoretical underpinnings of BupaQuit

Instead of developing an app from scratch, we used an app that was already available on the app stores, called SF28 ('SmokeFree28') as a basis for BupaQuit. SF28 supports smokers to be smoke-free for 28 days, as the first step to long-term abstinence (www.smokefree28.com) (West and Stapleton 2008, Ubhi et al. 2015). SF28 is informed by the PRIME theory of motivation, which postulates that quitting requires maintaining sufficiently high desire and capacity to override emerging impulses to smoke (West 2007b).

SF28 was judged to contain evidence-based features that might be expected to improve cessation (Ubhi et al. 2016a, Ubhi et al. 2016b). Specifically, the app supports users to set a clear goal (a quit date), monitors their progress towards abstinence, and offers tools supporting quitting, such as advice on medications, a distracting game, and *4Weeks2Freedom* comprising inspirational videos from smokers trying to quit (Ubhi et al. 2015). An observational study of SF28 produced self-reported short-term abstinence rates (18.9%) that were higher than would have been expected with unaided cessation (Ubhi et al. 2015). It also achieved relatively high engagement rates (8.5 (SD=9.0) mean logins) (Ubhi et al. 2015). It was hoped that using SF28 that already had relatively good engagement rate would mitigate one of the key issues faced when evaluating apps – attrition and possibly seeking out other apps (Michie and West 2016).

7.3.3. Practical assumptions underlying BupaQuit development

Several assumptions informed BupaQuit development, which were also relevant for its subsequent evaluation. First of all, just as SF28, BupaQuit was meant to offer automated and standalone cessation support, which assisted users in preparing for quitting and then assisting them during a 28 days long abstinence challenge. Secondly, the app would retain core functionality, content and user-journeys from SF28. Thus, the app was meant to support smokers who download the app without any assistance, are already motivated and ready to set a quit date within two weeks from downloading the app. Thirdly, recognising the importance of iterative and data-driven development (Craig et al. 2008), from the outset BupaQuit was planned to be a long-term project involving several cycles of iterative development and mixed-methods evaluation following the first planned trial.

Fourthly, it being a software project marked with high ambiguity, but with fixed resources and timelines, BupaQuit was to be developed using agile principles. Fifthly, in line with user experience (UX) practices, in addition to offering advice informed by evidence, BupaQuit was meant to be intuitive and user-friendly, requiring an input of user experience (UX) designers and digital health teams at Bupa. Finally, future versions of BupaQuit were meant to offer increasingly personalised advice based on the user characteristics and app usage patterns (*Note*: data scientists based at Bupa were conducting separate data analyses to the work reported in this thesis).

Given that the selection of the evaluation design would impact on the app development, the former was considered at the start of the project. Several study designs and control conditions were considered, including observational studies and waitlist controls. Following consultations and internal discussions, it was decided that the app will be evaluated through a two-arm parallel RCT design (the details are reported in Chapter 8) supplemented by nested qualitative interviews (reported in Chapter 10). Although RCTs have several important limitations, especially in terms of being resource-intensive, as outlined in Chapter 2.4.3, it was judged that it would be feasible to conduct a sufficiently-powered trial given Bupa resources and support. Conducting an RCT would also provide a stronger test of whether the provision of CMTs would improve cessation in comparison to a version without them.

Finally, as reviewed in Chapter 2 (sections 2.5.2), there exist many challenges in identifying an appropriate control condition for apps evaluated through RCTs. Using a bespoke app that would act as a minimum credible intervention (MCI) was judged to be a fair and most informative comparison, which would additionally facilitate study promotion, participant enrolment and data collection. Furthermore, given the long-term research plans for BupaQuit, it was important that the control app would meet the expectations of potential users regarding app-based cessation support, which would help to protect the reputation of the BupaQuit platform.

7.4. Methods

7.4.1. Steps in BupaQuit Platform development

BupaQuit was developed between June 2014- February 2015. The app was developed for iOS and Android by developers at Bupa (www.bupa.com), with the process overseen primarily by AM and me, and in consultation with RW, HKU and SF28 developers. Two versions of BupaQuit were created simultaneously: the intervention (complete) app version with a set of CMTs, and a control version (MCI) without them (see Section 3.5 below for details). These two versions were available from the same BupaQuit app platform that included the enrolment and randomisation procedures.

BupaQuit involved adapting the original SF28 content (Ubhi et al. 2015), creating new content and designs to reflect Bupa branding, adding Bupa and UCL logos, and developing a bespoke database. The appearance of SF28 was redesigned while keeping the key logic, content, and user flow similar. Additionally, in line with agile processes, the work on the app was organised around “sprints”, or periods lasting 1-2 weeks, during which the development team worked on a specific app functionality, consulted the UCL team about major decisions, and conducted internal testing. Where possible, consultations with other employees at Bupa were conducted. Where appropriate, Bupa legal and communications teams were consulted to ensure that documentation about the study and within the app (e.g. the End User Licence Agreement) contained all the necessary information required by the law and followed Bupa templates.

First, Bupa purchased a non-exclusive perpetual licence to SF28 source code and content. Secondly, the content and user journeys of SF28 were reviewed by me and a new user flow was created to focus the functionality of BupaQuit Intervention app on craving monitoring and management. Any new content required was drafted by me and by Bupa members. Moreover, recognising the needs of the users and best design practices in user experience, e.g. making the system forgiving of mistakes, several further features were changed with respect to the original SF28. For example: in the original SF28 application, participants who reported lapsing for the third time were forced to re-start their quit attempt, and their progress was deleted, as it was recognised that without sustaining continuous abstinence for the first weeks since the quit date participants may fail to remain abstinent long term (Hughes et al. 2004). This function in SF28 was considered to be overly conservative and not user-friendly, and not to

account for any instances of testing or experimenting with the app functionality, or mistakes made by the users. Therefore, users of BupaQuit who reported lapsing into smoking three times were reassured that they could still quit smoking completely, were allowed to continue with their current journey, and were encouraged to reset their quit date and start a new attempt only if they felt it would benefit them. Additionally, participants were provided with options to reset their quit date and state other parameters about quitting (e.g. use of cessation support).

Thirdly, the app design was adapted to reflect Bupa branding, including the choice of company colours and fonts. An externally contracted company (Jam, www.jam.co.uk) provided expertise in design and user experience, and created a series of prototype as well as the final app designs and user journeys, which were based on the specifications and the planned content, as well as the trial requirements (e.g. registration, follow-up and other data collection). The code repository used for source code was Github. App Hosting was in Microsoft Azure (for testing), and Rackspace (for production, release and maintenance during the study).

Internal user testing was conducted regularly during app development to assess new functionality, usability, data collection, in-app follow-up, and reminder settings. A separate usability testing session was organised at UCL among novice users to identify any additional usability issues and bugs that were addressed before the app was finalised and released on app stores for the trial (e.g. adding app tutorial, making fonts larger on some instructions, providing clearer instructions).

7.5. Results of app development

7.5.1 The BupaQuit Platform

A single BupaQuit platform was developed that hosted both app versions, the enrolment tunnel, and follow-up survey. BupaQuit was accessible during offline use, except for changing the quit date and completing follow-up questionnaires to enable data synchronisation. Participants were free to use the app *ad libitum*, but the intervention app encouraged regular (daily) use through (i) push notifications set to be triggered around 6 pm every day but which could be switched off, and (ii) new content that was ‘unlocking’ with use. Figure 7.1. presents screenshots of the landing page and

the dashboard that were similar for the intervention and control app versions. Appendix 7.1. presents screenshots of SF28 and BupaQuit, Appendix 7.2. journeys through the app for returning users, and Appendix .7.3. provides a comparison of SF28, BupaQuit intervention and control on functionality and BCTs (Michie et al. 2013).

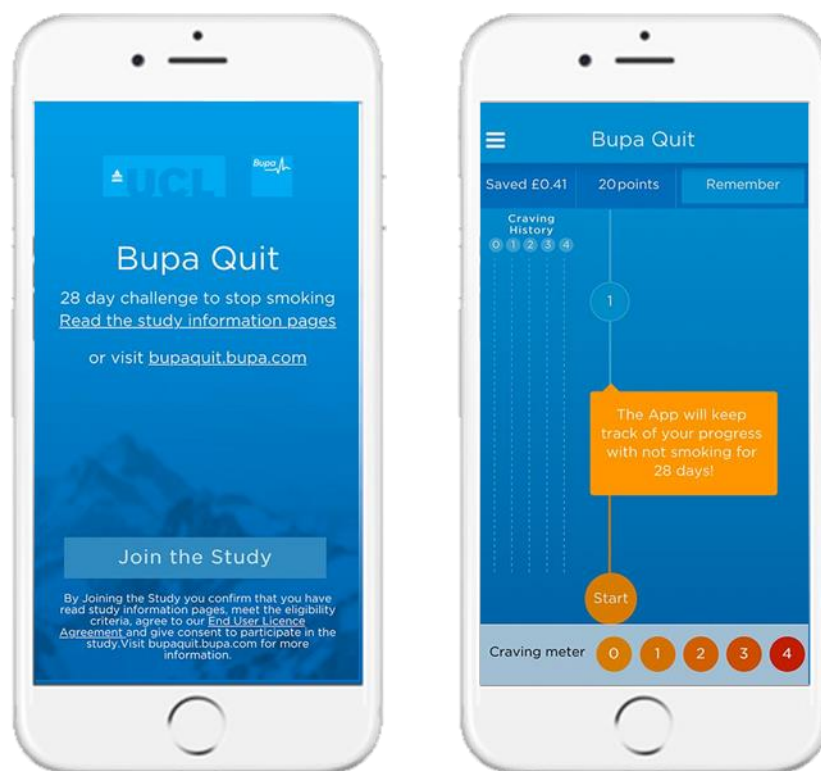


Figure 7.1. Screenshots of the BupaQuit app landing and dashboard screen (common across the intervention and control).

7.5.1.1. BupaQuit control - functionality

The control version of BupaQuit was developed simultaneously as an MCI, providing basic functionality that users could expect from a cessation app. The quit plan, and look and feel of the control and intervention versions were identical. The control app required setting a quit date within two weeks of app download, encouraged use of cessation medications, offered minimal support for up to 6 weeks (14 days before the quit date: *pre-quit*, and up to 28 days after the quit date: *post-quit*), including advice on pharmacotherapy, lifestyle changes, daily push-notifications that could be disabled, brief feedback on smoking status, sections ‘about the study’, ‘about the app’, a timeline with progress and tracking of money saved, a meter for momentary cravings (a scale

from 0-4 (Welsch et al. 1999, Berkman et al. 2011, Jorenby et al. 2017)), and an option to share the progress on social media.

7.5.1.2. BupaQuit Intervention – functionality

In addition to the functionality in the control app, the intervention app included CMTs that were suggested to users reporting ≥ 1 on the craving meter during *post-quit* app use. The CMTs included components from SF28, and were informed by research or theory that suggested potential usefulness at managing cravings: a game promoting distraction (May et al. 2010, Ploderer et al. 2014), *4Weeks2Freedom* videos presenting self-recorded accounts of smokers trying to quit, which was designed to boost motivation and self-efficacy (Brown et al. 2016), music, audio recordings of guided relaxation routines (e.g. ‘body scan’) (Cropley et al. 2007, Tang et al. 2013), descriptions of exercises and activities (e.g. fist clenching, brisk walking (Ussher et al. 2001, Scerbo et al. 2010, Ussher et al. 2012a, Haasova et al. 2013)), and motivation boosting tips (e.g. strengthening ex-smoker identity) (Michie et al. 2011b). The app also offered gamification features (e.g. unlocking of craving aids when engaging with the app), a new piece of brief advice on lifestyle changes that unlock in weeks 2-4, and longer feedback on smoking status. Some intervention content (e.g. videos, or music) was available for free upon additional download.

7.6. Conclusion

The work described in this chapter resulted in the creation of two versions of the BupaQuit app which were designed to be evaluated in a subsequent pragmatic RCT reported in Chapter 8. The intervention version of BupaQuit included components for which there was some evidence to suggest they should be of interest to smokers, and which could aid craving management and cessation.

Chapter 8: The BupaQuit Trial

8.1. Chapter 8 overview

This Chapter reports on findings from a pragmatic RCTs of the BupaQuit app, which was described in detail in Chapter 3.

8.2. Contributions

I co-designed the trial with Robert West (RW), and in consultation with Harveen Kaur Ubhi (HKU), with the final protocol consulted with the collaborators at UCL and Bupa. I then planned and conducted or oversaw all tasks related to setting up and running the trial. I prepared all trial documentation (e.g. documentation required by Ethical Committees at UCL and to register the study on ISRNCT registry, the trial protocols, data collection forms, information sheets and consent forms, drafts of email communications with the participants, and text for the project website and other recruitment materials). I also worked closely with the Bupa team on managing the trial and recruitment for it day-to-day. To support data collection I recruited and trained research assistants (Olga Perski OP, Courtney Kwan, CK, and Georgina Knock, GK) and oversaw their work at Bupa. Finally, I independently processed and analysed the data from the app and the follow-ups, and wrote up the findings. In the process I have pre-registered a data analysis plan on Open Science Framework, with the document consulted with Emma Beard (EB). The UCL collaborators provided feedback on the write-up.

8.3. Introduction

As has been reviewed in the Chapter 1.10.1, use of face-to-face and telephone-based smoking cessation support is low even when it is free at the point of access (Kotz et al. 2009, Raupach et al. 2013). Smartphone apps may appeal to smokers not willing to use these traditional forms of support (Pulverman and Yellowlees 2014), and additionally may offer unique support with different aspects of quitting smoking, including management of cigarette cravings. However, we lack empirical evidence that apps that offer craving management tools (CMTs) aid cessation.

We developed a stop smoking app called BupaQuit which aimed to support smokers to prepare for a quit attempt and then during the first 28 days after the set quit date. The intervention version of BupaQuit additionally included CMTs. Chapter 7 reports the development and functionality of the intervention and control app versions.

The present study involved a pragmatic RCT to assess how far the inclusion of CMTs in BupaQuit could impact cessation and app usage in comparison to a version that did not include CMTs (a minimum credible intervention, MCI). The rationale to use MCI in the trial is discussed in Chapter 2.5.2 and Chapter 7.3.3 In addition, one of the underlying aims for the BupaQuit trial was to evaluate the app in a more ecological setting than previous studies had done (Bricker et al. 2014, Buller et al. 2014, Bricker et al. 2017); namely, one with limited contact with the researcher throughout the trial and low participant burden at enrolment.

8.3.1. Aims

The study aimed to evaluate the complete version of BupaQuit in comparison with a control version of the app in terms of app effectiveness to increase quit rates, app usage, and satisfaction. The specific hypotheses were:

1. The participants randomised to receive the intervention version of BupaQuit will have higher cessation rates at short- and long-term follow-up in comparison with the control arm participants.
2. The intervention participants will have (i) greater engagement with the intervention, as assessed through logins and time spent, as well as (ii) greater satisfaction with the intervention.

Additionally information on (i) follow-up rate and channels, and (ii) use of unassigned cessation aids during the trial was assessed to help inform the design of future research on cessation apps.

8.4. Methods

8.4.1. Design

This study was a two-arm parallel double-blind pragmatic RCT conducted remotely in the UK. Participants were randomised automatically within the app after completing registration in a 1:1 ratio to either the intervention or control app version. The randomisation was based using a standard JavaScript library that generated random numbers. The study involved also nested telephone interviews with a sample of trial participants, which are described in Chapter 10. The study was approved by the UCL Research Ethics Committee (6212/001) and was prospectively registered with the ISRCTN Register (ISRCTN10548241) on 17th February 2015. Trial documentation was made available on Open Science Framework (OSF, <https://osf.io/ge6vh/>). The reporting of the trial follows the CONSORT (Ruano-Ravina et al. 2003) and TIDieR guidelines (FDA 2018).

After the recruitment commenced, but before the trial data were unblinded, a few changes were made to the original protocol. The changes were explained on the updated ISRCNT registration and Open Science Framework website for the project. The most important change was to the primary outcome, as due to the challenges to secure biochemical verification it was changed to self-reported abstinence. The other changes included amendments to (a) the inclusion criteria (due to missing data on cigarettes smoked per day among a sample of participants, the requirement of smoking ≥ 5 cigarettes per day was removed, and replaced with a requirement to smoke cigarettes daily); and (b) secondary outcome measures (the biochemical verification of abstinence at 6-month follow-up was suspended).

Due to the study protocol and policy changes introduced in Spring 2015 for the iTunes store regarding data collection within the apps (iTunes were no longer accepting new apps that require the provision of personal details to function), no changes or bug fixes to BupaQuit could be made during the trial. The exception was increasing the size of the control app to match that of the intervention app to minimise differences in user experience on download (the change did not require submitting a new app version to iTunes for review). This modification was implemented after 196 eligible participants were enrolled.

8.4.2. Participants

8.4.2.1. Recruitment

Participants enrolment lasted between 18th February 2015 and 16th March 2016 and involved open and remote online recruitment (Eysenbach and Group 2011, BinDhim et al. 2018), with no researcher involvement and minimal participant burden (i.e. the registration spanned only few screens and asked a limited number of questions). The study was advertised through paid advertisements on social media (Twitter and Facebook), and by emails and posters distributed among Bupa and UCL community (see Appendix 8.1). The recruitment materials invited potential participants to a study conducted in a collaboration between UCL and Bupa that aimed to compare different features within a new stop smoking app. The differences between conditions were concealed. The app could also be found through online searches and on UK app stores. Interested participants were directed to the project website (Appendix 8.1) that contained detailed study information sheet, and encouraged to download BupaQuit for free. Study information was also available upon app download.

8.4.2.3. Eligibility

Participants were eligible if they (a) were living in the UK, (b) were 18 years or older, (c) smoked cigarettes daily, (d) downloaded the app to make a serious quit attempt, (e) completed registration via the app, including providing plausible, complete contact details, (f) were willing to set a quit date within 2 weeks of registration, (g) agreed to be contacted for follow-up and, if invited, confirm abstinence with a personal CO monitor posted to them for free, (h) consented to participate and agreed to Bupa's End User Licence Agreement (EULA, which clarified that the data would be shared with UCL for independent evaluation). Criteria (a)-(e) were assessed through a baseline questionnaire. Criteria (f)-(h) were part of consent and app onboarding.

Eligibility screening was initially automated, but in some cases, it failed to detect a duplicate registration, e.g. when users spelled out the same information differently on subsequent registrations. Therefore, eligibility was checked manually and considered unique device ID, name and contact details (24/32, or 75% of duplicate accounts were identified manually; duplicate registrations could be generated by participants downloading the app on different phones). Only the first registration per person and

household was included in the trial.

8.4.2.4. Sample size calculations

There was limited information to predict the effectiveness of programmes such as BupaQuit. Therefore, the effect size estimates were based on results from the observational study of SF28 (Ubhi et al. 2015). It was assumed that in comparison with SF28, the BupaQuit control app would be slightly less effective and the intervention app slightly more effective. The predicted success rate was 17% and 25%, respectively (OR=1.6, corresponding to RR=1.5), which would be clinically meaningful (West 2007a). A sample size of 812 would be required to detect this effect size in a two-tailed test with alpha set to 5% and power to 80% (calculated using GPower 3.0.5 software). However, due to slower recruitment into the trial than anticipated, and under-recruitment within the time and resources available, the final study sample consisted of 425 participants. The recruited sample had 51% power to detect the predicted effect.

8.4.3. BupaQuit intervention and control app versions

The development and functionality of BupaQuit intervention and control apps that were evaluated in this study are described in Chapter 7.

8.4.4. Procedure

Figure 8.1 presents the flowchart of participants through the study, and Appendix 8.2 presents the participants. After downloading the app, participants provided consent and accepted EULA (via tick box), set a quit date for today or a date in the next two weeks, provided contact details, completed baseline, and received access to the allocated app version. Participants meeting eligibility criteria were followed-up at 4 weeks and 6.5 months after the final quit date set during their first quit attempt (to account for two week grace period following the quit date (West et al. 2005)).

In the first months of the trial, we found out that for some participants (called '*app-data-missing*') a set of usage and quit-related data were missing (due to the

architecture of BupaQuit database these included data on the quit date, operating system, cigarettes smoked per day, and weekly spent). After internal testing of different scenarios of participant enrolment, the possible causes identified were: (i) offline app use leading to failed synchronisation of the data between the app and study servers (for seven participants this data synchronized with a delay), (ii) interrupted registration, or (iii) not accessing the app after registering successfully. As a result, due to the missing data on the quit date, these participants were followed-up at 5 weeks and 7 months since the registration to account for a possibility that they might have set their quit date to a future date. We decided to retain these participants in the main analyses as the specific reasons for data “*missingness*” could not be determined for each participant, but we excluded them in sensitivity analyses.

All assessors were blind to condition allocation. At 4-weeks, the follow-up was via the app (up to three push notifications), e-mail (two emails), and over the phone (up to four calls). At 6.5 months, the follow-up was via email and phone only. Participants reached over the phone were asked only about their smoking status as the calls rarely allowed for any longer conversation. Halfway through the study, SMS texting was trialled as a method to collect follow-up data, but it was unsuccessful and was discontinued. Remote biochemical verification of abstinence was attempted with personal carbon monoxide monitors developed by Bedfont® Scientific Ltd (COcompact Smokerlyzer®), but this proved to be infeasible (the observations from the CO testing are reported in Chapter 9). Appendix 8.2 outlines participants journey through the RCT embedded in the BupaQuit app and through other trial procedures, and Appendix 8.3. presents the schedule of procedures and all questionnaires.

8.4.5. Measures

Baseline measures

The baseline survey was embedded in the registration tunnel, and all the questions were mandatory. The survey collected data on socio-demographic characteristics (e.g. age, sex); smoking and quitting (e.g. strength of cravings and use of past cessation aids), restriction on phone use during the day (yes/no), and recruitment channel (e.g. word of mouth, search on app stores) (Appendix 8.4 provides a list of questions and answer options). We also recorded device operating system (iOS, Android, or Unknown for participants with app-missing-data), and the quit date set (dichotomised to ‘set the quit

date to today' or other days in the future).

Primary outcome

Appendix 8.5 lists the follow-up questions. The primary outcome was self-report of not smoking in the past 14 days at the 4-week follow-up (Brown et al. 2014, Herbec et al. 2014b). As per intention to treat (ITT), participants lost to follow up were presumed to have resumed smoking.

Secondary outcomes

Secondary outcomes included (1) 6-month point prevalence (not smoking in the past 7-days) and continuous 6-month abstinence (allowing for smoking of ≤ 5 cigarettes in the past 6 months, and not smoking in the past 7 days); (2) app usage (total logins, total time spent, time spent per session, proportion of users accessing pre-, or post-quit app or both, and proportion of users accessing CMTs); and (3) satisfaction ratings collected via app or email (West et al. 2005). A set of additional data was recorded to assess feasibility of key RCT procedures: (4) follow-up channel (app, email, SMS, or phone), and (5) use of unassigned support (stop smoking services, cessation medications, e-cigarettes and all other support, including websites and apps).

8.4.6. Data analysis

Data analyses were conducted independently by myself, in consultation with project members at UCL. Bupa was not involved in data analysis. Information on group assignment was kept separate from the primary outcome data until an analysis plan was registered on OSF (<https://osf.io/3kydr/>). The primary outcome was analysed by Fisher's exact test and ITT. Relative risk (RR) and 95% confidence intervals were calculated. Abstinence at short- and long-term was also assessed using log-binomial regressions with and without adjustment for baseline characteristics. Analyses of the continuous secondary outcomes were conducted using t-test and Mann U-Whitney test, and chi-square. All tests were 2-sided with alpha set to 5%.

A series of sensitivity and subgroup analyses of the primary outcome were conducted [* denotes analyses that were pre-registered]: (a) using complete case

analysis* (limited to those who responded to the follow-up), (b) limited to *Users Sample**, (c) limited to participants who used the app after the quit date (as in analysis of SF28 (Ubhi et al. 2015)).

As the study was underpowered, and in anticipation of nonsignificant results as calculated using frequentist statistics, Bayes factors were also calculated for ITT analyses of primary and secondary cessation outcome data using the online calculator (see Chapter 4.5.6) to determine if the data supported the null hypothesis or whether the data were insensitive (Dienes 2008, Dienes 2014, Brown et al. 2016, West 2016). A uniform distribution with an expected effect size of OR of 1 to 3 vs. 1* was used. In exploratory analyses a more conservative approach was adapted with a half-normal distribution that had the mode at 0 (indicating no intervention effect), and the standard deviation equal to the expected effect size of OR=1.6. The calculations were repeated for other plausible effects of OR=1.2 and OR=2.5 (Brown et al. 2016).

8.5. Results

8.5.1. Participants

During the trial, we recorded 1171 downloads of BupaQuit, primarily on iOS devices (see Fig 8.1). This number may be an underestimate, however, as for the first two months of recruitment iOS app analytics did not allow developers to download the record on app downloads. Among those who downloaded the app, 695 complete all registration steps, and of these 425 participants met eligibility for the trial (217 were randomised to the control and 208 to the intervention).

Figure 8.1: Flowchart of participants in BupaQuit trial.

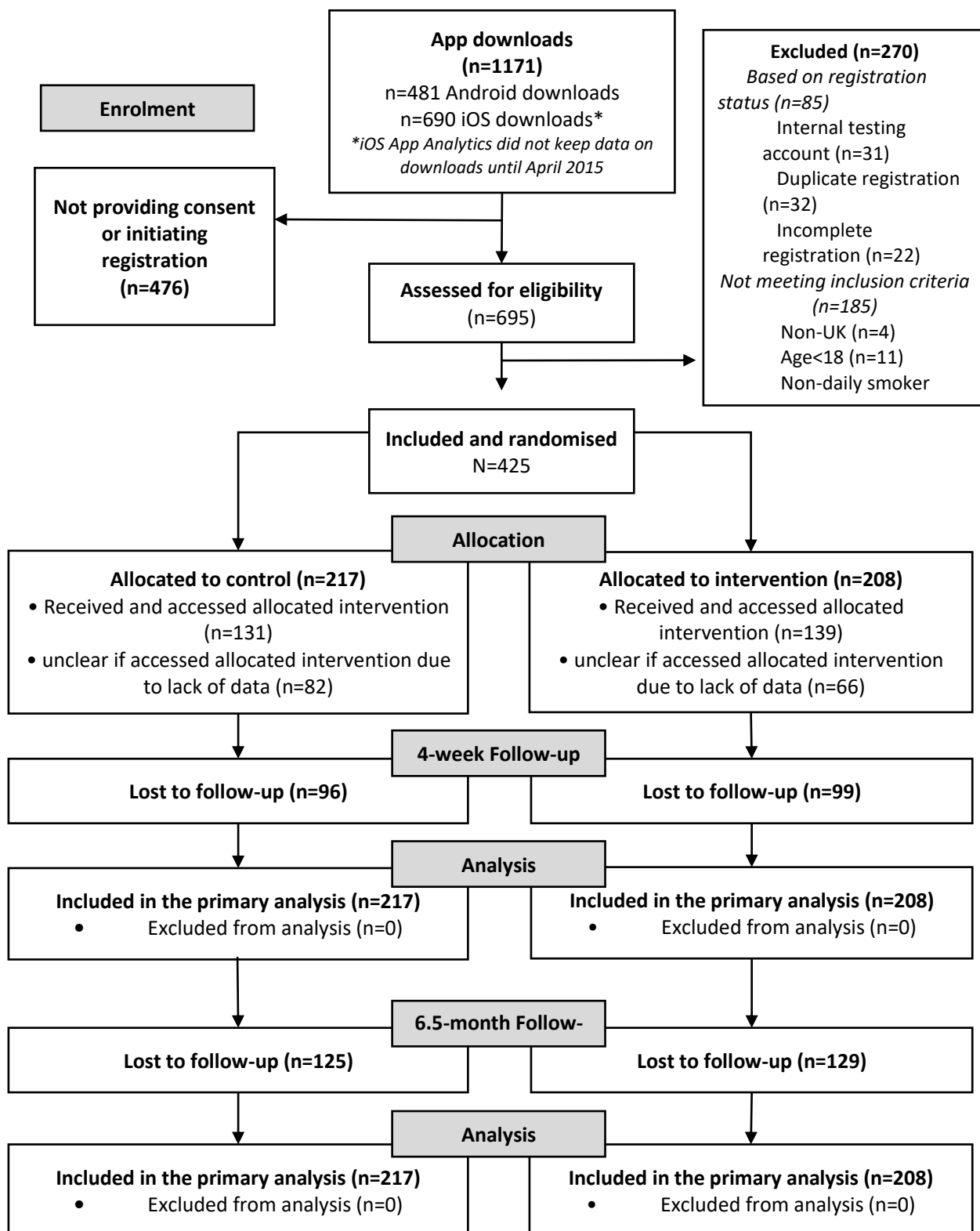


Table 8.1. Baseline Characteristics of BupaQuit trial participants

	Total (n=425)	Intervention (n=208)	Control (n=217)
Female % (N)	45.5 (193)	44.7 (93)	46.1 (100)
Age (years) Mean (SD)	32.9 (11.19)	33.05 (10.10)	32.76 (11.40)
CPP¹ Mean (SD)	15.32 (7.17)	15.08 (7.32)	15.58 (7.03)
Weekly spent on cigarettes (GBP)* Mean (SD)	39.92 (50.11)	39.85 (66.08)	40.01 (24.02)
Smokes within 5min of waking up % (N)	21.4 (91)	19.7 (41)	23.0 (50)
Confidence to stop (1-7) Mean (SD)	4.88 (1.36)	4.98 (1.35)	4.78 (1.37)
Occupation % (N)			
Manual	49.2 (209)	51.0 (106)	47.5 (103)
Non-manual	26.4 (112)	25.0 (50)	28.6 (62)
Other (incl. retired, unemployed, student)	24.5 (104)	25.0 (52)	24.0 (52)
Has post-16 yrs qualification % (N)	68.7 (29)	70.2 (146)	67.3 (146)
Time with urges (0-5) Mean (SD)	3.71 (.99)	2.7 (.95)	2.7 (1.05)
Strength of urges (0-5) Mean (SD)	2.81 (.86)	2.75 (.86)	2.8 (.94)
Made an attempt to quit last year % (N)	63.1 (268)	63.9 (133)	62.2 (135)
Stopped smoking for more than 1 week % (N)	76.0 (323)	77.9 (162)	74.2 (161)
Recruitment channel			
Advertisement on Twitter/Facebook	33.9 (144)	33.7 (70)	34.1 (74)
App store searches	36.5 (155)	39.4 (82)	33.6 (73)
Other (email, word of mouth, poster)	29.6 (126)	26.9 (56)	32.3 (70)
Restricted phone access during the day % (N)	23.3 (99)	22.1 (46)	24.4 (53)
Used any cessation aids in the past[#] % (N)			
No aids	19.1 (81)	18.8 (39)	19.4 (42)
Stop smoking services	31.1 (132)	31.2 (65)	30.9 (67)
Medications	52.7 (224)	47.6 (99)	57.6 (125)
E-cigarettes	50.1 (213)	51.4 (107)	48.8 (106)
Apps	20.2 (86)	21.2 (44)	19.4 (42)
Other incl. websites and quitline	16.2 (69)	17.3 (36)	15.2 (33)
Current use of cessation aids ^{*,#} % (N)			
No aids	54.2 (150)	59.2 (84)	48.9 (66)
Stop smoking services	5.1 (14)	4.9 (7)	5.2 (7)
Medications	19.9 (55)	14.8 (21)	25.2 (34)
E-cigarettes	26.0 (72)	24.6 (35)	27.4 (37)
Other (incl. apps, websites, quitlines)	6.1 (17)	7.0 (10)	5.2 (7)
Operating system* % (N)			
iOS	36.2 (154)	36.1 (75)	36.4 (79)
Android	28.9 (123)	32.2 (67)	25.8 (56)
Unknown	34.7 (148)	31.7 (66)	37.8 (82)
Set Quit Date to Today*	68.9 (190)	69.7 (99)	67.4 (91)

* Data available for 277 participants (135 from control and 142 from intervention). The data missing from the remaining participants could be due to failed synchronisation, use of app offline only, or not opening the app after registration. # Participant could select 'no aids used' or select one or more aids

Table 8.1 presents participant characteristics reported through baseline questionnaire. Participants were on average 32.9 years old, almost half were female (45.5%) and employed in manual occupation (49.3), the majority had post-16 education and had previously used stop smoking services or pharmacotherapy. A third of eligible participants (34%) classified as app-data-missing participants, and the rest were classified as Users Sample. The Users Sample were slightly older (31 vs. 34 years, $p=.01$), but there were no other significant differences in baseline characteristics between participants with and without the app data (data not reported).

8.5.2. Follow-up rates

At 4-week and 6.5-month follow-up, 230 (54.1%) and 171 (40.2%) participants were successfully contacted, respectively. Responses via e-mail or app were low, and participants were primarily reached through phone calls (Table 8.2). Only smoking status was collected via the phone. There were no statistically significant differences in follow-up rates between the study arms, across baseline characteristics, or between participants with or without the app data (results not reported).

Table 8.2. Follow-up rate and follow-up channels in the BupaQuit trial.

	Intervention	Control	<i>p</i>¹
Follow-up rate at 4 weeks % (n/N)	52.4 (109/208)	55.8 (121/217)	.49
Follow-up channel for primary outcome at 4 weeks % (n/N)			
App	7.3 (8)	12.4 (15)	.58
Email	9.2 (10)	9.9 (12)	
Phone	80.7 (88)	76.0 (92)	
SMS	2.8 (3)	1.7 (2)	
Follow-up rate at 6.5 months % (n/N)	38.0 (79/208)	42.4 (92/217)	.35
Follow-up via phone (vs. email) at 6.5 months % (n/N)	77.2 (61/79)	84.8 (78/92)	.21

¹*p-values* from Fisher's exact test for 2x2 tables, chi-square test for other categorical

8.5.3. Cessation

The quit rates were similar between the study arms on the primary (13.5% vs 15.7%, RR=.859, 95% CI=.541-1.365, $p=.583$) and secondary cessation outcomes (sustained 6-month abstinence: 11.1 vs 13.4%; and 6-month point prevalence: 14.4% vs 17.1%, see Table 8.3). The findings remained the same after adjustment for baseline characteristics (not reported) and in sensitivity analyses. The overall quit rates were somewhat higher (with no significant difference across the arms) when the sample was restricted to those using the app in post-quit.

The Bayes factor calculated for the primary outcome using a pre-planned uniform distribution supported the null hypothesis ($Bu[0, 0, 1.0986]=.201$). The Bayes factors using the half-normal distribution suggested that the data on primary outcome were insensitive for low effect sizes, but for large effect sizes of OR=2.5, the data supported the null hypothesis (see Table 8.4). Similar findings emerged from Bayes factor calculations for the secondary cessation outcomes.

8.5.4. App usage

The usage data are presented in Table 8.5. Overall, usage of the intervention and control apps was similar in terms of the number of logins (median=4 vs 5, $p=.45$; mean=9.55 vs 10.5, $p=.63$), total time spent using the app (median=202s vs. 209s, $p=.54$; mean=401.8 vs. 325.8, $p=.20$), or the proportion of sample accessing only pre-quit content of the app (23.2% and 16.3%). The intervention users tended to spend more time on the app per login (median=44.6s vs 32.9s, $p=.01$; mean=64.0s vs 43.5, $p=.003$). Among the intervention participants who had access to the quit aids, only 48 (23.1% of all intervention participants, 44% among those using BupaQuit post-quit where craving aids were available), accessed any craving aids, with a median number of three aids accessed (range: 1-34).

Table 8.3. Abstinence rates at 4 weeks and 6.5 months in BupaQuit trial.

Outcome (all self-reported)	Intervention	Control	RR (95% C.I.) (unadjusted)²	
14-day continuous abstinence at 4-weeks	% (n/N)		p¹	
14-day abstinence ^{FS, ITT}	13.5 (28/208)	15.7 (34/217)	.58	.86 (.54 to 1.36)
14-day abstinence ^{FS, CC}	25.7 (28/109)	28.1 (34/121)	.77	.91 (.60 to 1.40)
14-day abstinence ^{US, ITT}	14.1 (20/142)	16.3 (22/135)	.62	.86 (.50 to 1.51)
14-day abstinence ^{US, CC}	26.3 (20/76)	28.2 (22/78)	.86	.93 (.56 to 1.56)
14-day abstinence ^{PQU ITT}	16.5 (18/109)	19.5 (22/113)	.60	.85 (.48 to 1.49)
14-day abstinence ^{PQU CC}	30.0 (18/60)	32.8 (22/67)	.85	.91 (.54 to 1.53)
Abstinence at 6.5-month				
Sustained ^{† FS, ITT}	11.1 (23/208)	13.4 (29/217)	.55	.83 (.50 to 1.38)
Sustained ^{FS, CC}	29.1 (23/79)	30.4 (29/92)	.74	.92 (.59 to 1.46)
Sustained ^{US, ITT}	10.6 (15/142)	14.1 (19/135)	.46	.75 (.40 to 1.42)
Sustained ^{US, CC}	26.8 (15/56)	32.8 (19/58)	.54	.82 (.46 to 1.44)
Sustained ^{PQU ITT}	12.8 (14/109)	15.9 (18/113)	.57	.81 (.42 to 1.54)
Sustained ^{PQU CC}	31.1 (14/45)	35.3 (18/51)	.83	.88 (.50 to 1.56)
7-day PP ^{FS, ITT}	14.4 (30/208)	17.1 (37/217)	.51	.85 (.54 to 1.32)
7-day PP ^{FS, CC}	38.0 (30/79)	40.2 (37/92)	.88	.94 (.65 to 1.38)
7-day PP ^{US, ITT}	14.1 (20/142)	18.5 (25/135)	.33	.76 (.44 to 1.30)
7-day PP ^{US, CC}	35.7 (20/56)	43.1 (25/58)	.45	.83 (.52 to 1.31)
7-day PP ^{PQU ITT}	15.6 (17/109)	21.2 (24/113)	.30	.73 (.42 to 1.29)
7-day PP ^{PQU CC}	37.8 (17/45)	47.1 (24/51)	.41	.80 (.50 to 1.29)

^{FS} Full Sample eligible at baseline; ^{ITT} Intention-to-treat analysis; ^{CC} Complete Case analysis (excluding participants who were not reached at follow-up); ^{US} Users Sample (excluding participants with app-data-missing). ^{PQ} Post-Quit Users (limited to participants who used the app after the quit date, when more features were available, including craving aids). [†]Sustained abstinence = smoking ≤ 5 cigarettes in the past 6 months and not smoking in the past 7 days; PP=point prevalence; RR=risk ratio; ¹p-value from Fisher's exact test. ²We conducted adjusted analyses of short and long-term abstinence among the full study sample, which did not affect the results.

Table 8.4. Bayes Factors for cessation outcomes in the BupaQuit trial.

	Intervention	Control	Bayes Factor ^a distribution	
			Uniform	half-normal
14-day continuous abstinence at 4-weeks	% (n/N)			
14-day abstinence ^{FS, ITT}	13.5 (28/208)	15.7 (34/217)	.20	.64 ^b , .34 ^c , .19^d
Abstinence at 6.5-month				
Sustained ^{† FS, ITT}	11.1 (23/208)	13.4 (29/217)	.21	.65 ^b , .35 ^c , .19^d
7-day PP ^{FS, ITT}	14.4 (30/208)	17.1 (37/217)	.18	.61 ^b , .32 ^c , .17^d

^a For Bayes Factor calculation using U=uniform distribution [pre-registered] we set the expected effect to be between odds ratio of 1 and 3, versus 1. For Bayes Factors calculation using the half-normal distribution [exploratory], the effect sizes used to specify the *standard deviation of the theory (normal logarithm of ORs)* for the half-normal distributions representing the alternative hypotheses were as follows: ^b OR=1.2; ^c OR=1.6, ^d OR=2.5 (Brown et al, 2016; Naughton et al, 2017). The Bayes Factors presented in bold mean that the findings supported the null hypothesis, and the rest suggested the data to be insensitive.

Table 8.5. App usage in the BupaQuit trial.

	Intervention	Control	<i>p</i> ¹
Usage data available (during trial only) % (n/N)	68.3 (142/208)	62.2 (135/217)	.19
Total logins, Median (IQR)	4.0 (8.0)	5.0 (9.0)	.45
Mean (SD)^a	9.6 (14.7)	10.5 (18.0)	.63
Total time (sec)[‡] Median(IQR)	202.0 (423.3)	209.0 (342.0)	.54
Mean (SD)^a	401.8 (551.8)	325.8 (418.3)	.20
Time per login (sec) [‡] Median(IQR)	44.6 (59.9)	32.9 (37.9)	.01
Mean (SD)^a	64.0 (70.6)	43.5 (40.6)	.00
App usage classification[§]			
Accessed only pre-quit app	23.2 (33)	16.3 (22)	.20
Accessed only post-quit app	25.4 (36)	33.3 (45)	
Accessed both pre- and post-quit app	51.4 (73)	50.4 (68)	

[‡]Total time, excluding registration, from the first use until follow-up. The time spent is an underestimate: (a) data from offline app use save locally on user's device but would not synchronize if users had not accessed the app while being online on a future occasion; and (b) the interaction between an app page and the server occurs when a page is loaded. No further communication with the server occurs until another page is loaded. Hence, it is not possible to identify the exact duration of the last interaction when it ends with exiting the app. [§]Only assessed among the sample with usage data available. Pre-quit app use only means that participants set the quit date in the future and accessed only pre-quit content; only the post-quit intervention app offered craving aids. ^a we provide Means to enable comparison with other studies. However, the usage data were skewed and hence we conducted and report results from non-parametric tests comparing usage between the two study arms. ¹*p-values* from Fisher's exact test for 2x2 tables, and from independent t-test and Mann-Whitney test for continuous data.

8.5.5. App satisfaction

Only 31 participants (7.3% of the trial sample) provided data on satisfaction from using the app, and there were no significant differences in the ratings between intervention and control apps (Table 8.6).

Table 8.6. Satisfaction ratings of the BupaQuit app.

	Intervention	Control	<i>p</i>¹
App being helpful with managing cravings (1-5)^b, Mean (SD)	3.3 (1.5)	2.8 (1.5)	.33
Would use the app in the future, % (n/N)^b	83.3 (10/12)	78.9 (15/19)	.76
Would recommend the app to a friend, % (n/N)	83.3 (10/12)	78.9 (15/19)	.76

^aTo limit burden, these questions were only asked via app and email. The data were provided by 31 participants in total, during the eligible follow-up period at 4 weeks (26 participants provided the data via the app - three of these participants reported data on primary outcome first via phone or email before completing the follow-up survey via the app; and 5 via email). ^b 1-not at all, 5- very helpful (Brown et al. 2014). ¹*p-values* from Fisher's exact test for 2x2 tables, chi-square test for other categorical

8.6. Discussion

The intervention version of BupaQuit app had no detectable effect on the quit rates in comparison with the control app version, and Bayes factors suggested the data were not sensitive for low effects but supported the null hypothesis for large effect sizes. The engagement levels across the conditions were similar and low, and relatively few participants accessed CMTs, which could offer an explanation for the lack of effect found. The automated follow-up with complete questionnaires delivered within the app and via email were not successful, leading to limited data collection on secondary outcomes. The lack of contact with the researchers at enrolment might have contributed to the suboptimal engagement with the app and also high attrition (Ozer 2000, Perski et al. 2017b).

The self-reported quit rates were similar to those reported in other studies of smartphone-based stop smoking interventions (Bricker et al. 2014, Bricker et al. 2017, BinDhim et al. 2018). Moreover, the overall quit rates were also comparable to the quit rates observed in the SF28 study, when the analysis was restricted to a similar sample of participants (i.e. to participants who used the app post-quit date) (Ubhi et al. 2015). The mean engagement levels with BupaQuit were also similar to those with SF28 (Ubhi et al. 2015), but were nevertheless relatively low, thus echoing findings from other studies (Eysenbach 2005, Shahab and McEwen 2009).

However, it is also plausible that even with greater engagement, any impact of CMTs would be too small to be detected, especially over and above the impact of other active components included in both app versions, such as setting up the quit date, monitoring of progress, and recommendations to use pharmacotherapy (West et al. 2010, Lorencatto et al. 2012). Another factor possibly contributing to the null findings could be the use of unassigned cessation support reported at baseline by an almost half of both the intervention and control participants, which would further make it difficult to detect an effect of the CMTs.

Finally, sensitivity analysis suggested that participants who were accessing BupaQuit app post-quit, which offered additional features (monitoring and feedback on smoking in both app versions, and craving aids in the intervention), had somewhat higher quit rates than those who set the quit date in the future but never accessed the app post-quit. Future research should explore and account for the impact that different pre- and post-quit features in stop smoking apps might have on user behaviour and cessation.

8.6.1. Methodological observations

BupaQuit was evaluated through an RCT with open and automated recruitment involving the collection of contact details embedded within a cessation app that was available to anyone on UK app stores. This was a different enrolment process to the two-stage enrolment used in other studies that collected baseline data through a website and involved some communication with the researchers (Bricker et al. 2014, Buller et al. 2014, BinDhim et al. 2018). Over half (almost 60%) of users who initiated registration completed baseline assessment with all the fields mandatory, and of these the majority provided plausible contact details. However, changes to data protection policies for the iTunes store but also the introduction of international data protection laws may limit what identifiable data could be requested from users, thus affecting study procedures in the future.

Furthermore, the study identified several challenges to conducting automated remote trials of quitting apps. Reliance on the automated screening of app registrations emerged as insufficient, for example, due to difficulties identifying duplicates caused by the differences in spelling in the contact details provided. Additionally, most participants were recruited during periods when paid advertisement campaigns were run

on Twitter and Facebook. Furthermore, only a minority of participants responded to the follow-up through the app and email. Although the telephone follow-up was the most successful, it rarely allowed for a longer discussion with participants. This limited the volume of secondary outcomes that could be feasibly collected. Together, these observations suggest that even studies of automated cessation apps may require dedicated budgets and human resources to monitor recruitment, enrolment, data management and follow-ups.

Finally, a major challenge encountered in the BupaQuit trial was related to recruiting potential participants into a study of an app that was live on app stores and thus available for anyone to see and download. The same issue was present in the NRT2Quit trial reported in Chapter 4, but was particularly problematic for the present study due to the reliance on the online recruitment. Specifically, even though the study used short online ads, all users could access information about BupaQuit on app stores that required an accurate app description and provision of app screenshots (this seemed especially strict in the case of iTunes). Such a situation risked disclosing to potential users the differences between the conditions, thus risking unblinding.

Moreover, any informational and promotional materials had to conceal the differences between the app versions. In practice, it meant using only the descriptions and screenshots of the control app. This prevented promoting many of the core features offered only within the intervention app version, thus resulting in potentially less appealing recruitment campaigns. To improve the reach of recruitment campaigns, future studies could explore diversifying promotional strategies and partnering with national or local organizations to support app promotion within their networks.

8.6.2. Limitations

First of all, due to the low recruitment rate and early termination of the study, the study was underpowered to detect the original effect expected. However, it is unlikely that a greater sample would change the conclusions considerably. Secondly, despite the relatively intensive follow-up outside of the app that aimed to improve response rates and to limit differences across conditions (Edwards 2002, Free et al. 2011, Brown et al. 2014, Herbec et al. 2014b), the follow-up rates were falling within the lower end of the spectrum for re-contact rates observed in other studies (Bricker et al. 2014, Brown et al.

2014, Taylor et al. 2017). Thirdly, data on satisfaction was available only for a minority of participants who responded to the follow-up via the app or e-mail.

Fourthly, we used self-reports for the primary outcome, which tend to overestimate the actual quit rates, although the bias should not differ across study arms and may be lower in trials of remote interventions (Glasgow et al. 1993, Patrick et al. 1994). Fifthly, we were missing app usage data from a third of participants who met eligibility criteria, and it was not possible to account for this data missingness. However, except for the younger age, these participants did not differ on other baseline characteristics from those with complete usage data, and excluding them from the analyses had not affected the results. Finally, the burden of joining the trial was higher than that of accessing other stop smoking apps on the market, but was lower than that in previous studies of cessation apps (Bricker et al. 2014, Buller et al. 2014, Bricker et al. 2017). Nevertheless, the generalisability of the findings from this study is limited.

8.6.3. Future directions

Managing cigarette cravings can benefit cessation (May et al. 2010, Haasova et al. 2013) and research (Herbec et al. 2014a, Hartzler et al. 2016) as well as findings from the interviews on NRT2Quit (Chapter 6) show that smokers expect CMTs in smartphone apps. Therefore, future research should explore new ways of delivering more engaging and usable CMTs through smartphone apps. This could involve greater utilisation of person-centred approaches (Yardley et al. 2015), study by design (Ploderer et al. 2014) and Multiphase Optimization Strategy (MOST; (Collins et al. 2007, Collins et al. 2014)), to assess usability and impact of a range of, or a combination of, CMTs. It would also be valuable to identify what app architecture and user journeys could improve the use of such features. Future research should also ascertain if more contact with researchers at enrolment could improve engagement and outcomes.

8.7. Conclusion

In this pragmatic trial, the addition of craving management tools to the BupaQuit app did not affect cessation. Limited engagement with the app, as well as the use of an active control app, may have contributed to the lack of effect observed in this trial.

Chapter 9: Use of personal CO monitors in BupaQuit

9.1. Chapter 9 overview

This chapter reports findings from a secondary analysis of data related to the use of personal carbon monitors (CO) monitor to remotely validate self-reported abstinence in the BupaQuit trial described in Chapter 8.

9.2. Contributions

I planned this study, oversaw data collection, analysed the data and written up the findings. Two research assistants at Bupa (Courtney Kwan, CK, and Georgina Knock, GK) supported data collection. Robert West (RW), Lion Shahab (LS) and Jamie Brown (JB) commented on the manuscript prepared for the publication.

9.3. Dissemination

A version of this chapter was published as a research article in a peer-reviewed journal:

Herbec, A., Brown, J., Shahab, L., & West, R. (2018). Lessons learned from unsuccessful use of using personal carbon monoxide monitors to remotely assess abstinence in a pragmatic trial of a smartphone stop smoking app—A secondary analysis. *Addictive Behaviors Reports*. Available as: Open Access (distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>)).

9.4. Introduction

Biochemically verifying self-reported abstinence in trials of digital cessation interventions is important (Benowitz et al. 2002)(West et al. 2005), but remains challenging in studies that involve remote follow-up of participants who are spread across vast geographical locations, such as in the BupaQuit trial described in Chapter 8. As a consequence, many such studies use self-reports to assess abstinence (Ubhi et al. 2015, Whittaker et al. 2016, Taylor et al. 2017). This study involved assessing the

extent to which it would be feasible to verify abstinence in the pragmatic BupaQuit trial (reported in Chapter 8) by means of personal carbon monoxide (CO) monitors posted to participants during the follow-up.

Self-reports may lead to over-estimation of the actual quit rates (West et al. 2007), although the bias should not differ across study arms, and may be lower in low-intensity interventions, such as digital behaviour change interventions (DBCIs) (Glasgow et al. 1993, Patrick et al. 1994). Chapter 2.5.4 discusses a number of methods available for verification of abstinence in the trials of cessation intervention.

CO testing remains the most commonly used method, but in-person testing of CO levels is often not practical in remote trials. To date, researchers have managed to accomplish remote CO testing by posting traditional CO meters to participants and asking them to return the devices at the end of the testing period, e.g. (Dallery and Glenn 2005, Hertzberg et al. 2013, Karelitz et al. 2017, Garrison et al. 2018). However, such devices tend to be bulky and expensive, thus limiting the feasibility of their use for remote assessment.

A new generation of personal CO monitors (e.g. devices manufactured by Bedfont® Scientific Ltd, <https://www.bedfont.com/>) offers new possibilities for remote CO testing. These devices are smaller, lighter and more affordable (under £50 in the UK) in comparison with the traditional CO monitors (cost starting at around £170 in the UK). Therefore, such personal monitors could be purchased and posted to smokers for home-based testing, and the final cost may be comparable to that involving saliva testing and reimbursement.

Additionally, information on the CO levels is acceptable and of interest to smokers (Shahab et al. 2011, Beard and West 2012, Goldstein et al. 2018), also if it is part of regular and remote assessments (McClure et al. 2015). Thus, there are grounds to believe that personal CO testing could be attractive to participants in remote trials because it would enable them to assess their progress, and possibly also act as an incentive to remain abstinent (Shahab et al. 2011, Beard and West 2012). Personal CO devices could be retained by participants for future private use, in which case they could be a form of reimbursement for participants' time and inconvenience, especially in the absence of other compensations in a study. Importantly, and similarly to the traditional CO meters, a single personal CO device could be used for multiple testing and follow-up assessments. Therefore, at least in theory, using the new generation of personal CO

monitors could be cost-effective and acceptable to participants. However, the feasibility of using this method to assess self-reported abstinence during follow-ups in trials of smartphone-based cessation interventions is yet to be ascertained.

In this exploratory study, we assessed the feasibility of remote verification of self-reported abstinence through using one model of personal CO monitors that connect to Windows PCs. The devices were posted to participants who were self-reporting not smoking in the BupaQuit trial described in Chapter 8.

The procedure of home-based CO testing was aligned with the methods applied to saliva sampling in a trial of a web-based cessation intervention (StopAdvisor) conducted by our group (Brown et al. 2014). The procedure in the StopAdvisor trial involved posting with a first-class mail a saliva testing kit to the postal address provided by the participants during study enrolment. The letter included written instructions accompanied by photographs of the testing procedure, as well as gift vouchers as an ‘advance’ reimbursement. The main difference in the procedure adopted for the present study was the lack of cash or voucher reimbursement for providing CO readings. Instead, participants could keep the CO device for private use in the future. Adopting comparable procedures was judged to be important because if remote CO testing was to be a feasible alternative to saliva testing, it should be used in a context with similar resource level.

9.4.1. Aims

This exploratory study aimed to assess feasibility by documenting the different aspects using personal CO Monitors to verify abstinence remotely in the BupaQuit trial. The specific research questions were:

1. What was the proportion and timeframe of the CO tests returned?
2. What was the proportion of tests confirming abstinence (<10 ppm and <5ppm)?
3. What were self-reported usability, acceptability and correct use?
4. Where there any differences in baseline characteristics between participants who have returned the CO readings and those who have not?
5. What are the reasons for no return of CO results?

9.5. Methods

9.5.1. Design

The study involved secondary analysis of data related to remote validation of abstinence using personal CO monitors in the BupaQuit trial (reported in Chapter 8). The ethical approval was secured together with the approval for the main trial (see Chapter 8.4.1)

9.5.2. Study sample

During the 4-week follow-up in the BupaQuit trial, 62 (14.6%) participants self-reported not smoking in the past 14 days and were eligible to receive personal CO monitors. The current study concerned a sample of 59 trial participants who self-reported not smoking, and who were posted the CO monitor (three participants were not posted a monitor due to one participant declining to receive one, and the other two due to temporary lack of access to the storage of CO monitors caused by extended refurbishments at Bupa offices from where the monitors were posted).

5.5.3. Procedure

Participants self-reporting abstinence at 4-week follow-up were posted the COmpactUSB™ Smokelyzer® developed by Bedfont Scientific Ltd (the only such device available for purchase at the time). The monitors were posted in a 1st Class small parcel (normally delivered on the next business day within the UK; CO box size 25x15x5cm plus padded envelop; stamp cost starting at £3.30/\$4.50). The package included additional mouthpieces (enabling hygienic sharing of the device, e.g. for future personal use – this was not encouraged for the trial), and instructions and information about CO testing (see Appendix 9.1). The instructions asked participants to send only one CO reading upon receiving the CO device as soon as possible.

Verification of contact details before posting the device was not possible for all participants. Only those participants, who were contacted over the phone (66.1% of the current study sample) could be opportunistically asked about their postal address before the device was posted. However, while most participants contacted over the phone

seemed positive about receiving CO device, a longer discussion about the procedures was not possible - the participants often insisted on ending the calls due to being busy (insights based on internal communication within the research team).

Participants who reported not smoking over the app or email were not contacted separately just to confirm the postal details for the CO monitor. There were several reasons for this. First of all, the study aimed to re-create conditions in other trials that involved biochemical verification that did not routinely confirmed postal details and instead relied on the information provided at baseline (Brown et al. 2014). Secondly, it was judged unlikely that contacting participants over these channels would enable efficient confirmation of postal addresses due to low response rate. Thirdly, such additional communication could over-burden the participants, and negatively affect their responses to the planned follow-up at 6 months. Moreover, attempting to confirm such details (would require additional resources and staff time, and would most likely delay posting the devices, or even prevent it altogether.

In order to use COmpactUSBTM Smokerlyzer® participants had to download a dedicated software for the Windows PCs. The software was created and adapted for the BupaQuit trial by Bedfont® Scientific Ltd (Appendix 9.2). The need to use this software could be a barrier to use, but it was expected that many participants would have access to a Windows PC at home or work (NetMarketShare). The software allowed participants to send the result directly to the trial e-mail address at Bupa.

Participants were also able to take multiple tests without the researchers knowing and to decide which of the results to share with the research team. This allowed participants to use the device without the researchers' knowledge, but it prevented situations when multiple CO results would be available for the same participant (e.g. participants could be practising taking the test, or sharing the monitor with others). Participants were sent one information email (with a summary of instructions and a link to the software download page), and a reminder within a week. Participants were not reimbursed but were informed they can retain the device for personal use. Packages with CO devices were posted through Bupa internal postal services and were not tracked due to high cost, and practical difficulties of setting up tracking services within the Bupa postal office.

9.5.4. Measures

Anonymised data were recorded and managed in Excel spreadsheets by myself and a team of trained research assistants. The device manufacturer had no access to the data.

Baseline measures

The same baseline measures were assessed as are listed in Chapter 8.4.5 reporting on the BupaQuit trial.

Outcome measures

The outcomes of this study were: (a) proportion of participants sending their CO results, (b) number of days to receiving results (counted from the date of CO posting), (c) proportion of tests confirming abstinence (the results were tested against two cut-offs: <10 ppm (meeting the Russel Standard criteria for abstinence (West et al. 2005)) and a more conservative cut-off of <5ppm suggested more recently (Perkins et al. 2013). Only the first result sent by the participants was considered (*note*: only one participant had sent two CO results). Additionally, several questions on usability and acceptability were asked through the CO monitor software: (d) acceptability: *Did you find the CO monitor an acceptable way to assess your abstinence status?*, (e) ease of use: *Did you find the CO monitor easy to use?*, (f) correct use: *Do you think you managed to use the CO monitor properly?*. Additionally, identified reasons for missing CO results were opportunistically collected and recorded in the database, where possible (e.g. during future communication with trial participants, such as during the interviews reported in Chapter 10, or during the phone-based 6-month trial follow-up).

9.5.5. Data analysis

Participants with and without the CO results returned were compared on baseline and process variables using chi-square for categorical and t-test for continuous data. We applied Sidak correction to account for multiple comparisons, and the p-value cut-off was set to 0.007. Descriptive statistics for all other data are presented. Data were

analysed in SPSS (22.0).

9.6. Results

The flow of participants in this study is presented in Figure 9.1. Fifteen out of 59 (25.4%) participants returned their CO readings. On average the CO readings were returned after 8.4 days (median=5 days) (for one participant the date of returning the CO reading was not recorded in the database). Five participants returned their readings within two days, six within a week, and three after 9, 22 and 47 days since the device was posted. Thirteen (86.6%) of the returned readings were below 10ppm and eight (53.3%) were below 5ppm. This corresponded to 20.9% and 12.9% of all participants in BupaQuit trial self-reporting abstinence, respectively. Among those who sent their CO readings and thus also completed the questions through the software, 12 (80.0%) reported they used the device correctly, 14 (93.3%) that it was easy to use, and 15 (100.0%) that the test was acceptable.

Those who returned the CO readings were more likely to have used electronic cigarettes before (40.9% vs 73.3%, $p=0.04$), but there were no other statistically significant differences between participants returning the CO readings or not with respect to baseline characteristics or the study arm (Table 9.1). A significantly greater proportion of participants self-reporting abstinence via the app (53.8%) sent their CO readings in comparison to those reporting it via e-mail (0.0%), or phone (21.1%) ($p=0.01$). Participants who had usage data and thus for whom it was possible to determine the app device system had a marginally greater proportion of results returned than those with device status Unknown (Android: 35% vs iOS: 22.7% vs Unknown; 17.0%). There were no statistically significant differences on trial outcomes between those who returned CO readings and those who did not return them.

Figure 9.1. Participant flow through the CO testing procedure in the BupaQuit trial.

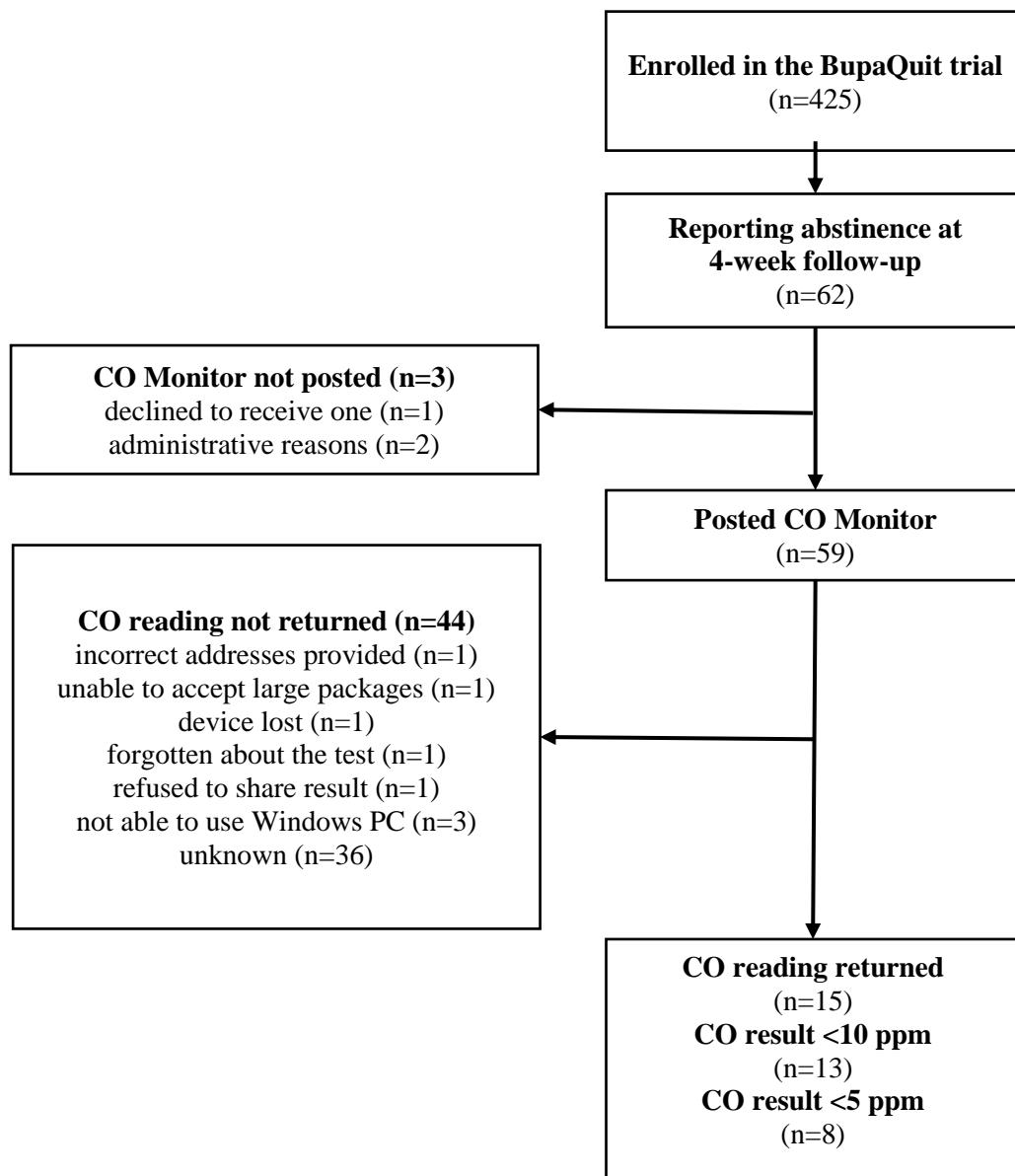


Table 9.1. Baseline characteristics of BupaQuit trial participants who self-reported not smoking and who returned or did not return their CO readings.

	Total (n=59)	Did not return CO readings (n=44)	Returned CO readings (n=15)	p^a
Study arm in BupaQuit trial, %(N)				
Intervention	42.4 (25)	40.9 (18)	46.7 (7)	0.77
Control	57.6 (34)	59.1 (26)	53.3 (8)	
Age (years) Mean (SD)	33.0 (10.6)	33.1 (10.9)	32.7 (10.0)	0.90
Smokes within 5min of waking up % (N)	20.3 (12)	18.2 (8)	26.7 (4)	0.48
Confidence to stop (1-7) Mean (SD)	4.9 (1.4)	4.8 (1.4)	5.3 (1.3)	0.17
Female % (N)	32.2 (19)	29.5 (13)	40.0 (6)	0.53
Occupation % (N)				
Manual	55.9 (33)	54.5 (24)	60.0 (9)	0.92
Non-manual	20.3 (12)	20.5 (9)	20.0 (3)	
Other, retired, unemployed, student	23.7 (14)	25.0 (11)	20.0 (3)	
Has post-16 yrs qualification % (N)	74.6 (44)	77.3 (34)	66.7 (10)	0.50
Strength of urges (0-5) Mean (SD)	2.8 (.8)	2.8 (.8)	2.7 (.8)	0.80
Made an attempt to quit last year % (N)	59.3 (35)	54.4 (24)	73.7 (11)	0.24
Stopped smoking for > 1 week % (N)	84.7 (50)	81.8 (36)	93.3 (14)	0.42
Recruitment channel				
Advertisement on Twitter/Facebook	33.9 (20)	29.5 (13)	46.7 (7)	0.42
App store searches	30.5 (18)	34.1 (15)	20.0 (3)	
Other (email, word of mouth, poster)	35.6 (21)	36.4 (16)	33.3 (5)	
Restricted phone access during the day % (N)	22.0 (13)	25.0 (11)	13.3 (2)	0.48
Used any cessation aids in the past[#] % (N)				
No aids	22.0 (13)	25.0 (11)	13.3 (2)	0.48
Stop smoking services	32.2 (19)	31.8 (14)	33.3 (5)	1.00
Medications	50.8 (30)	52.3 (23)	46.7 (7)	0.77
E-cigarettes	49.2 (29)	40.9 (18)	73.3 (11)	0.04
Apps	13.6 (8)	13.6 (6)	13.3 (2)	1.00
Other incl. websites and quitline	23.7 (14)	20.5 (9)	33.3 (5)	0.32
Smartphone operating system				
Android	33.9 (20)	29.5 (13)	46.7 (7)	0.46
iOS	37.3 (22)	38.6 (17)	33.3 (5)	
Unknown (app usage data missing)	28.8 (17)	31.8 (14)	20.0 (3)	

^ap-value from Fisher's exact test for 2x2 tables, from chi-square test for other categorical variables, and independent t-test for continuous variables; # Participants could select one or more answers.

Only eight of the 44 missing CO readings were accounted for through subsequent opportunistic communication with some of the participants and thanks to one parcel being returned to the office with a note that the recipient is not available at that address. Among these, one parcel was returned due to the incorrect address, one participant was unable to accept large packages, one lost the device, one had forgotten about the test, one refused to email readings and share them with Bupa seeing it as an intrusive

procedure, and three had no access to a Windows PC.

9.7. Discussion

Remote validation of self-reported abstinence in trials of smartphone-based interventions using personal CO monitors is a new and potentially an attractive and cheaper alternative to other available methods. However, in this study, the CO readings were provided by only a quarter of participants. This is much fewer than around 60-80% observed in other studies (e.g. (Glasgow et al. 1993) and unpublished data from (Brown et al. 2014)). These findings suggest that using CO monitors that connect to Windows computers to remotely assess abstinence in a trial of a cessation app developed for iOS and Android smartphones was not feasible as per the current protocol. The possible reasons could be lack of reimbursement, no contact with the researcher at enrolment or a high burden of the task.

The findings suggest that for the follow-up in trials, CO testing may require implementing additional procedures than those used for the remote collection of saliva samples. Furthermore, the procedure may not be acceptable to some smokers at least (acceptability of personal CO that connect to a smartphone was explored in the final study of this thesis reported in Chapter 11). Finally, given that CO results tended to be more frequently returned by those who reported not smoking via the app than the other channels may suggest that those reporting abstinence over email or over the phone had been possibly already fatigued by the study tasks, were not sufficiently engaged with the programme (i.e. they already deleted the app), or they might have over-reported abstinence in the direct communication with the researchers.

Indeed, better engagement with remote CO testing was observed in studies that adopted different procedures to those in the BupaQuit trial. These included (i) using CO testing not only for abstinence validation, but also as an integral part of quitting or cutting down; (ii) offering additional resources to supplement CO testing (e.g. a website, pharmacotherapy, behavioural support); (iii) providing supervised training on using the CO device; (iv) offering incentives (e.g. cash or vouchers) for reporting any CO readings or for meeting certain CO thresholds; (v) encouraging regular and video-recorded CO testing (e.g. daily, or twice daily); and (vi) involving other regular contact with the researchers (e.g. remote monitoring of the readings to identify falsifications, or

lab-visits) (Dallery and Glenn 2005, Hertzberg et al. 2013, Alessi and Rash 2017, Karelitz et al. 2017). Finally, some studies also used the traditional and more expensive CO devices (e.g. piCO Smokerlyzer® developed by Bedfont® Ltd for clinical use) (Dallery and Glenn 2005, Alessi and Rash 2017, Karelitz et al. 2017), which could improve the experience of testing itself. The ecological validity of such interventions is low and the costs can be high (e.g. the average cost of CO testing with only 4-week follow up in one study was \$350 per participant (Alessi and Rash 2017).

Among key challenges to use CO monitors in in this BupaQuit trial was that we had no affordable and practical means (i) to trace the packages, (ii) to determine whether CO devices were used by participants who did not share results, (iii) and to retrieve the unused devices (if there were any), (iv) or to reliably collect information about the missing results. The limited contact with the participants and lower accountability, and little opportunity to discuss the procedures could be among possible reasons (Brown et al. 2014).

Other possible reasons for the low return rate of the CO readings could include: (a) over-reporting of abstinence at follow-up and unwillingness to share CO data confirming smoking, (b) no reimbursement (retaining CO monitors might not be a sufficient incentive), (c) incorrect or no longer valid address (we could not verify most of the addresses), (d) participants used the CO software but did not share the results with the researchers; and (e) low commitment to the study or low app engagement. The latter possibility has some support in findings that the CO results tended to be returned more often by those participants who reported abstinence via the app (i.e. those who were still engaged with the programme at follow-up), and those engaging with the app in the first place (i.e. any usage data were available).

9.7.1. Limitations

First of all, it was an exploratory and observational study using secondary data from the BupaQuit trial. A more detailed assessment of the CO testing procedure was not feasible and could risk burdening the trial participants further. Moreover, contacting participants to collect other trial outcome data was challenging, and it is unlikely that attempts at collecting further data on the CO test would be fruitful.

Secondly, for the CO tests returned, it was not possible to verify that participants

used the device correctly, or that they provided the data themselves. Some studies required participants to live stream videos of them taking the CO measurements (Dallery and Glenn 2005, Hertzberg et al. 2013, Karelitz et al. 2017). This was not possible in the present study, but might have also been a further barrier to participation. Thirdly, contrary to studies that require lab-based assessment of saliva samples, participants could not be blinded to the results of their home-based CO testing. Thus, participants could decide to withhold undesirable results from the researchers.

9.7.2. Future directions

The COmpactUSB™ Smokerlyzer® model used in this study has been discontinued and replaced by a smartphone-based model (iCO™ Smokerlyzer®). The feasibility of using these new devices (Meredith et al. 2014) to verify abstinence requires further research, but the observations from this study should nevertheless apply to other settings when the CO devices are posted as part of the follow-up procedures.

In the present study, the CO monitors were posted to participants only for the follow-up. Among the key benefits of using personal CO monitors is that they allow for repeated testing and monitoring of progress. Future research could assess if providing participants with the CO monitors at the start of the trial could increase acceptability and engagement, as well as cessation outcomes (Dallery and Glenn 2005, Shahab et al. 2011, Beard and West 2012). Additionally, a head-to-head comparison of the different tests for biochemical verification would be needed to determine the most optimal method for trials of stop smoking apps.

9.8. Conclusion

Studies using personal CO monitors to validate abstinence remotely in trials of stop smoking apps may require separate reimbursement and establishing a better rapport with participants, as well as using software that records installation and initiation of device use without the researchers collecting non-trial data.

Chapter 10: Qualitative study with BupaQuit trial participants

10.1. Chapter 10 overview

This chapter reports findings from nested qualitative telephone interviews with a sub-sample of the BupaQuit trial participants.

10.2. Contributions

I designed the study and the data collection instruments, trained research assistants who collected the data (Courtney Kwan and Georgina Knock) and who supported second coding (Rhea Kohli), oversaw the scheduling and progression of the interviews, analysed the data, and wrote up the findings.

10.3. Introduction

The findings from the BupaQuit trial showed no difference in cessation between the intervention and control versions of the BupaQuit app, as well as limited engagement with the app (see Chapter 8). The recent guidelines for the evaluation of complex interventions such as digital behaviour change interventions (DBCI), recommend the use of mixed-methods, including qualitative studies, to iteratively develop the interventions and to help interpret the quantitative findings (Gustafson and Wyatt 2004, Campbell et al. 2007, Ayala and Elder 2011). Exploring the experiences of trial participants with the BupaQuit app and the wider study could elucidate reasons for the trial findings and help guide future app development.

In the context of the iterative and person-centred intervention development, qualitative studies can help to identify what users find beneficial, attractive, and acceptable in an intervention, as well as ways in which a DBCI can be improved (Yardley et al. 2015, Struik et al. 2018). Several recently published qualitative studies explored preferences of smokers for stop smoking apps, including among adult smokers and pregnant women (e.g. (McClure et al. 2017, Wu et al. 2017)), and among

participants in one randomised controlled trial (RCT) who were provided with an app supporting craving management (Struik et al. 2018). Nevertheless, the individual stop smoking apps deliver a unique combination of active ingredients and differ from each other in many respects, such as their interface and user journeys, thus requiring a dedicated evaluation to improve their design.

Secondly, qualitative research, e.g. nesting interviews as part of a larger trial (Herbec et al. 2014b), can provide insights on the potential individual and contextual factors that affect outcomes, implementation or engagement with the intervention (Campbell et al. 2007, Ayala and Elder 2011), as well as reveal surprising findings and generate new hypotheses (Campbell 2003, Borkan 2004). However, research exploring experiences relating to the participation in remote trials of stop smoking apps remains scarce. The present study aimed to address this gap in research.

10.3.1. Study aims

The study aimed to answer two main research questions:

- 1) What were the experiences and views of the participants regarding their participation in the BupaQuit trial?
- 2) What were the participants' experiences with, and views on the BupaQuit app and how it could be improved to increase satisfaction and effectiveness?

10.4. Methods

10.4.1. Design

The study involved individual structured interviews conducted over the phone, and which were nested in the BupaQuit trial. The ethical approval for the study was obtained together with the approval for the wider trial (see chapter 8.4.1). Participants provided separate informed consent to participate in the interview. The reporting follows the COREQ guidelines for qualitative studies (Tong et al. 2007).

10.4.2. Participant recruitment

Participants were recruited from among BupaQuit trial participants who (a) had data on app usage recorded in the database, which confirmed they opened the app at least once (thus enabling them to comment on its functionality), and (b) would have already completed the short-term follow-up (regardless of whether they were contacted or not, and regardless of their trial outcome data). Participants were sent invitations to the interview to the email provided at registration. Up to 20 participants were planned to be recruited, with the aim of interviewing at least ten intervention participants, and a similar number of control participants.

10.4.3. Procedure

The interviews were conducted after the short-term trial follow-up was completed as not to compromise primary data collection, but no later than 4 months after their quit date so that they could recall more details about their experiences. To limit barriers to participation, and to avoid duplicate sign-ups as part of the ongoing trial, the interviewees were not asked to download BupaQuit again if they deleted it already, nor were they asked to study the app ahead of the interviews. Eighteen interviews were conducted by two research assistants (RA; CK and GK) and two by me. The RAs were provided with data collection forms and scripts (e.g. the interview schedule and suggested prompts, see Appendix 10.1), and were trained by myself on interviewing techniques. The interviewers were blinded to participant's results from the RCT.

The interview guide was designed to be as short as possible and prioritised issues relevant to the research questions. This was due to limited resources available, and was informed by insights from an earlier study regarding challenges associated with conducting telephone interviews (e.g. the interviews may be interrupted at any point or be affected by a poor connection) (Herbec et al. 2014a). The core themes explored were: (a) views and experiences of trial procedures, e.g. context of enrolling into the trial, views on the follow-up, (b) experiences with using BupaQuit during the trial and while quitting, (c) views on the BupaQuit app and its features, (d) suggestions for app improvement, (e) views on the possible impact of using the app on quitting efforts and outcomes.

Additionally, to collect contextual data that could help to interpret the findings on these core issues, participants were also asked about (f) their experiences and views on using other digital aids for cessations. The interview guide was identical for the participants allocated to the control and intervention app versions, except for the intervention participants being explicitly asked how using the app has helped them to manage their cravings (as craving aids were the main feature that distinguished the two app versions). The interviews lasted around 25 minutes, were audio-recorded, and transcribed intelligent verbatim by a company that signed confidentiality agreements. Participants were offered £20 Amazon vouchers as compensation for their time.

10.4.4. Measures

At the end of the interview, participants were asked about their smoking status, number of cigarettes smoked (if still smoking), use of cessation aids since downloading BupaQuit, and age (to cross-check with the information provided at registration) (see Appendix 10.1 for questions). To describe the interviewed sample, the following data from the trial database were extracted for each participant: age, gender, cigarettes smoked at baseline, use of cessation aids before the trial, use of cessation aids on app download, data on app use (total logins, total time spent in seconds, and, for the intervention participants only, the total number of craving aids accessed), and BupaQuit trial arm (for the wording of questions and answers see Appendix 8.4).

10.4.5. Data analysis

Data were analysed in NVivo 12 using framework analysis (see Chapter 5.5.4, (Ritchie and Lewis 2003, Srivastava and Thomson 2010, Beard and West 2012, Herbec et al. 2014a, Parkinson et al. 2015), and a combination of an inductive (bottom-up) and deductive approach (with themes informed by the interview guide, findings from other research on digital health, including my earlier research with pregnant smokers (Herbec et al. 2014a) and findings from the qualitative study on NRT2Quit reported in Chapter 6)).

I conducted the first round of the analysis and created the thematic framework. The transcripts were read several times, and labels for emerging themes. Initially, data from participants assigned to the control and intervention versions of BupaQuit were

analysed separately. However, as no clear pattern of accounts emerged that could distinguish these two groups, the data from all participants were analysed together. Data could be coded to multiple themes. Through the iterative reading of the interviews and data assigned to initial themes (nodes), and through applying the constant comparison (Madill et al. 2000) and deviant case analysis (Mays and Pope 2000), the themes were refined and grouped under common higher-order themes. The validity of the final framework was checked by a third RA (RK), who applied the thematic framework to four interview transcripts. Due to the lack of contact details for the interviewees (the personal data were not shared with our team), external validation was not possible. Finally, descriptive accounts were drafted for the major and minor themes.

10.4.6. Reflexivity and researcher positionality

These are reported in Chapter 1.14.

10.5. Results

10.5.1. Participants

Tables 10.1 and 10.2 present the characteristics of the interviewed sample and their use of BupaQuit and other support during the BupaQuit trial. The interviewees were on average 34.9 (SD=9.14) years old, used BupaQuit for a mean of 402,6 sec (SD=391.7 sec; range 4 to 1731 seconds, which may be an underestimation – see note under Table 8.5). Most participants (n=16, 80%) had used at least one cessation aid before joining BupaQuit (n=6, 30% stop smoking services, n=12, 60% e-cigarettes, and n=8, 40% - medications), and 13 (65%) tried to quit smoking in the year prior to enrolling into BupaQuit. During the interview, n=11 (55%) participants reported having used additional cessation aids while enrolled in the trial, n=10 (50%) reported not smoking, and a further n=8 (40%) cutting down or switching to smoking irregularly since registering into the trial. All participants provided current age that was concordant with the age provided at registration (i.e. same age or being older by one year).

Table 10.1. Characteristics of BupaQuit interviewee participants
(note: data were collected through the app except for the age, smoking status and the number of cigarettes smoked at the time of the interview).

ID	Arm	Age ^b	gender	Employ- -ment	post16	OS	Smoking during interview ^b	CPD at trial enrolment / interview ^b
P1	Cont	27	M	Non-m	Yes	iOS	Not Smok	10 / 0
P2	Cont	24	M	Non-m	Yes	iOS	Not Smok	15 / 0
P3	Cont	34	M	Manual	Yes	iOS	Not Smok	5 / 0
P4	Int	35	M	Manual	Yes	iOS	Smok-red	15 / 10
P5	Cont	49	F	Non-m	No	And	Smok-red	25 / 20
P6	Int	43	M	Non-m	No	And	Not Smok	18 / 0
P7	Int	45	F	Manual	No	iOS	Not Smok	11 / 0
P8	Cont	27	F	Manual	Yes	And	Not Smok	10 / 0
P9	Int	29	F	Other	Yes	iOS	Not Smok	10 / 0
P10	Int	55	F	Manual	No	iOS	Smok-red	5 / 4 irregular
P11	Int	43	F	Non-m	No	iOS	Not Smok	6 / 0
P12	Cont	35	M	Non-m	Yes	iOS	Smok-red	7 / 5-6
P13	Cont	46	M	Non-m	No	iOS	Smok-red	20 / 10
P14	Cont	19	M	Student	Yes	iOS	Smoking	5 / c.10 on weekends
P15	Int	28	M	Manual	Yes	And	Smok-red	15 / 1-2 with drinks
P16 ^a	Int	31	M	Non-m	Yes	iOS	dna	10 / dna
P17	Int	33	F	Other	No	iOS	Not Smok	25 / 0
P18	Cont	28	M	Non-m	Yes	iOS	Smok-red	25 / 4
P19	Int	39	M	Non-m	Yes	iOS	Smok-red	10 / 5-10 on weekends
P20	Int	28	F	Manual	Yes	And	NS	10 / 0

ID=participant ID; OS=Operating System (iOS= iOS iPhone, And=Android), CPD=cigarettes smoked per day; NS=not smoking, Smok-red=Smoking but reduced since enrolment into the BupaQuit trial; dna=data not available; M=male, F=female a= interview cut short and not able to reconnect; b=data collected during the interview, Non-m=non-manual occupation, other=retired, unemployed, other occupations.

Table 10.2. Use of unassigned support during the BupaQuit trial and BupaQuit use by the interviewees.

ID	Arm	Use of other support while enrolled in BupaQuit trial (reported during the interview)				BupaQuit app use during the trial (collected via the app)				
		SSS /GP	e-cig	any meds	any digital	Time spent (sec)	Number of Logins	Post-QD logins	Pre and Post-QD logins	CMTs accessed
P1	Cont	SSS	Yes	Yes	Yes	815	12	Yes	Yes	N/A
P2	Cont	-	Yes	-	Yes	300	5	Yes	-	N/A
P3	Cont	-	Yes	-	-	377	13	Yes	-	N/A
P4	Int	-	-	-	-	202	6	Yes	Yes	0
P5	Cont	-	Yes	-	-	730	8	Yes	Yes	N/A
P6	Int	GP	Yes	Yes	Yes	1731	63	Yes	Yes	0
P7	Int	-	-	-	-	47	3	-	-	0
P8	Cont	GP	-	Yes	Possibly ²	235	2	Yes	Yes	N/A
P9	Int	-	Yes	Yes	Yes	681	13	Yes	-	4
P10	Int	-	-	-	-	4 ³	3	Yes	-	3
P11	Int	-	-	-	-	649	10	Yes	Yes	1
P12	Cont	-	Yes	-	-	196	1	-	-	N/A
P13	Cont	SSS	-	Yes	Yes	231	7	Yes	Yes	N/A
P14	Cont	-	-	-	-	317	5	Yes	-	N/A
P15	Int	-	-	-	-	109	1	-	-	0
P16 ¹	Int	dna	Dna	dna	Dna	128	3	Yes	Yes	0
P17	Int	-	Yes	-	-	418	1	Yes	-	7
P18	Cont	-	-	-	-	94	4	Yes	Yes	N/A
P19	Int	-	-	-	-	264	3	Yes	-	0
P20	Int	-	-	Yes	Yes	524	8	Yes	-	4

ID=participant ID; SSS=stop smoking services; GP=General Practitioner; Post-QD = accessed app following the quit date, which included craving management tools; 1= the interview cut short and it was not able to reconnect; 2=participant used other digital aids but could not remember if it happened during the BupaQuit trial or just before entering it; 3=possibly an error in the database that did not record all activity for that participant.

10.5.2. Overview of findings

The analysis revealed four pertinent overarching themes, which are described below, together with illustrative quotes.

Theme 1. Views and experiences with participating in the BupaQuit trial

Theme 1.1. Views on research and enrolment into the study

Participants downloaded BupaQuit and registered into the trial following

recommendations from others, active search for quitting apps, or seeing study advertisement on social media. Reasons for joining included expectations for the app to assist with quitting, curiosity (with no specific expectations for the app), interest in technology or science, as well as perceived app's credibility leading to high expectations for the quality of the app due to UCL's, but especially Bupa's involvement in the project as a private healthcare company.

“I was actually looking to quit smoking and I wanted something to give me some sort of motivation and I mean all I did was go into iTunes and type in ‘stop smoking’ [...] I went for BUPA Quit. I think just purely on, because of BUPA, the name BUPA.” (P1-Control).

Participants had positive views about being enrolled in the trial, and few spontaneously mentioned reading and remembering the information about the study procedures presented during the registration. However, none of the participants commented on being allocated to a different version of the app to others, nor suggested remembering about different app version being tested.

Theme 1.2. Follow-up procedures and the interview

The interviewed participants were accepting of the follow-up procedures and were keen to share feedback on the app. Some felt that being contacted meant that someone cared for their progress. Four of the interviewees were posted the CO Monitor for home-based testing, and three sent back the readings (one reported forgetting about the device). Those three participants were positive about the devices, some used them on other smokers, and some voiced a preference for receiving the device at the start of the programme.

“I mean that was fine, I actually sort of preferred it that way because [...] it felt as though you guys cared more, if that makes sense.” (P2-Control)

“No, it's absolutely fine, I think it's useful for people that are still using the app or are going to be using it, obviously it helps you improve it and make it better for everybody.” (P15-Intervention)

“More sort of information on that carbon monoxide test, that would be great. And then if you did send that out at the beginning of the test I think it would motivate people”. (P1-Control)

However, a few participants voiced dissatisfaction and disappointment with the

brief and impersonal follow-up survey and feedback, which focused on assessing complete abstinence, and which did not allow participants to report on other progress made (e.g. cutting down or having smoked only a single cigarette in the past two weeks).

“..the study focused on the study rather than the person that’s being studied.” (P12-Control)

“So the reason why I was demoralised was because it sounded as if they hadn’t taken on board whether I was continuing to not smoke, or whether it was just the one cigarette, so I think more follow-up from that would have been better.” (P8-Control)

Theme 1.3. Using non-assigned cessation support

Many of the intervention and control participants used a range of additional cessation support while using the BupaQuit app, or during the follow-up period for the trial. These included face-to-face support (from a GP or cessation advisors), medications (NRT and Champix), e-cigarettes, as well as other apps. They also often reported experimenting or switching from using one aid to the next as part of their quitting journey.

„So I’d just leave that there [a widget from one stop smoking app] so that it would show me how long I quit for and then I’d use the apps that I preferred to actually look at their stats and other things. Because there wasn’t one app that did all of the things really well, which is why I, kind of, used a combination.” (P20-Intervention)

“Yeah, I tend to have three or four on the go, to be honest, [BupaQuit, NHS Stop Smoking App, Smoke Free] ...” (P13-Control)

Theme 2. Expectations and general views on cessation apps

Theme 2.1. Apps supporting quitting

Participants’ views towards cessation apps fell within four broad categories: (i) believing apps on their own can aid cessation, e.g. with some participants attributing quitting successfully to using BupaQuit, (ii) viewing apps as ‘the future’ of quitting, but only if they were “*designed right*” (P19-Intervention; i.e. the current apps were not perceived as sufficiently comprehensive or helpful), (iii) considering apps as useful only when combined with other support (e.g. e-cigarettes, medications, professional or peer

support), (iv) having low expectations for apps as cessation aids, which was often related to viewing quitting as a matter of strong willpower, or viewing smartphones and apps as low-impact technology.

„I think that there is a need for a good smoking app because there are hundreds and hundreds and hundreds of quit apps but none of them I personally think meet the requirements of smokers to stop smoking.” (P8-Control)

„I think there’s limits to what the app can do on its own so I think what is more interesting is the combination of a nicotine replacement therapy like patches or gum.” (P4-Intervention)

“...the cravings which you get when you want to smoke, and an app really can’t match up to that.” (P14-Control)

“The user’s got to be motivated and want to quit as well, so you could have the best app out there but if the user isn’t motivated them the app can become pretty useless.” (P15-Intervention)

Participants who were positive about using apps as cessation aids named privacy, convenience, ease of access, and unique features that could aid quitting (e.g. offer distraction from cravings) as the main reasons to use apps. These participants also expected cessation apps to focus on progress monitoring (especially on tracking health and money gains), and to offer motivation and encouragement, as well as support with relapse.

Theme 2.2. Experienced ‘appers’

Echoing findings from the NRT2Quit interviews (Chapter 7, theme 7.2), BupaQuit participants drew on their own or other people’s experiences with using different apps when discussing preferences for cessation apps. For example, they saw themselves as customers or commercial users (rather than patients seeking treatment), and discussed getting bored quickly with apps or not treating apps as serious programmes.

„...[people] think of it [a quitting app] too much as an app or a game, like you could almost think of like well quitting smoking is just like an exercise routine almost, so [...] calling it like, you know, ‘this is your tailored programme for you’, that’s way more [...] motivating and incentive [...] and the customer thinks ‘oh, my God, like, you know, they care and this is for me.’” (P2-Control)

Participants also expected quitting apps to provide similar experience to other apps, especially in terms of being engaging (e.g. through use of gamification features, well-timed reminders or informative notifications, novel content on app launch, and multimedia instead of long text), relevant (e.g. through personalisation of content based on user profile, and offering manual customisability), as well as having attractive design and offering a frictionless user experience (e.g. being forgiving of mistakes, allowing unconstrained exploration of content).

“So things that show you your progress or feel like you’re achieving something, it turns it into, kind of, yeah, a game. [...] I think it’s universal across the apps. [...] because people, maybe, playing games on their phones so if you’ve got the app you’re more likely to feel gamified.” (P20-Intervention)

Theme 3. Use and views on BupaQuit

Theme 3.1. Using BupaQuit

Reflecting the usage data recorded on the server (Table 10.2), many participants used the app sporadically and reported terminating use within one or two weeks of downloading it. The reasons provided included the app not meeting their needs or preferences (e.g. providing insufficient support, or lacking in novelty), low perceived need and relevance for long-term use (e.g. because they were managing to remain abstinent, or they relapsed) or switching to a different aid. However, some participants mentioned using the app more regularly, especially as a distraction from cravings.

“Because I was on the phone, I was sort of like, I’d be like ten or twenty minutes and then the craving would pass and then that’s it then, then I’d be at work and then obviously I started on a vape cigarette at the moment...” (P6-Intervention)

“I think [I stopped using BupaQuit] it’s just because I stopped thinking about smoking really, smoking wasn’t, it wasn’t a part of my thoughts anymore, it wasn’t a part of my life, I didn’t find it difficult.” (P17-Intervention)

Theme 3.2. General views on BupaQuit app and its impact on quitting effort

Participants differed in their evaluation of BupaQuit, ranging from seeing it as an early, unfinished prototype, to a complete app. However, none of them mentioned they

might have received a different app version to other participants. Few participants attributed their cessation success only to using BupaQuit, while some others felt that the app helped them to initiate the attempt (e.g. by setting the quit date) and then to monitor their progress in the first weeks. However, not all participants could remember details about BupaQuit during the interview (e.g. because they had used it sporadically, in the more distant past, or alongside other apps).

“Can’t think of anything specifically. This is the trouble with having used so many apps is that they kind of blend into an array of the same sort of thing.” (P20-Intervention)

Nevertheless, most participants had suggestions for the improvement of BupaQuit and other quitting apps, some of which were based on their experience with using other quitting apps (Theme 1.3), or apps in general (Theme 2.2). Commonly mentioned limitations of BupaQuit were that it offered ‘not enough push’, and not enough support, encouragement, motivation to remain abstinent, especially in case of relapse, and had limited novelty and relevance (i.e. limited personalisation or customizability).

“Expectations? I expected more. [...] Well, I thought it’d be more intense, more informative. Yeah, more informative because I received daily texts but didn’t really encourage me to stop.” (P19-Intervention)

“I think it needs to be more personalised to the individual, for instance, having your personal details and using the health information for that category of person and using it in the app to target those people.” (P8-Control)

However, some participants offered suggestions for app’s features and content, while admitting that they themselves tend not to use similar features.

“Yeah, perhaps, you know like links to perhaps chat rooms [Interviewer: Do you have similar experiences with chatting to other people within different apps...?] Oh no I don't, no no, I don't use social media an awful lot, no.” (P10-Intervention)

Theme 3.3. Design and Usability of BupaQuit

Only few participants made comments about the design of BupaQuit, possibly due to relying on their recollections of the app, rather than having a visual prompt to comment on. However, several participants commented on the text in the app being too wordy. In terms of usability, participants felt the app was easy to set up and to use, but

some complained about a lack of clear instructions on how to make the best of the different app features and the wider quit programme.

“I think some kind of, yeah, some kind of format where you actually, you know, tell people how to actually use the app would be beneficial because obviously it’s there for a reason, it’s there to help quit, isn’t it?” (P7-Intervention)

Theme 4. Views on individual features in BupaQuit

Theme 4.1. Information and advice on quitting

There was little consensus in participants’ evaluations of the advice and information offered within BupaQuit. Some participants were positive about the information offered, considering it well-researched and clinical. Other participants were more critical, especially those with prior experience with quitting smoking. They felt the information was too generic or already well-known, did not support making the suggested changes in lifestyle, did not assist with choosing the right medications mentioned in the app nor covered the increasingly popular e-cigarettes. Participants also differed in their preferences for information on health risks and ‘scary’ facts about smoking, with some preferring information on positive, non-smoking themes.

“I think the only confusing part that I would suggest [...] I think I remember the medications not specifically telling you which is the most effective [medication] and I think that’s one of the pieces of information that I, sort of, wish I had from the get-go.” (P8-Control)

Theme 4.2. Quit plans and targets

Participants were interested in having a quit plan and support throughout the programme (e.g. regular communication and reminders before the quit date and afterwards). Some were keen on setting targets for quitting, but they often preferred to set targets for cutting down, instead of quitting abruptly, and additionally many discussed lapsing into smoking and re-setting the quit date several times.

„...if I could give myself a target and say today I’m going to try and limit myself to ten cigarettes, and then I could go in and log every time I’d had a cigarette, [...] and then to get some sort of motivation at the end of it, or a well done at the end of it I think, psychologically, that that would go a long way in helping me to work towards reducing that number.” (P12-Control)

Theme 4.3. Progress and outcome monitoring, feedback and support with relapse

Participants were particularly interested in features that helped them to monitor their progress and track benefits of quitting, especially health improvements and money saved. However, they also discussed that the impact of such monitoring may be short-lived.

„Each time, the sort of incentive of saving money and everything, I think the novelty just wears off, so there’s only so many times you can be prompted by a certain incentive.” (P9-Intervention)

However, participants differed in their interest in, or acceptability of, reporting regularly on smoking status or other experiences they had.

“...initially I thought that I would be able to, every time I had a cigarette, sort of log that and track it and make me aware, but it didn’t seem that that was the way the app was designed. [Interviewer: Okay, so would that be useful if you could?] Yeah, absolutely, and I say this from the experience of having counted calories before, or been on diets before” (P12-Control)

“Initially it was a sort of thing, I suppose I think it used to ask, “Have you smoked at all today?” and then it would give you, “Oh, X amount,” and some measure, and that was fun for a while, I mean, but that really is all I remember.” (P9-Intervention)

Some participants were critical of BupaQuit assessing smoking status on every app launch, especially without providing appropriate support to those who lapsed into smoking, but also of the app overly focusing on feedback related to smoking rather than other gains.

„I remember getting frustrated with the Bupa app quite quickly. [...] it keeps asking you if you’ve smoked, am I right? [...] I don’t know, maybe if it asked you if you have and then if you have smoked again, it provides you with some kind of encouragement or a way to start again that is positive, [...] that makes you feel like it’s actually okay.” (P20-Control)

“...a lot of health interventions try and control the problem by focussing on the problem [...rather than focus on positives such as...] am I eating the right things, am I exercising more, rather than progress that I’m not craving [...] or I’ve saved x amount of money because that’s basically throwing results out that focus on the negative aspects of smoking.” (P4-Intervention)

Theme 4.4. Craving monitoring and management

There were mixed views on the utility of the craving meter in BupaQuit. Some participants suggested different ways of improving the feature, for example by delivering personalised support with quitting.

“I mean, I’m sure it works for some people, but I just don’t have the time to think, “Oh, you know, I’m having a craving, I’d better tell my phone.” (P13-Control)

„I quite liked your craving meter, I thought that was quite good to sort of track when you were craving things, but I think that could also be built on. [...] like some inspiration, or [...] if you had somebody who looked after the site, [...] that person could, sort of, check at the end of the day, sort of, ‘Have your craving histories increased or have they decreased? You’re doing good, carry on.’” (P8-Control)

Participants in both the intervention and control arms tended to mention some form of craving management support as a desired feature in quitting apps in general, especially as a distraction, and if they found it useful in other apps.

“...like sort of craving help, something that would take your mind off, off, uh, smoking because it only lasts a couple of minutes. [...] I think the NHS [app] takes you to a link with some games on it, quick puzzle games so you’re sort of distracted from the cravings you’re getting.” (P1-Control)

However, the specific craving aids offered as part of BupaQuit app were only sporadically and briefly mentioned, possibly due to low engagement with this feature (also as suggested by the usage data). Indeed, one of the intervention participants learned about them only during the interview, and on initial exploration had quite a positive view on them, but felt they should have been more visible:

“Oh right, I can see that there, just bear with me. [Looking at app]. Yeah, I’d not seen that before. [Pause] Yeah, I can see you’ve got like relaxation, meditation and stuff, yeah, yeah, [...], that’s quite interesting, I’ll take a look at that. [...] perhaps if you’d put some tips on it somewhere [...] about where to find these, [...] But that’s probably my fault for not looking at it properly in all fairness [laughs]. (P10-Intervention).

Nevertheless, some participants were sceptical about app-based craving management having an effect, unless it offered a really engaging distraction game or communication with peers or specialists.

“I don’t think that you can manage cravings with an app. [...] I know that there are lots of apps that if you’re having a craving it’ll give you a game to distract you [...] and I haven’t seen any that have got good games [...] that could really engage you for five or ten minutes while you’re dealing with a craving, so that would be interesting.” (P20-Intervention)

Theme 4.5. Reminders and Notifications

There was little consensus on the reminders, especially their frequency. The interviewees often distinguished between simple reminders to re-open the app, and notifications that carried additional information. Some felt the app did not provide enough of the reminders to keep them engaged, nor that the reminders carried any useful information.

“..the daily reminder, it was helpful but it was just a reminder to log into the app which over time got a bit annoying actually [...] it was just a reminder to use the app as opposed to pushing out a positive message that reinforces the behaviour change.” (P4-Intervention)

However, relevance of the reminders seemed to change depending on participants’ interest to remain engaged with the app, their smoking status, whether the app offered any rewarding experience on re-engagement, as well as how the reminders fitted with participants’ daily routines.

“..maybe a message should come up [...] saying you don’t have your notifications on, would you like, a bit more motivation by switching them on and maybe set the time that you don’t get, maybe some people don’t want a notification every day, they might want one once a week.” (P11-Intervention)

“I think if you had not smoked, you’d be very keen to reply, “Yes, I’ve not smoked,” but if you had smoked, you would probably either ignore the notification, which suggests that you have smoked, or respond, “No.” I think if you hadn’t smoked and you got that notification, you’d be very keen to respond, “Yes,” quite quickly, you know.” (P13-Control)

10.6. Discussion

This interview study explored views of the BupaQuit trial participants on the study procedures, their experiences with the BupaQuit app, and their views on how the app could be improved. Participants had positive views on research on apps, but the

follow-up procedures could be improved in future trials to accommodate the need of some participants to report more details on their progress. Findings related to the use of unassigned support, numerous factors contributing to disengagement with the app, as well as the shortcomings in app's functionality emerged as possible reasons for disengagement and the lack of effect found in the BupaQuit trial. Finally, while there was a consensus on general qualities of cessation apps, especially on being motivating, engaging, and supporting in relapse, there were important differences in individual preferences for many of the app features, which pose challenges for further app development.

10.6.1. The BupaQuit trial

Several insights from the interviews may help explain the low overall quit rates in the BupaQuit trial and the lack of a difference on cessation between the intervention and control arms. First, randomisation and possible differences between app versions did not emerge as a theme. On the one hand, it is possible that participants might not have carefully considered or remembered the study procedures, but also that blinding was effective and that the control app functioned well as the minimum credible intervention.

On the other hand, however, it suggests that the differences between the app versions were not sufficient to translate into notable differences in impressions and experiences, which would also explain the lack of impact on cessation. Even more surprisingly, the discussion of the craving aids in the intervention app was very limited. Although the interview guide included dedicated questions on it, it is still possible that the interviewers did not prompt sufficiently about the craving aids, but another likely possibility is that these features were not particularly helpful, memorable, usable, or discoverable to the users.

Secondly, echoing findings from the BupaQuit trial (Chapter 8) as well as other research on digital cessation programmes (Danaher et al. 2006, Danaher and Seeley 2009), many participants engaged in cessation-related activities or used unassigned cessation aids (most notably other apps, e-cigarettes, and medications) while engaging with BupaQuit or during the follow-up period. Thirdly, participants discussed BupaQuit being predominantly useful in the early phases of quitting, which explains attrition from the app but also may mean limited impact on long-term outcomes.

Finally, participants discussed many ways in which the app had not met their expectations or failed at assisting quitting. The main shortcomings included not being engaging and motivating enough, as well as offering insufficient support in relapse. Some accounts also suggested that app-based support may not be treated as a proper cessation programme, possibly further undermining accountability and engagement with the app and the wider study. Taken together, any added value to cessation provided by BupaQuit or its components might have been very limited, and additionally, the pragmatic design of the trial might have made identifying any effect extremely unlikely.

Regarding enrolment, context and motivation to join the trial differed across the participants, but Bupa branding seemed to be an important factor that increased the app's credibility and participants' expectations. This suggests that healthcare companies may be in the right position to promote such support in the future, but smokers may have especially high hopes for the quality and impact of such apps. Finally, follow-up procedures were acceptable in general. Some of those who had received the CO Monitors valued them as potential cessation aids.

However, important ethical and clinical concerns regarding the follow-up emerged. The follow-up procedures in both BupaQuit and NRT2Quit trials were designed to be as brief as possible to limit the burden on participants that could lead to an even greater loss of the follow-up data. However, some participants may find such an impersonal and brief follow-up unacceptable and demotivating, suggesting it may be important to provide additional debriefing, or at least a possibility to qualify answers to the standardised and discrete follow-up questions in case participants would find it useful.

10.6.2. The BupaQuit app

The interviews captured a range of views and suggestions regarding BupaQuit and its further development. Some participants were positive about BupaQuit, and particularly about the features supporting monitoring and feedback on the quit progress and outcomes, which are important behaviour change techniques (BCTs) (Lehto and Oinas-Kukkonen 2011, McClure et al. 2015, Morrissey et al. 2016, Samdal et al. 2017). The areas for improvement included increasing engagement and relevance of the app, adding features boosting motivation to remain abstinent, and offering more support

following a relapse.

Additionally, participants tended to evaluate BupaQuit more as a commercial product rather than a clinical intervention undergoing evaluation, which was evident in them comparing BupaQuit to other apps on the market. These findings echo insights from other interview studies conducted as part of this thesis (Chapter 6 and Chapter 11). Together, they highlight the importance of considering functionality and design of the apps available on the market as potential proxy indicators of what smokers may find attractive or desired in future cessation apps.

Moreover, as was the case of its precursor, SF28, BupaQuit has been designed based on a number of assumptions and research findings, one of which being that complete abstinence following the quit date is predictive of long-term success (West and Stapleton 2008, Ubhi et al. 2015). This has informed a range of features within the app, including selecting the quit date, the frequent monitoring and feedback on the smoking status, emphasising the ‘not a puff’ rule, and adoption of a relatively conservative approach to lapsing (i.e. recommending re-setting the quit programme if lapsing continued). However, as this study suggests, and what is not entirely surprising, such design decisions may negatively impact on app engagement and satisfaction, especially among those who are lapsing into smoking, or who prefer to cut down gradually.

10.6.3. Strengths and limitations

The study had notable strengths. First, it had relatively high external validity, as it explored accounts of how smokers motivated to quit had used BupaQuit during a quit attempt in the real world and with no communication with the researchers. Secondly, the interviews offered insights on the behaviour of participants during the BupaQuit trial and on factors that could be affecting its quantitative outcomes. Most interviews were also conducted by the interviewers who were not directly involved with app development and thus might have been more impartial. On the other hand, those interviewers were less experienced in conducting qualitative studies, possibly leading to less in-depth exploration of the issues emerging in the interviews. Nevertheless, it was not feasible to conduct a much longer discussion over the telephone.

The findings have to be interpreted with caution, however. First of all, the study was conducted among a small and self-selected sample of the BupaQuit trial participants, and the findings may not be reflective of views of other trial participants and be even less generalisable to the smokers in the general population not interested in using apps. The sample likely included participants who held more favourable attitudes or greater interested in cessation apps and research, but possibly also those who had more extreme views on BupaQuit. Nevertheless, due to demand characteristics and not to offend the researchers, participants might have still refrained from offering strong criticism. Additionally, the interviews have taken place weeks or even months after participants had used the app, leaving them prone to recall bias. It was evident from the interviews that only some participants still had access to the BupaQuit app, meaning that many had to rely on their memories when discussing the app, and few participants admitted they no longer remember details about it.

10.6.4. Implications and future directions

The implications for cessation app development that emerge from this study are discussed in more detail in the final discussion in Chapter 12.5. However, it is important to highlight that while this study has identified a number of app features and qualities that could be incorporated in future versions of BupaQuit or similar apps, these findings on their own do not provide clear guidelines on how to implement these individual features to increase their acceptability and impact. This matter would still need to be resolved through different research methods and systematic and iterative evaluation.

This study points to further research avenues. First of all, there was some indication that participants who received CO monitors to confirm their abstinence continued to use the devices in private (including sharing them with others). Personal CO devices, especially those that connect to smartphones, may become more frequently used as part of cessation programmes in the future, which warrants further research, and which has also motivated the final study of this PhD reported in Chapter 11.

Secondly, the use of unassigned support alongside cessation apps poses challenges to conducting RCTs of such interventions. What is also interesting is that the interviews suggest that even participants who are interested in supporting research on cessation apps may still have a relatively ‘light-hearted’ attitude towards such

programmes, and be quite unapologetic about the use of other programmes not related to the research studies. Importantly, these insights point to a need for the interventions to incorporate mechanisms that integrate data on the use of a range of pharmacotherapy, e-cigarettes and other aids to increase the relevance of such programmes and to offer appropriately tailored advice.

Finally, this study demonstrated the value of conducting qualitative research nested in RCTs. However, the procedure could be improved by asking additional questions about other trial procedures (e.g. to explore whether participants read and understood the study information sheet or whether they had any thoughts on randomisation procedures). Additionally, due to limited resources, a decision was made to interview only those participants for whom data on app engagement were available to ensure they could comment on the app and their experiences with using it. However, this meant we lost an opportunity to investigate the cases of participants with missing data on app use, which would have been useful for the interpretation of the missing data in the trial.

10.7. Conclusion

This interview study with participants who used BupaQuit as part of the trial indicated a number of possible reasons for the low engagement with the app, attrition from the trial, and low cessation rates. It also highlighted the challenges to evaluating cessation apps through pragmatic RCTs, including the use of unassigned support and low commitment to the study and app. Finally, both the intervention and control versions of the BupaQuit app fell short of meeting the needs of users, particularly around relevance, encouragement, motivation, and post-relapse support, which will be important areas for future research into app development.

Chapter 11: Personal CO monitors and associated apps

11.1. Chapter 11 overview

This chapter reports findings from a mixed-methods qualitative study about personal smartphone-based CO Monitors and associated apps.

11.2. Contributions

I designed the study, selected or co-created interview prompts by communicating with app developers and designers, created the interview schedule, secured ethical approval and data protection registration for the study, run participant recruitment, conducted most of the interviews, analysed the data, and written up the findings. Dario Baretta (DB) and Shamaila Muzammil (SM) conducted one interview each. Olga Perski (OP) assisted with the second coding and validating of the thematic framework. OP, Lion Shahab (LS), and Robert West (RW) provided feedback on the published manuscript version of this chapter.

11.3. Dissemination

A version of this chapter was published in a peer-reviewed journal:

Herbec, A., Perski O, Shahab, L. & West, R. (2018). Smokers' Views on Personal Carbon Monoxide Monitors, Associated Apps, and Their Use: An Interview and Think-Aloud Study. *Int J Environ Res Public Health*, 15(2), 288. Available as: Open Access (distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>)).

11.4. Introduction

As was reviewed in Chapter 1.8, assessing carbon monoxide (CO) levels using traditional CO monitors has been an important element of many stop smoking programmes and was shown to be acceptable to smokers. In the future, individual

smokers could access CO testing outside of the clinical and research contexts due to the development of smaller and more affordable CO monitors that connect to smartphones (Meredith et al. 2014). As a result, CO testing could be incorporated into cessation apps in the future. However, very little data is available on the acceptability of such interventions or to guide the creation of apps to accompany the CO monitors. In line with the person-centred and iterative development of digital behaviour change intervention (DBCI) (Craig et al. 2008, Yardley et al. 2015, Michie et al. 2017), this study explored smokers' views and suggestions on the new personal CO monitoring devices and associated apps, which could help inform future work in the field.

Personal CO monitors could allow smokers to independently monitor and track CO levels and thus progress towards quitting or cutting down. They could also help smokers achieve other pre-defined goals, such as reaching particular CO levels, and provide momentary feedback on behavioural outcomes, which are important self-regulatory and behaviour change techniques (BCTs) (Michie et al. 2013) in both smoking cessation (Michie et al. 2011b, Bartlett et al. 2014) and other domains (French et al. 2014, Mairs and Mullan 2015, Samdal et al. 2017). Furthermore, preliminary research suggests that personal use of CO monitors is acceptable and valued as a potential motivational tool for smokers (Shahab et al. 2011, Beard and West 2012, Grant et al. 2015).

CO monitors that connect to smartphones and associated apps could be described as 'CO Smartphone Systems' (CSSs). CSSs offer several important clinical, research, and practical advantages over other methods. Smartphones offer a range of possibilities in creating dedicated apps that could harness incoming data from CO monitors to record, display, or otherwise manipulate information as part of complex behaviour change interventions. With the emergence of new technologies and programming solutions, there is scope for personalisation and interaction; integration with other platforms, data sources or social media; and implementation of other creative solutions with potential clinical implications. Smartphone apps are also valuable research platforms, enabling efficient data collection and sharing, as well as testing of new design concepts through observational studies, A-B testing, factorial studies, and randomised controlled trials (Michie and West 2016).

A number of studies explored smokers' views and preferences for digital cessation programmes in general, including apps (Herbec et al. 2014a, Perski et al.

2017a, Wu et al. 2017, Oliver et al. 2018). However, very little is known about the views of potential users on personal CO monitors, associated apps, and their use, all of which could impact on satisfaction, the uptake of, engagement, and effectiveness (Perski et al. 2017a, Perski et al. 2017b). One recent pilot study using one such device and an app Coach2Quit did not find an effect on cessation, but the intervention was received well by the participants (Krishnan et al. 2018).

This study explored smokers views regarding iCO™ Smokerlyzer® (Figure 11.1) manufactured by Bedfont® Scientific Ltd as it was the only such device available for purchase in the UK at the time. This device connects to smartphones and requires a dedicated app to compute and display the CO levels. Although the manufacturers developed one app to work with these monitors already (based on the same Windows PC software as used in the BupaQuit trial, see Appendix 9.2), it was possible to create new apps for these monitors by using dedicated source code shared by Bedfont® Scientific Ltd (i.e. an application programming interface, or API).



Figure 11.1. iCO™ Smokerlyzer® developed by Bedfont® Scientific Ltd.

Images sourced from: <https://www.bedfont.com/shop/smokerlyzer/ico-smokerlyzer> with permission from Bedfont® (© 2017 Bedfont® Scientific Ltd.)

11.4.1. Study aims

In line with person-centred and iterative development of digital health

programmes, this study aimed to address the existing gaps in research and our understanding of the potential value of CO monitors that connect to smartphones. It also aimed to provide information to guide both app development and its subsequent evaluation. The specific research questions were:

1. What are smokers' views on the smartphone-connectable CO Monitor device?
2. What are smokers' views on and expectations regarding existing and future apps that could work with the CO Monitor device?
3. How do smokers anticipate to use the CO Monitor and the associated apps?

11.5. Methods

11.5.1. Study Design

This was a mixed-methods study involving semi-structured face-to-face interviews followed by a think-aloud procedure involving a personal CO monitor and existing and prototype apps. Due to the progression of the project and the challenges encountered, the interviews were conducted in two phases: eleven in 2016, and five in 2017. The 2016 interviews helped to inform a prototype of a new CO Monitor app. The last five interviews were conducted as part of a small study that aimed to also pilot the use of the personal CO monitor and the new prototype app. The 2017 study involved an in-person interview, which was planned to be followed by a week of testing at home, but the latter was discontinued due to the technical challenges encountered by participants (these challenges are reported at the end of the results section below). The two studies were approved by Research Ethics Committees at UCL (Project IDs: CEHP/2013/508; 6212/008).

11.5.2. Participant recruitment

We used convenience sampling, with participants recruited through online advertisement (e.g. Gumtree) and within the UCL and Bloomsbury area (e.g. mailing lists and posters). The recruitment materials invited participants to an interview study at UCL, which aimed to explore smokers' preferences and views on smartphone apps that connect to personal CO monitors, and which could be used as tools to support smoking

cessation or reduction.

The eligible participants: (1) were 18 years or older, (2) a current daily smoker interested to quit, (3) owned a smartphone and be interested in trying to use a stop smoking app, (4) be fluent in English, and have good or corrected vision (to ensure participants could discuss a range of visual prompts). Additionally, in light of the plans to conduct home-based piloting of the new CO System, participants recruited in 2017 also had to (5) be smoking 10 cigarettes/day (it was judged that such participants would benefit more from regular CO measurements and cutting down), (6) have an Android phone (supporting the app) and (7) be interested in testing the new CO monitor and app at home for a week while trying to cut down on smoking. Recruitment and data collection for this face-to-face interview study stopped after data saturation was reached, meaning that no new themes or issues were arising during the analysis (Francis et al. 2010, Carlsen and Glenton 2011).

11.5.3. Interview procedure and materials

Participants provided informed consent and were provided with unique codes to protect their identity. Participants also completed an online screening survey prepared in SurveyMonkey and then a paper-based survey that assessed their history of smoking and quitting, prior use of CO monitors, as well as use of and interest in stop smoking apps. The survey questions are listed in Appendix 11.1.

The interviews lasted between 50-90 minutes. Fourteen interviews were conducted by myself. Two of the 2017 interviews were conducted by research assistants (RAs: MSc and PhD students), who were trained by myself and who followed detailed instructions for data collection. These instructions and protocol were developed by myself, but then discussed piloted among us and by RAs before proceeding. Participants from the 2016 interviews were reimbursed with £30 Amazon gift vouchers, as the interview involved only one meeting up to 90 minutes long, and those in 2017 with a £100 Amazon gift voucher for participation in the initial interview and then the week-long pilot testing. However, due to technical challenges with getting the devices to work with the different phones, the home-based testing was terminated.

All interviews followed a semi-structured interview guide and used a range of

prompts to help elicit views on the potential CO systems and their features (see Appendix 11.2 for details). The prompts included actual working apps or app prototypes, or app designs of apps. The interview guide was created drawing on my experience of developing and evaluating BupaQuit and NRT2Quit apps, and the insights learned from a User Experience course. The guide was designed to elicit information that could be useful to future manufacturers of CO monitors, developers of associated apps, as well as researchers who may evaluate CSSs. Core sections of the interviews were common across 2016 and 2017, but a few changes were introduced in the second phase reflecting project progression. The interviews were audio-recorded and transcribed intelligent verbatim by a professional company.

The interviews were divided into the following sections, and the interview guide was structured to explore these issues in depth: (1) current smoking patterns, experiences and views on smoking, quitting, and cutting down; (2) prior experience with CO testing, and with any cessation or health apps; (3) preferences for and expected use of hypothetical personal CO monitors and associated apps; (4) a think-aloud involving the iCO™ Smokerlyzer® developed by Bedfont® Scientific Ltd (Figure 11.1), which was purchased for the study; and (5) a think-aloud procedure on apps, during which participants freely explored and said out loud their thoughts and impressions about working apps, app prototypes, or designs. Participant responses guided interview progression within each of the interview sections, but the interviewer ensured that all core topics were discussed. Impromptu probes were used to prompt elaboration.

The apps used in 2016 interviews included the Smokerlyzer® app which accompanied the iCO™ Smokerlyzer®, was developed by Bedfont® Scientific Ltd, and was available on the iTunes and Google Play app stores; two prototype apps (V1-2) and designs created for the study. The 2017 interviews included a new UCL prototype app (V3), informed by findings from the 2016 interviews, in addition to the other apps. App designs were only used in 2016, as they helped to inform the new app prototype. After initial analysis, it became clear that their use did not contribute additional theoretical or practical considerations beyond those already emerging from the other parts of the interviews.

11.5.4. Data analysis

The analysis followed the methods and principles of framework analysis (FA) outlined and methodology outlined in Chapter 5.5.4 (Ritchie and Lewis 2003, Beard and West 2012, Herbec et al. 2014a, Parkinson et al. 2015). The final coding framework was agreed through three rounds of iteration and internal validation with OP. First, myself and OP independently coded 11 and three interview transcripts from 2016 interviews, respectively. The resulting coding frameworks (v1a and v1b) were compared. I then prepared a revised framework (v2), which was applied by OP to two new interviews. Following discussion and adjustment, I created a final version of the thematic frameworks (v3) and applied it to all transcripts. OP checked for internal validity and consistency the summary tables with the coding framework and exemplary interview quotes. Constant comparison (Madill et al. 2000) and deviant case analysis (Mays and Pope 2000) were used to ensure internal validity. As part of external validation, a short summary of findings was emailed to all participants, who could provide additional comments if they wished (Birt et al. 2016). The 2016 participants did not respond, but four out of five participants from 2017 interviews replied that the findings reflected their experiences and views, and did not suggest any changes.

11.6. Results

11.6.1. Participants

Sixteen participants took part in the study. Table 11.1. presents the characteristics of the interviews: there were aged 20-51, eight (50%) were women, seven (44%) had some prior experience with CO testing as part of stop smoking support, and three (20%) had used stop smoking apps before (see Table 11.1).

11.6.2. Findings from the interviews

Five main themes with several subthemes each were identified. These are reported on subsequent pages, together with illustrative quotes. Tables 11.2-11.6 present summaries of findings for each of the five theme.

Table 11.1. Characteristics of the interviewed participants

ID	Sex	Age	Post-16 yrs edu	Employment	CPD	Last quit attempt last year	Ever quit for > 1wk	CO testing before	Used stop smoking apps before	Used EBCS before
P1	M	20-29	Yes	student	3-20	Yes	Yes	Yes, once	-	Yes
P2	F	30-39	Yes	non-manual	10-15	-	-	-	-	-
P3	F	20-29	Yes	student	5	Yes	Yes	Yes, once	Yes	Yes
P4	F	40-49	Yes	non-manual	1-2	-	Yes	-	-	Yes
P5	M	30-39	-	non-manual	15	Yes	Yes	-	-	-
P6	F	20-29	Yes	non-manual	10	-	Yes	-	-	-
P7	M	30-39	Yes	student	5-8	Yes	Yes	Yes, >once	-	Yes,
P8	M	50-59	Yes	non-manual	15-20	Yes	-	Yes, once	-	Yes
P9	F	30-39	-	manual	10-12	Yes	Yes	Yes, once	-	Yes,
P10	M	20-29	Yes	manual and student	6-20	Yes	Yes	-	Yes	-
P11	M	20-28	Yes	non-manual	7-10	Yes	Yes	Yes, >once	-	Yes
P12	M	40-49	Yes	non-manual	15	-	Yes	-	-	Yes
P13	F	20-29	Yes	non-manual	15	-	Yes	-	-	-
P14	F	30-39	Yes	non-manual	10	Yes	Yes	-	-	Yes
P15	F	20-29	Yes	non-manual	16	Yes	Yes	Yes, >once	-	Yes
P16	M	20-29	Yes	manual	10	Yes	Yes	-	Yes	Yes

EBCS = evidence-based cessation support (e.g. stop smoking services, medications)

Box 11.1. General views on CO testing and design suggestions for CO devices (adapted from (Herbec et al. 2018b))

Theme	Key findings
1	CO Testing—General Views and Motivation to Use
1.1	General Views on CSSs <ul style="list-style-type: none"> • A potentially valuable tool for self-exploration and a cessation aid • Offers autonomy, convenience, and independence from healthcare professionals.
1.2.	Motivation to use—a novel cessation aid <ul style="list-style-type: none"> • Potentially helpful at increasing motivation to quit and remain abstinent • Monitor and inform about health damages from smoking • A long-term companion through the smoking and quitting journeys
1.3.	Motivation to use—other reasons <ul style="list-style-type: none"> • The ‘quantified self’ • Opportunity to learn new things about oneself • Willingness to contribute to science • Tech gadget; something to show off with friends
1.4.	Concerns over CSS <ul style="list-style-type: none"> • Accuracy of CO testing and possibility to manipulate results • Anxiety and worry over high results • Annoyance and demotivation due to lack of sufficient progress • ‘Moderate’ CO levels reassuring and permitting of continued smoking
2	Personal CO monitor: features and qualities <ul style="list-style-type: none"> • Small size and light weight • Wireless connection • Rechargeable batteries • Possibility to take CO test and temporarily store results without needing to connect to a smartphone for each individual test • Possibility to display the result on the device • Option of different colours • Case provided to fit all the necessary items (e.g. cables)

Box 11.2. Practicalities of CSS use (adapted from (Herbec, 2018b))

Theme	Key findings
3	Practicalities of CSS Use
3.1.	<p>Commercial use versus use as part of study</p> <ul style="list-style-type: none"> • Study: acceptance to record personal details, share CO results, use CSS according to schedule • Outside of the study: expectations to use ad libitum and anonymously
3.2.	<p>Smoking status and CO testing</p> <ul style="list-style-type: none"> • Preferences for testing: when the result is expected to be low vs. high • Interest to test and record CO levels across a range of situations and smoking levels
3.3.	<p>Location of use</p> <ul style="list-style-type: none"> • Different preferences to use at home, in private vs. in front of friends and family vs. In public
3.4.	<p>Sharing the device</p> <ul style="list-style-type: none"> • Device is private, not to be shared, vs interested to share with family and friends
3.5.	<p>Timing and duration of use</p> <ul style="list-style-type: none"> • Morning and evening most likely times for testing, especially for home-only testing • Different preferences for the duration of CSS use (only during a quit attempt vs long-term to document smoking and quitting journey)
3.6.	<p>Barriers to CSS use</p> <ul style="list-style-type: none"> • Annoyance or inconvenience of blowing into the device • Annoyance or inconvenience of needing to connect the device to a phone • Dislike for carrying around or displaying the cable • Anticipated embarrassment to test in public • Limited battery life • Low relevance for light smokers or abstainers

Box 11.3. Design suggestions for apps working with personal CO monitors (adapted from (Herbec et al, 2018b)).

Theme	Key findings	
4	Features and qualities in apps accompanying CO devices	
4.1	CO testing and display of CO results	
4.1.1.	CO testing journey	<ul style="list-style-type: none"> • Immediately accessible on app launch • Quick and easy testing procedures • Clear presentation of a numeric result (in ppm)
4.1.2.	Feedback on CO results	<ul style="list-style-type: none"> • Presentation of the result on the scale or colour-coded • Relevant feedback (e.g. health impact) • Encouraging advice on lowering the CO levels
4.1.3	Recording contextual data	<ul style="list-style-type: none"> • Possibility to collect contextual data on CO readings (e.g. timing and number of cigarettes smoked, levels of urges and stress)
4.2.	Interactive infographics	<ul style="list-style-type: none"> • Long-term record of CO results • Interactive display (zooming in/out, changing timescales) • Displaying CO results against targets and thresholds • Displaying CO results together with contextual data recorded
4.3.	Factual content	<ul style="list-style-type: none"> • Information and advice on CO and CO testing, • Advice on quitting and cutting down, managing CO levels
4.4.	Additional features	<ul style="list-style-type: none"> • Customisable reminders to take CO tests • Possibility to set targets and goals for CO levels • Rewards for reaching targets (in-app or external, e.g. diplomas) • Sharing CO results on social media or with selected persons • Multimedia demonstrating CO testing procedure
4.5.	External expert support	<ul style="list-style-type: none"> • Possibility to contact a healthcare professional when concerned • Possibility to share CO results with clinicians as part of quitting • Integration with traditional cessation interventions
4.6.	Onboarding and registration	<ul style="list-style-type: none"> • Registering with personal details for the study, with option to remain anonymous for commercial use • Creating detail profile supporting personalisation • Tutorial with key information and advice on CO, CO testing and app use presented at the start, but available on request
4.7.	General app qualities and Information architecture	<ul style="list-style-type: none"> • Key and interesting information presented in bite-sized shot communications at different stages of the app • Longer text (e.g. advice) available for optional browsing • Skippable content and options to re-visit content • Use of visuals and imagery to convey information or feedback • Imagery and colours friendly for visually-impaired users

Box 11.4. Factors Potentially Affecting Preferences, Views and Engagement with CSSs (adapted from (Herbec, 2018b))

Theme	Key findings
5	Factors Potentially Affecting Preferences, Views and Engagement with CSSs
5.1.	Smoking profile <ul style="list-style-type: none"> • Patterns of smoking (regular vs irregular) • Perceived role of smoking (e.g., habit, mood regulation, socialising) • Dependence levels
5.2.	Barriers to quitting <ul style="list-style-type: none"> • Motivation • Self-efficacy and capability to remain abstinent, manage cravings • Other concerns, e.g., weight gain
5.3.	Views on, and plans for quitting <ul style="list-style-type: none"> • The timing of a quit attempt (near vs distant future) • Preferred levels of support (e.g., assisted vs unassisted) • Approach to quitting (cutting down vs abrupt cessation)
5.4.	Prior experience with digital programs and user digital behaviours <ul style="list-style-type: none"> • Preferences for features found and enjoyed in other apps • Extending behaviours with other apps to other apps
5.5.	Prior experience with CO testing

Theme 1. CO Testing – general views and motivation to use

Theme 1.1. General views on CSSs

Except for a few participants, especially those with suboptimal prior experiences of CO testing, many participants were keen on using CSSs, and viewed them as a valuable and promising novel tool for self-exploration and smoking cessation. They also appreciated that CSSs gave them autonomy, convenience, and independence from healthcare professionals.

“it’s exciting to be part of something new, and also if that helps, anything that helps kicking of a habit is welcome” (P13)

Theme 1.2. Motivation to use CSSs – a novel cessation aid

CSSs were seen as valuable new cessation aids, which were expected to be especially helpful for increasing motivation to quit or to remain abstinent, particularly by showing the health damage of smoking.

“I would continue to smoke normally just to see how big it’s going to get so I can frighten myself so I can stop.” (P10)

“I think it’s to try to help me to stop smoking [...] or even to cut right down [...] I’m going to feel, psychologically I’m going to feel better because I want to see the results showing me that I’m you know, getting healthier in a sense” (P12)

Some participants also believed that a CSS could become a long-term companion through the smoking and quitting journey, enabling the documentation of milestones and cessation support access

“..in an ideal situation, I would have it just to use indefinitely, and I would start off and I would keep smoking for the first couple of weeks at least, start getting some feedback, building up a bit of a data pattern, and then I would sort of put it together with some other [stop smoking] approaches” (P5)

Theme 1.3. Motivation to use CCSs – other reasons

Participants expressed additional reasons to use CSSs. These included: interest in the ‘quantified self’ (i.e. to assess and document in detail one’s behaviour and its outcomes); the opportunity to learn new things about oneself; willingness to contribute to scientific research; having a new tech gadget; or being able to show off among friends.

“Well, I suppose it would be, I think, it would seem to me to be, like, a bit of a novelty, so that I’d, I’d imagine, sort of, doing it and showing my friends, being like, hah, look, I’ve got lower CO than you, or whatever” (P1)

“I’m really excited, because again it’s something that will tell me somebody about me or my body, that I’m not aware of” (P13)

Theme 1.4. Concerns over CSS

The accuracy of CO testing was an important factor in appraising the value of CCSs. Participants expressed some concern over the precision of CO testing, but also about factors that may affect the results, such as the type of cigarette smoked, timing and method of CO testing, co-use of other substances, or smokers’ characteristics.

“Well there will be still a trace of scepticism, just a bit, this is why I’d still try the 2 weeks’ challenge with the cigarettes, so I’ll try to smoke with people, I’ll try to smoke on my own on different days and just, I want to see if there’s going to be a difference in the level.” (P10)

“But like doesn't it matter your height, your weight? [...] if it's a person that's 60 years old and he's been smoking for thirty it's going, isn't it going to be harder for his blood to clean up the system than it would have been for an 18 year old...” (P6)

Participants also discussed potential negative or undesired outcomes of using CSSs, such as worries about high CO results, or annoyance and demotivation when not seeing sufficient decline in CO readings.

“And it's quite scary tough to know how much is in my body. God, it's quite scary.” (P14)

“Like, it's kind of an encouraging thing, if you see something getting better each day, or each read, then it kind of encourages you, but if you see that it's not making a difference, you kind of feel a bit...demotivated.” (P4)

The interviews also revealed possible unintended outcomes, whereby low or moderate CO readings or goals for harm reduction (e.g. allowing smoking as long as the CO results stayed below 10 ppm) could be seen by some smokers as permissive and reassuring of continued smoking.

“..there's a bit of a fine line between telling people that it's, the number that they're at is okay and showing the benefits of lowering that number” (P16)

“..you actually see what the middle is [on the CO scale] and if you're in the middle I don't think you would be very scared.” (P10)

Theme 2. Views on personal CO monitor and design suggestions

Many participants were positive about the iCO™ Smokerlyzer®, and praised its small size, good appearance and packaging, and low weight. The clinical appearance of the device was either seen as an advantage or disadvantage.

“It's cute and like I think, yeah, it's designed really well, it's like something that goes, that you can put in your bag and doesn't take up much space...” (P3)

However, some participants were disappointed by the short battery life (warranty

for 3 years, or for 200 readings), especially those who envisaged using a CSS long-term. Also, many participants felt that the cable connecting the device with the app was too long and that it negatively affected the appearance and usability of the device.

“Yeah, if it was the wire, I'd take it in my bag, I'd carry it around, but because I know that I have to use it with the wire, in my phone, it wouldn't come out of the house, it would probably go in the drawer.” (P9)

“..if you were to have it Bluetooth wise or Wi-Fi wise you'd probably gain, because then you don't have to kind of set yourself up to do the monitoring” (P15)

The simple functionality was favoured by many participants, but some were disappointed that the results are not displayed directly on the device, and the reliance on connecting the monitor to the smartphone during each use. Some voiced preferences for the device to collect additional data, ideally automatically.

Theme 3. Practicalities of CSS use

Theme 3.1. Commercial or private use versus use during a study

Participants tended to make a distinction between using CSSs as part of a study, which was related to commitment to a certain schedule, and using it more freely as a commercial product (e.g. for longer, or less frequently). This distinction appeared to affect acceptance and readiness to register any personal details on the app, or share results with other app users, clinicians or researchers.

“I'm assuming that this is just for the research purposes, I wouldn't, if I was to be a general customer I wouldn't be expected to have to put all these numbers in would I?” (P16)

Theme 3.2. Location of use

About half of participants wanted to use the CO monitor only in private, and ideally at home, while others seemed happy to use it in public or in front of friends, sometimes also strangers.

“I wouldn't whip it out at a pub necessarily, but yeah, with friends why not?” (P13)

“Err, yeah looks great, I suppose that, I guess you wouldn’t carry it round, I suppose it’d be something that you’d just have at home.” (P1)

Theme 3.3. Duration and timing of use

Some participants perceived CSSs as a potential aid during a specific quit attempt. However, many participants expected to use CSSs over extended periods of time, e.g. for several months or even a year, especially when they were interested to learn more about their smoking patterns or to document their smoking and quitting journey.

“I want something that I can charge and use and at least for, because I mean you can’t really say you’ve quit smoking unless you have like at least six months behind you, six months to a year.” (P6)

Regarding the specific timing of testing, participants voiced different preferences, although many considered morning and evening testing as the most likely times to test CO levels, especially among those interested in using CSSs only at home. However, some participants were keen to use CSSs throughout the day and in a range of situations.

“Lunchtime, yeah, or yeah, lunchtime normally.” (P11)

“I mean I imagine you’d do it maybe 3 times in a day perhaps or twice in a day, the start and the end of the day or something.” (P16)

Theme 3.4. Smoking and CO testing

Some participants were interested in documenting CO levels across different experiences and stages of quitting or cutting down. Others had clear preferences for testing when they expected the results to be either high (e.g. to scare themselves into refraining from smoking), or low (e.g. to confirm and reward abstinence).

“I would like to use it in situations when I am smoking more, for example sometimes you go through a patch in your day when you are overly stressed” (P4)

“I’ll probably only do it when I know that I haven’t smoked in a while.” (P1)

Theme 3.5. Sharing CO monitors

Participants differed in their readiness or interest to share their device with others. Some participants thought of it as a very personal item, never to be shared, while others were very keen to share it with friends or family as a way of encouraging them to quit, to compare results, or just to demonstrate the CSS's capabilities.

"I could carry it around with me and blow into it, and I could probably pop it out and show somebody I would see smoking and say, "Test your breath as well and see how you're doing". (P9)

Theme 3.6. Barriers to CSS use

A few participants did not voice any concerns over using CSSs, while others mentioned several potential barriers. Some of these emerged only after the demonstration of the iCO™ Smokerlyzer®, and were related to the appearance or usability of the device. These included: annoyance or inconvenience related to the action of blowing into the CO monitor or needing to connect it to a phone each time a CO measurement was taken; dislike for carrying and using the connecting cable; dislike for the irreplaceable battery; or embarrassment of using the monitor in public. The latter was especially emphasised among participants who were not satisfied with the device's appearance.

"I would use it more if it didn't have, probably, the wire, I think. [...] I don't think a lot of people would want to take their phone out and plug that in in front of someone to show [...], I'd want to do that, definitely at home, in private, yeah." (P9)

Finally, some participants saw little relevance of using CSSs when smoking lightly or successfully abstaining, or anticipated losing interest in CO testing long-term.

"I guess [...] it will only work for people who are smoking quite heavily, because if you're, if you're smoking quite light then [...] you're not going to see huge improvements." (P4)

"I suppose that's the same thing with apps as well is that you get an app or a thing and you get excited about it for like the first couple of weeks or so and then you get bored of it." (P1)

Theme 4. Desired features in associated apps

Participants discussed a range of features and content of apps that could work alongside personal CO monitors, both during the discussion of hypothetical, or "ideal"

apps, and in response to the different prompts used.

Theme 4.1. Features related to taking and displaying CO results

The central feature of the CSS app was the CO testing user journey, from initiating the CO test to the display of the results. Participants expected the CO test to be immediately accessible when launching the app, to follow a quick and intuitive process with limited text on the screen, and perhaps include visual aids to guide users through the test procedure, which was implemented in the Smokerlyzer® app. Participants also tended to have a strong preference for seeing detailed, numeric results on screen (in particles per million), rather than a range.

“..the reading [in V1-2 apps] was more specific than the other one [Smokerlyzer®] so it give you a value which was what I said that would be good.” (P3)

Many participants expected the result to be accompanied by brief feedback that would help explain the results, including use of visual or colour-coded scales, or provide relevant, motivational information, especially for high CO readings. Some participants expressed the need for additional feedback and advice on how to modify their smoking or quitting behaviour to improve their CO readings.

“I need to know what this means, like what is normal and is this horrible, is this not so horrible? [...] Yeah, I would like to have a record of this as well [...] and if it gives information on how to cut down as well, yeah.” (P8)

“Of course the problem with lots of red is that’s where most smokers are going to probably fall [...] there’s sort of very little possibility for you to demonstrate some improvement in the simple emotional response of a kind of lighter shade of red or something.” (P5)

Finally, some participants were interested in collecting pertinent, contextual data on their individual CO readings to better understand their behaviour and outcomes, such as quantity and timing of cigarettes smoked, use of cessation aids, context of CO testing (e.g. location, timing), or self-reported levels of stress, cravings or other emotions.

“My smoking is quite mood-related right, [...] I would like to do is that I can quickly record why I am having a cigarette and two, three things, how much was the craving [...], what triggered this particular smoke and is there I can do something alternative to not go for this cigarette.” (P7)

Theme 4.2. Interactive Infographics

Having access to a detailed history of CO readings was seen as another vital feature in a CSS app, with many participants voicing preferences for interactive timelines, with adjustable timeframes, and the possibility to combine different pieces of information, e.g. about contextual data on CO readings.

“I like graphs, I like visual, whatever the graph, but visual representations speaks to me, colours but not too many, and then I guess less is more, is kind of the rule.” (P13)

“Yeah, and maybe sort of just a little bit more interesting or more integrated so it’s got sort of like, potentially like goals [...] so it’s the sort of thing that suggests what you could do in the future...” (P1)

Theme 4.3. Factual content

The concepts of CO and CO testing were novel to many participants, who were curious about learning more details about the scientific, health and practical aspects of taking the measurements. This became especially clear in the first phase of the project when participants explored the Smokerlyzer® app that included lengthy descriptions of CO and CO testing. Such information caught the attention of many participants and was often praised as being more interesting than the more commonly available information about smoking and quitting.

“I’m spending a lot of time on the information [in Smokelyzer® app], like I want to read through it, [...] Just by reading it I feel like I would smokeless cigarettes tomorrow just by reading it [...]. amazing, I love the health section.” (P10)

Nevertheless, some participants were still expecting to see tips and advice on smoking cessation and reduction.

Theme 4.4. Additional features

A range of additional features was discussed, such as customisable reminders about CO testing, a possibility to set target CO levels or other goals, in-app rewards (e.g. badges), external rewards (e.g. certificates), as well as craving management aids.

“...something about this app would help sort of fidget oneself away from wanting a cigarette.” (P2)

Different participants expressed interest in different features, but none of them emerged as a priority feature. There were also mixed views on sharing CO results with others, including on social media, with some participants keen to be part of an interactive peer support group, and others considering CO readings too personal to share.

Theme 4.5. External expert support

While CSSs were recognised and praised as standalone programmes, some participants believed that it would be beneficial to integrate them with existing face-to-face cessation programmes, include functionality allowing users to share their CO results with clinicians who may oversee cessation efforts, or at least provide contact to a qualified person who could address any concerns arising due to high CO levels.

“I think it needs to be part of a package rather than just its own thing, [...] like you have to like forward along the readings and then like you go back like sometime later for like a follow-up and they like look at your readings with you and they give you some information about that kind of thing.” (P3)

Theme 4.6. Onboarding and registration

Some participants were interested in creating a detailed profile at registration, especially if it could help to tailor advice and feedback on CO testing and smoking. Participants also expected to see some tutorials on CO testing to ensure that they completed the test correctly.

“...it could be like you know you create an account for this and all your data gets stored you know, so it's sort of personalised to you” (P2)

Theme 4.7. General app qualities and information architecture

There were mixed views on how the information within the app should be presented, with some liking long texts, and others preferring advice to be distributed across the different parts of the app, or presented gradually (e.g. as part of tutorials, as regular new tips, or part of the feedback on CO readings). Use of images or graphics,

including traffic-light imagery for feedback, was preferred to longer texts, but attention was drawn consider colour-blind-friendly designs.

“..it’s a lot of information but it also gives the app a level of seriousness, and when you’re quitting smoking it’s serious” (P2)

“..this still looks very prototypey, [...] is very texty so like I’m not sure that lots and lots of people will bother reading all of this stuff and it’s also kind of hidden, [...] you wouldn’t know that it’s there.” (P3)

Theme 5. Factors potentially affecting preferences, views and engagement with CSSs

Theme 5.1. Smoking profile

Participants differed on how much they smoked. Around half of participants described an irregular pattern of smoking across the week (e.g. smoking primarily during workdays, in the evenings, or when stressed). Additionally, participants often described smoking as a strong habit, or playing a certain role, e.g. for lifting mood, socialisation, a pretext to escape irritable situations, or to relax. Participants analysed their smoking patterns and the reason for smoking when discussing their preferred timing or context for CO testing, such as expecting to use the CSS when normally smoking a cigarette or soon after. This also made some smokers sceptical of the value or practicality of regular CO testing.

“Yeah, yeah, I suppose it’s the difficult thing about err, because I smoke quite sort of irregularly if you will so like I’ll have one day of smoking about 20 and then another day of smoking, you know, like one or two or maybe none you know.” (P1)

Theme 5.2. Low motivation and other barriers to quitting

Participants described a number of barriers to initiating and succeeding at quitting long-term, which were broadly falling within (i) low capability to quit, including low self-efficacy at quitting, sustaining abstinence, and breaking with the smoking routine, (ii) low motivation to initiate a quit attempt, but especially to sustain long-term abstinence, and (iii) other concerns, such as weight gain. Participants expressed preferences for apps that would address these barriers, but particularly had high expectations for the CSS to help them raise and maintain motivation to quit and prevent relapse.

“I always I give up for like two three months and then take it back up again, so maybe you know bits of, I don’t know, something about the long term I suppose would be quite useful.” (P1)

Theme 5.3. Views on, and plans for quitting

Participants seemed to fall within two broad categories in terms of their views on quitting, with some seeing in as a long-term journey involving some self-discovery and experimentation with quitting methods, while others were more focused on the goal of abstaining completely. Participants also differed in their preferences and plans for quitting, and particularly with regards to the approach (cutting down or quitting abruptly), the levels of support (e.g., no support, minimum advice, or intensive support from healthcare professionals), and timeframe (soon or distant future). These preferences and plans were also reflected in participants’ preferences for CSS features and expected use.

“I think for me at least it will take at least a month before I cut back to say less than ten a day, at least a month, and then another three months before I can go for five a day. So having that constant log of information would be really great.” (P2)

Theme 5.4. Experienced ‘appers’

Almost all participants had some prior experience of using digital devices (e.g. wearables) or health apps, but few had ever used stop smoking apps. Some participants voiced preferences for using CSSs that included features that they enjoyed elsewhere (e.g. the solutions used for data collection and display within running apps), and often compared the designs and functionality in the demonstrated apps with other, familiar apps. Participants also described their habits or preferred interactions with existing digital programmes, which they were also generalising to potential CSSs, such as skipping tutorials, reluctance to register with personal details or to share data, or limited patience for apps that ‘freeze’.

“I think maybe a little timer somewhere or a sand timer or something, ‘cos if I was at home I might have thought it had crashed, and I do that a lot, if an app doesn’t respond quickly I’ll close it.” (P11)

Theme 5.5. Prior experience with CO testing

Many participants with prior experience of CO testing viewed CSSs as beneficial and important. However, one participant described being able to easily ‘cheat’ or manipulate the CO result, which made him more sceptical about the value of CO testing.

“I don’t think it’s that accurate. Because if you smoke just before you take the test you’re going to blow a high reading, but if you don’t smoke for, I don’t know, two or three hours beforehand and blow...” (P11)

11.6.3. Note on practical challenges to using personal CO monitoring devices

Although not central to this study, a set of additional insights emerged when we tried to pilot the use of CO monitors in the real world among the sample of 2017 participants. First, being single-person use (with no replaceable mouthpieces), each CO monitor device could only be used by a single participant, which meant that providing such devices for testing as part of usability testing in the lab would dramatically increase the costs of such sessions. Equally importantly, it was not possible to assess if the devices worked or to test their reliability or validity before providing them to participants. This may be a key challenge, as during the few opportunistic occasions to test individual CO devices (e.g. while demonstrating them in the lab or providing them for home-based use) we encountered different problems. For example, some participants struggled to make the devices work with their phones, or to get a reliable reading on all testing occasions. The reasons included the device failing to connect or synchronise with the app software, providing different (even grossly incorrect) readings on repeat tests, or working with only one version of the app (i.e. either the original manufacturer’s or our UCL app).

Additionally, some participants could not use the devices due to their phones having different audio-jacks inputs, or not having them at all – as was the case with the new iPhone models. We were not able to test the devices in any systematic way, and admittedly, some of the technical faults might have been due to the devices used being old (series 1) and already past their warranty time. However, many of the same technical and practical challenges encountered (e.g. no possibility to test the devices or use them by multiple users) would most likely apply to the new devices as well. Importantly, it was clear that participants were disappointed by these technical

challenges, and this would likely lead to attrition or inaccurate findings if these models were used in a proper study in the real world.

11.7. Discussion

11.7.1. Summary of findings

This study explored smokers' views and preferences for a potential new type of quitting aid – a CSS. Participants were interested in using CSSs, especially as a novel quitting aid and a tool for self-discovery. They also tended to have high expectations for CSSs, and discussed a range of desired features and qualities of CSSs. However, engagement with CSSs is likely to be dependent on the satisfaction with the personal CO monitors and their accuracy. Moreover, although CSSs were seen as a potential motivational tool, there is a risk for unintended negative consequences, including reassurance of continued smoking. Finally, notable differences emerged in participants' motivation to use CSSs as well as the anticipated patterns of use. These differences should be accounted for when designing and evaluating future CSSs.

11.7.2. Development and evaluation of CSSs in the future

Smokers voiced preferences for a range of functionality and features in future CSSs. First of all, the personal CO monitoring devices were expected to be convenient, visually attractive, and accurate. There was a strong preference for a wireless connection between the device and the phone. Given the high expectations for such devices, smokers' expectations should be managed before enrolment in future studies to limit disappointment and disengagement.

In terms of the features in the associated apps, there was a preference for: (i) an easy and quick CO testing user journey, together with (ii) a clear visual presentation of CO results, accompanied by relevant and encouraging feedback and advice, which echoes previous research (Raiff et al, 2013). Additionally, smokers expressed interest in (iii) collecting contextual data on CO readings that could help them interpret the results

and adjust their behaviour. In line with prior research (Perski et al. 2017a), attractive visual design in future apps was emphasised.

One concerning issue that emerged was that even smokers who are motivated to quit may interpret feedback from CSSs as permissive of continued smoking, especially if their CO levels do not reach the top range of CO values. CO testing has been used successfully in traditional face-to-face settings when it is accompanied by advice from healthcare professionals or cessation advisors (Shahab et al. 2011, Lorencatto et al. 2012, Louwagie et al. 2014). More research is needed on how to safely and effectively provide CO results in the absence of expert input and how to mitigate any negative impact that CSS use could have on cessation efforts.

Finally, these findings suggest that certain individual differences may impact both on smokers' preferences for CSS features and on their engagement with such interventions. A recent review (Perski et al. 2017b) identified a range of factors that may influence engagement with DBCIs, including socio-demographic and psychological characteristics (e.g. motivation), and prior experiences with digital programmes. The present study echoes these findings, but suggests that factors related to smoking and quitting should also be considered when developing and evaluating CSSs. These include end-users' smoking patterns (e.g. intensity and regularity of smoking), preferences for quitting approaches and methods (e.g. needs for support, abrupt cessation vs cutting down), the underlying motivation for CSS use (e.g. preferences to record low or high CO levels), preferences for when and how to use CSS (e.g. timing and location of testing), and readiness to share the device. These factors could have a non-trivial impact on how smokers engage with CSS, including attrition, but also the CO levels recorded in the evaluated apps. These individual differences among the users of CSSs may be especially important in studies evaluating CSSs during ad libitum use, but they could also affect compliance in research with a pre-determined schedule of CO testing. Therefore, these factors should be accounted for during app development and analyses of data from CSSs.

11.7.3. Strengths and limitations

This study involved a mixed-methods approach combining in-depth interviews and a think-aloud procedures about a new CO monitoring device and existing or

prototype apps, which is in line with guidelines on person-centred development of complex digital interventions (Craig et al. 2008, Yardley et al. 2015, Michie and West 2016). These methods enabled assessing the needs and preferences among the potential end-users of CSSs and exploring issues that could impact on the development and evaluation of such programmes.

This study had several limitations. First, the sample was relatively small and self-selected, and over-represented smokers with interest in digital cessation aids. Nevertheless, the sample size was adequate given the exploratory aims of the study, and data saturation was reached (Francis et al. 2010, Braun and Clarke 2013). Additionally, the findings encompassed diverse views and preferences for the design of CSS and elucidated important information on the facilitators and barriers to CSS use. Secondly, the interview guide and prompts changed between 2016 and 2017 interviews. However, all interviews had common interview parts and followed the same structure, allowing for data synthesis. Finally, the study explored views on only the hypothetical use of CSSs, and it was not possible to test these CO monitors in a real-world scenario as part of this research. As the potential users may not be able to articulate all of their preferences or predict their own behaviour (Cooper et al. 2014, Perski et al. 2017a), the findings require confirming in real-world setting.

11.7.4. Future research directions

First of all, it seems important to systematically explore and identify typologies of potential users of CSSs, and perhaps also of stop smoking apps more generally. On the one hand, this could help tailor functionality and content of a generic app to smokers' profile, needs and preferences. On the other hand, it could help create different versions of CSSs and other apps that are targeted to sub-samples of smokers with shared characteristics. Secondly, quantitative research is needed to assess the level of interest in such programmes among a wider group of smokers and the extent to which the findings emerging from this study reflect the preferences of smokers in the general population. Finally, future research should involve other study designs, e.g. action research and observational studies of CSS in the wild and with no healthcare professionals' input to appropriately assess CSSs and their use (Michie and West 2016). However, such research may be constrained by a number of existing technical and practical difficulties related to using personal CO devices, which were discussed in 11.6.3 above.

11.8. Conclusion

Some smokers show interest in using smartphone-enabled personal CO monitoring devices as part of quitting or cutting down. These smokers tend to have high expectations and hopes for the programmes and the impact they could have on increasing and sustaining long-term motivation to quit and preventing relapse. The main focus should be on ensuring that the CO monitoring devices are reliable, have appealing designs, while the apps are versatile to accommodate the different needs of end-users. Finally, research paradigms that will enable meaningful evaluation of CSS should be identified.

Chapter 12: General discussion

12.1. Chapter 12 overview

This chapter provides an overview of the findings from the studies informing this thesis and discusses their implications for the development and evaluation of smartphone-based cessation interventions. It also outlines the core limitations of the thesis and potential future research directions.

12.2. Overall summary of the thesis findings

The thesis' overarching aim was to inform the development and evaluation of future complex app-based cessation interventions for: optimising the use nicotine replacement therapy (NRT), managing cigarette cravings, and using personal carbon monoxide (CO) monitors. The thesis comprised seven studies that involved preliminary evaluations of effectiveness, use, acceptability, and preferences for new apps or app prototypes within these three themes of interest among adult, UK-based smokers interested in app-based support. The studies have yielded insights into the desired features of apps as well as their anticipated or actual use. Additionally, some of the studies have explored key methodological issues in evaluating such programmes through pragmatic randomised controlled trials (RCTs). Taken together, the findings can inform future smartphone-based stop smoking interventions and studies to evaluate them.

The work conducted as part of Theme 1 aimed to inform the development of a new app supporting NRT use – the NRT2Quit app, and then to evaluate it using mixed-methods. The process included a behavioural analysis informed by the COM-B ('Capability, Opportunity, Motivation – Behaviour') and the Theoretical Domains Framework (TDF) of data from the published literature, theories, and best clinical practice on NRT use and the factors affecting its use. This had resulted in the selection of 25 behaviour change techniques (BCTs) that could address barriers to optimal NRT use and which were subsequently implemented in NRT2Quit. The pragmatic RCT of the resulting NRT2Quit (Study 1) showed anecdotal-level evidence for the effectiveness of the intervention version of the app to improve biochemical-verified cessation and

NRT use in comparison with the control app version. Due to the low recruitment, the study was terminated early, but it also helped to identify a number of possible barriers to recruitment of participants into such RCTs through community pharmacies. These included insufficient engagement of the pharmacy staff and low visibility of the recruitment materials.

The subsequent interview study (Study 2), also informed by COM-B and TDF, identified two behaviours related to optimal NRT use (using NRT per se and engaging with support and information on NRT use). It also found a range of potential intervention targets for these two behaviours, some of which may be delivered through apps in the future. This study also provided further insights into the possible causes of poor recruitment into the NRT2Quit trial, such as smokers' low motivation (e.g. low expectations to benefit) and capability (e.g. limited awareness of the types and value of support with NRT use).

Finally, the think-aloud procedure (Study 3) identified the strengths and weaknesses of the NRT2Quit app from the point of view of the potential end-users, and their preferences for digital support with NRT use. Key areas for improvement included offering comprehensive and tailored cessation support, including craving management.

Theme 2 explored the role of smartphone-based support in supporting craving management, and involved developing a new app - BupaQuit. Study 4 was an RCT of the BupaQuit app that offered craving management tools (CMT) versus the control app version without them. The CMT had no detectable impact on cessation outcomes, but the trial contributed to our understanding of the challenges in app evaluation through online RCTs, such as study promotion while trying to conceal the differences between the study arms. Study 5 identified possible barriers to remote verification of abstinence by means of computer-based CO monitors posted to trial participants. Insights from both of these studies suggest that without greater communication with participants at enrolment, and possibly also without reimbursement, it may be difficult to obtain satisfactory retention and follow-up data.

The follow-up telephone interviews (Study 6) found that key RCT procedures might have been implemented well (e.g. blinding to condition allocation), but over half of the interviewees used unassigned cessation support. Additionally, both the intervention and control app versions have not met all of the participants' needs, including not offering sufficient support with craving management in terms of

distraction, as well as insufficient encouragement and little support with relapse. These findings are all possible reasons for the attrition from BupaQuit and the lack of effect in the trial.

Finally, for Theme 3, Study 7 involved mixed-methods to explore smokers' views on personal, smartphone-enabled CO monitors and associated apps. It found that smokers were interested in such support, especially given its novelty, and they had high expectations for its impact on their motivation to quit and to remain abstinent. However, the study highlighted challenges for usability and evaluation of such interventions, particularly given the individual differences in motivation and expectations for such programmes and their use.

12.3. Insights from the NRT2Quit and BupaQuit trials

Setting up and conducting the two trials as part of this thesis offered valuable insights on the potential effectiveness of such programmes and on the feasibility of their evaluation through pragmatic RCTs. These insights can inform future research and design of trials evaluating stop smoking apps, and are discussed in more details below. The specific suggestions for certain design elements and future research into the methodology of RCTs of cessation apps are listed in Box 12.1.

Box 12.1. Suggestions for design elements and future research on pragmatic remote trials of cessation apps.

Suggestions for:	Pragmatic RCT
Design elements	Secure staff time to monitor recruitment and to conduct follow-up beyond the app, especially over the phone.
Recruitment	
Future research	Identify how to better promote RCTs embedded within apps live on app stores without disclosing the differences between app conditions (e.g. disclose even less information about the app to spark curiosity)
Future research	Explore how different recruitment campaigns and the information presented about the cessation apps impact on their uptake and enrolment into the trials
Enrolment	
Future research	Explore ways to increase commitment to trials (e.g. increase the sense of accountability) and thus lower attrition without compromising external validity (e.g. creating additional automated messages during onboarding that are drawing on the expertise from other disciplines, e.g. marketing and brand loyalty building)
Future research and design elements	Identify what additional data may be important to collect to better understand engagement and outcomes from trials, and attempt to collect it at baseline using engaging and acceptable surveys (e.g. users' expectations for the quit attempt, app use, and data reporting)
Design elements	Collect more detailed information about additional cessation support used on enrolment
Design elements	Provide additional instructions (i.e. a tutorial) on how to use the app and its individual components during a quit attempt
Follow-up	
Design elements	Initiate telephone follow-up early during the follow-up to prevent delays in collecting primary outcome data
Design elements	Offer optional additional surveys and feedback forms as well as debriefing procedures and support for participants who require assistance or who want to provide additional data
Future research	Assessing if conducting the telephone follow-up first, followed by invitations to complete a longer survey, would lead to better response rates to the surveys
Design elements	Attempt to collect data on reasons for attrition from the study from those who fail to respond to the traditional follow-up questions on the smoking status
Biochemical verification	
Future research	Conduct a head-to-head comparison of different follow-up methods to determine what is driving the response rate (e.g. reimbursement, the method used, the level of communication).

12.3.1. App's impact on cessation

Neither of the two RCTs has demonstrated the effectiveness of the evaluated interventions, and both studies were underpowered to detect an effect. The Bayes factors calculated suggested that data from both trials were insensitive to detect the predicted effects. In the case of BupaQuit, there was little indication that the two app versions could lead to a differential impact on cessation. The differences in cessation outcomes between the two versions of the NRT2Quit app were relatively greater, although this result might not have held true if the NRT2Quit trial recruited the target sample.

Nevertheless, there are several plausible reasons for an intervention such as NRT2Quit having a greater impact on the quit rates than BupaQuit when compared with their minimum credible intervention (MCI) versions. Firstly, there were more pronounced differences (e.g. in terms of features and behaviour change techniques (BCTs)) between the intervention and control versions of NRT2Quit than in the case of the two BupaQuit app versions. Secondly, NRT2Quit was designed with high user attrition in mind and thus delivered core BCTs already from the first app launch. In this respect, NRT2Quit could be classified as an example of intensive brief advice, analogous to a self-help booklet. In contrast, the intervention version of BupaQuit was focused on craving management and thus was designed to offer continuous support across several weeks, with certain content made available only to those who continued to re-visit the app. Thus, attrition and limited engagement with BupaQuit would result in limited exposure to CMTs that incorporated a range of BCTs, which could have further minimized the differences in impact between the two app versions.

Moreover, the participants in the NRT2Quit trial might have been more motivated and committed to quitting having already purchased medications to assist them. The NRT2Quit trial participants might have also been more committed to the study, as indicated by higher rates of completion of the longer follow-up survey with the secondary outcomes than in the BupaQuit trial (29.3% vs 10.6% of all trial participants, respectively).

Furthermore, many apps on the market already offered similar functionally to BupaQuit in terms of monitoring and feedback on quit progress as well as brief advice on quitting in general (Abroms et al. 2011, Abroms et al. 2013, Ubhi et al. 2015, Ubhi et al. 2016a). Thus, detecting the impact of the BupaQuit intervention over the control app

might have been the more difficult if participants in either arm were familiar with similar apps or used them concurrently with BupaQuit. The situation was very different with NRT2Quit, which offered unique support and advice on NRT use that otherwise might not have been easily accessible even to those who accessed additional, unassigned support (Abroms et al. 2011, Abroms et al. 2013, Jacobs et al. 2014). This suggests that app-based interventions that are similar to other already available apps may be more difficult to evaluate in pragmatic trials.

Nevertheless, these studies suggest that unless there is a large effect size, any differences between the trialled app versions may not be detectable in such pragmatic trials, especially if studies are underpowered, there is considerable attrition, and if participants additionally use additional unassigned support.

In terms of app engagement, it was limited and lower than expected for both NRT2Quit and BupaQuit. However, these findings are in line with some of their research on DBCIs. It is not clear if greater engagement would equate with better cessation outcomes (Saul et al. 2016, Paz Castro et al. 2017). However, improving it would likely require redesigning the apps so that they prioritised engagement.

12.3.2. Conducting automated pragmatic RCTs of cessation apps

The pragmatic RCTs reported in this thesis were designed to have greater external validity than the previous studies of apps (Bricker et al. 2014, Buller et al. 2014), which could increase generalisability of the findings and scalability of the apps in the future. This involved (a) little barriers to entering the trials, (b) embedding the enrolment and randomisation procedures within the app, (b) limited communication and monitoring by the researchers, (c) no reimbursements, and (d) enabling participants to use the app *ad libitum*. The trials were also designed to limit the participant burden and barriers to engaging with study procedures, for example by limiting the number of questions asked at baseline and follow-up.

Some of these design elements might have negatively affected the evaluation and outcomes. For example, by lowering barriers to entry and making registration as effortless as possible, participants' accountability and commitment levels to the study might have been low, and some participants might have joined these studies without

realising the extent of the procedures involved. The lack of reimbursement and limited communication with the participants at enrolment might have also contributed to attrition and poor engagement with the app and the follow-up procedures. It is also possible that by offering participants more instructions on quitting and using the app as a cessation aid could lead to better engagement and cessation rates, which should be explored in future trials. Finally, the limited data collection, especially at the follow-up, including the focus on the binary smoking status, has narrowed the scope for the evaluation.

Additionally, even though the NRT2Quit and BupaQuit trials were remote and many procedures were automated, the two studies still required considerable engagement of the researchers to manually screen the registrations into the app for eligibility, as well as to plan and conduct the follow-up beyond the app.

12.3.3. Recruitment into pragmatic RCTs of apps

The slow pace of recruitment into the two trials was a challenge that I underestimated at their outset, especially given the resources available and preparations made for each trial. Recruitment into the BupaQuit trial relied on paid advertisement on social media, yet it was not very successful. Additionally, such recruitment was not feasible in the NRT2Quit trial due to different eligibility criteria and limited funding. The slow recruitment also had a negative effect on the two projects more widely. It delayed completing the first round of app evaluation, increased costs of running the projects (e.g. required additional months of staff time and active study promotion), and prevented many other planned research activities from taking place, such as creating and testing updated versions of each of the apps.

One of the key possible reasons for the slow recruitment was that both trials had to be promoted in ways that prevented disclosing the differences between the intervention and control app versions. In practice, the recruitment campaigns and materials (e.g. the project websites and information on the app stores) could only mention the features found in both app versions, which was often limited to the functionality of the control app. Thus, in comparison to similar apps on the market, NRT2Quit and BupaQuit might not have seemed as appealing, unique, or particularly helpful, and additionally required users to register with contact details and express consent to participate in the trial.

12.3.4. Data collection and follow-up procedures

Attrition from the studies was high, with just a handful of participants responding to the follow-up surveys collecting important secondary outcome data, including on the use of medications and additional cessation support, and satisfaction. This has limited the evaluation and the ability to inform future research and development. Other challenges to evaluation arose from missing app data due to attrition from the app, failures in data synchronisation between apps and study servers, unrecorded engagement during offline use, and no possibility to record the length of the last interaction in the app. When analysing the usage data, it is also impossible to distinguish genuine data entry by participants (e.g. on smoking and medication use) from data arising from experimentation with the app features, mistakes, or sharing the app or associated devices with others (e.g. sharing the CO device).

Finally, the follow-up procedures in the NRT2Quit and BupaQuit trials (i.e. sending out invitations to an email or online survey first, followed by telephone calls to those who failed to respond) were informed by earlier research (Brendryen and Kraft 2008, Bricker et al. 2014, Brown et al. 2014). However, by far the most effective way of re-contacting participants in the BupaQuit trial was through the telephone. This suggests that telephone follow-up for such trials should be initiated early during the follow-up procedure to prevent delays in collecting the primary outcome. On the other hand, the feasibility of collecting data on secondary outcomes over the phone may be low, especially if participants are surprised by the unscheduled calls and are busy while answering them. Future studies could, therefore, assess if using the telephone follow-up could be used to invite participants to complete the additional surveys.

12.3.5. Biochemical verification of self-reported abstinence

Biochemical verification using saliva samples collected through the post was successful in the NRT2Quit trial (85.7% of those invited provided the sample), with the return rates similar to those in other trials of DBCIs for quitting smoking (Brown et al. 2014). However, the remote CO testing using the personal CO devices posted to participants in the BupaQuit trial was not (25.4% among those invited sent their CO readings).

This might suggest that saliva sampling may be more acceptable and convenient to participants than computer-based CO testing. Alternatively, allowing the BupaQuit participants to choose which CO data they share with us in order to enable them to use the software in private could have contributed to the low rate of the CO tests returned for the trial. It is also possible that the reimbursement used in the NRT2Quit was responsible for the higher return rate of saliva samples. Indeed, the studies that demonstrated better effectiveness and engagement with remote CO testing tended to involve considerable contact with the researchers at enrolment (e.g. to screen out participants, to collect baseline data), or offered reimbursement for participation and submitting CO test results (Alessi and Rash 2017).

However, it was not possible to properly evaluate or compare these two procedures of remote biochemical verification. Therefore, the findings from this PhD should not be used to discount biochemical verification using the remote CO testing in future trials. Instead, more research is needed on how to design procedures to increase the acceptability and engagement with the CO testing.

12.4. Insights from the qualitative studies on the pragmatic RCTs of apps

Some of the findings from the four qualitative studies could help interpret the observations from the two trials, and inform future design of trials evaluating apps. The relevant insights pertained to prospective participants' expectations on enrollment, use of unassigned support, reasons for attrition, and acceptability of data collection procedures.

12.4.1. Expectations for app and their use

Across the interview studies, some participants had high expectations for stop smoking apps. The expectations seemed to be particularly high for apps associated with a healthcare company, like Bupa, or those relying on new technology, e.g. CO monitors. High expectations may attract potential users and study participants, but can also be a source of disappointment and lead to attrition when apps are not delivering on the promise, as might have been the case with BupaQuit.

This suggests that managing expectations among potential participants may be crucial, but presenting the information about the apps to still make a trial attractive to join may require more research. Additionally, the insights suggest that while app onboarding should be effortless and quick, participants should still be presented with additional information on how to use the apps and their features in the context of quitting smoking and participation in the research.

12.4.2. Use of unassigned support

It is impractical and also unethical to prevent smokers from accessing non-assigned support with quitting while being enrolled in trials of apps, and additionally, it is expected that some smokers may engage with auxiliary quitting aids. Nevertheless, it was interesting to note in the BupaQuit interviews the high readiness and ‘light-heartedness’ of some of the BupaQuit participants to use multiple aids while being enrolled in the trial. Since this cannot be prevented, measures should be taken to account for this information in the analysis and possibly also integrate it into the advice offered within the app itself.

12.4.3. Reasons for attrition

There exist very many reasons for why participants may disengage with apps. These include low satisfaction, getting bored, quitting, failing to quit or relapsing, switching to other cessation aids methods. Other technical reasons are possible, such as switching devices or upgrading operating systems that may alter access to the evaluated apps. The current evaluation processes in trials do not attempt to collect information from those who drop out, including on the reasons for attrition, and obtaining such information may not be possible. However, without such information, it is difficult to inform the next steps in intervention development.

12.4.4. Data collection and follow-up procedures

The three interview studies on apps showed that smokers differ on their preferences, intentions, and readiness to self-report information in an app on different

aspects of smoking and quitting. These differences were stark, from seeing any surveys as a burden, to expecting more features allowing for data entry (e.g. diaries). The challenges with collecting complete and valid data from users on their behaviour within app and outside of it make it difficult not only for app evaluation, but also to offer relevant and tailored support. If not accounted for, these differences in self-reporting could also lead to misleading conclusions about participants' progress with quitting or level of engagement with the apps. Indeed, there is little scope to verify the validity of the collected data, or the context and users' intentions behind the self-reports. For example, prompting users to complete assessments may lead to reactivity and mere measurement effects (French and Sutton 2010, Rodrigues et al. 2015), thus limiting the ecological validity of the data.

On the other hand, data from *ad libitum* app use can be even more problematic to interpret, as was apparent from the interviews on NRT2Quit (Chapter 6), BupaQuit (Chapter 10) and the CO monitor and associated apps (Chapter 11). These studies showed that participants had very different preferences and acceptability levels for the timing and frequency of recording their smoking status, their use of medications, craving levels, and CO levels (i.e. preferences to record successful abstinence vs smoking episodes).

Additionally, the follow-up procedures were designed to be as brief as possible. The limited communication emerged as potentially not acceptable to some smokers. Thus, the follow-up should include optional longer debriefing and possibly also a chance to provide additional information on the progress.

12.5. Insights from the qualitative studies on app development

The ultimate goal of the research as part of this thesis was to inform the development of an acceptable, usable, and effective app that could have high population-level reach, or at least be attractive to smokers interested in apps. The three interview studies explored participants' views in relation to the apps supporting quitting, with focus on NRT use (NRT2Quit, Study 3), craving management (BupaQuit, Study 6), and use of data from personal CO monitors (Study 7). These could inform future smartphone-based interventions in these areas, but also provided insights on the desired features in stop smoking apps more broadly.

12.5.1. Preferences for stop smoking apps

First of all, these studies showed that smokers can articulate a number of preferences for stop smoking apps in general, as well as for specific features, which can be candidate components for future cessation aids. Reassuringly, but perhaps also unexpectedly, the different qualitative studies resulted in converging findings regardless of the focus of the individual apps assessed, and were also echoing results from other research on digitally-supported stop smoking interventions (Herbec et al. 2014a, Ferron et al. 2017, Wu et al. 2017). Importantly, a substantial proportion of the interviewed participants had high expectations for the apps, with some participants turning to them after other approaches and support had failed them.

Secondly, the findings suggest that there is some consensus among adult smokers with regards to their preference for certain app qualities and specific functions (listed in Box 12.2), but there also exist important individual differences with regards to other aspects of cessation apps (Box 12.3) that will need to be considered when developing future smartphone-based cessation support. However, several important areas for future research on smartphone-based support emerged, and these are outlined in the Box 12.3.

Box 12.2. Desired app features and qualities for which a consensus was emerging among adult UK-based smokers interviewed as part of this thesis.

	Desired features and qualities of stop smoking apps
1	general advice and information on smoking, quitting, and medication use
2	support with a selection of the medications
3	craving management support, with focus on distracting features
4	features helping to increase and sustain motivation to remain abstinent
5	monitoring of the quit progress and benefits of quitting
6	encouraging feedback on progress, positive reinforcement
7	flexible quit plans supporting making changes to the quit date and allowing for cutting down, rather than offering only abrupt cessation
8	non-judgmental support with lapses and relapse
9	high relevance of the app and its support (through personalisation of advice, and customizability of quit plan and in-app settings, most notably reminders)
10	engaging content on re-visits (e.g. novel, fun, interesting)
11	effortless user journeys, low cognitive load
12	use of meaningful notifications (e.g. carrying novel information)
13	forgiving interface (e.g. allowing for editing of errors)
14	clear instructions on how to use the app and its features as part of a quit attempt

Box 12.3. Features and app qualities for which there was no consensus among adult UK-based smokers interviewed as part of this thesis.

	Contested features and qualities of apps
1	level of interactivity, participant burden and data entry (e.g. provision of features for entering data on smoking, quitting, medication use, e.g. diaries or surveys)
2	connecting with peers or experts
3	amount of advice (and text) provided and frequency of information delivery
4	message tone (clinical vs light/fun)
5	gamification elements, prizes, trophies
7	use of reminders and notifications

Box 12.4. Suggestions for future research on the design of stop smoking interventions delivered through apps

- What individual characteristics can be assessed to tailor support via apps and help interpret the quantitative findings? These could include prior experience with apps, preferences for data input, the motivation for data input, plans for the quit attempt.

- How to offer acceptable and flexible support with quitting (e.g. allowing for cutting down and lapsing) without compromising on the evidence-base advice and on rigorous and standardised evaluation?

- How to deliver effective craving management tools for smokers via apps?

- How to offer relevant support if participants' situation is changing, e.g. they change the auxiliary cessation support they use while enrolled in studies of specific apps (e.g. they initiate using e-cigarettes or medications)?

- How to provide feedback on CO testing through smartphones and in the absence of HCPs in a way that minimises unintended negative consequences?

- How to incorporate methods and approaches from non-academic fields to improve engagement, acceptability and effectiveness of stop smoking apps?

This thesis also provided more detailed insights into the features and functionality specific to each of the projects, which are discussed below.

12.5.2. Support with NRT use

From the behavioural analysis reported in Chapters 3 and 5, optimal NRT use is a complex behaviour requiring dynamically tailored support and advice addressing all COM-B components. There are several challenges to offering such support through smartphone apps. First of all, detailed information about NRT could be of interest to some smokers, but these studies suggested that such advice would need to be accompanied by highly personalised recommendations on medication selection and use.

Secondly, there are practical barriers to making a support with NRT use relevant to smokers. Specifically, the burden of entering in an app accurate data on medication use required for tailoring of the support (e.g. data on medication use history, current medication use patterns, side-effects, withdrawals, and smoking status), may be too high and unacceptable to many users. Similarly, participants may not be accepting of certain

advice on medication use offered within the app, especially if it contradicts their views and beliefs about medication effectiveness and safety. Therefore, an app such as NRT2Quit may be most useful as part of hybrid intervention programmes, i.e. when smokers already receive personalised recommendations on NRT and its use from an expert, followed by this recommendation being entered in the app, and additionally when they have a sufficient supply of the medications.

Thirdly, participants voiced a preference for apps that deliver comprehensive cessation support, including craving management. The emergence of e-cigarettes and their popularity may require incorporating advice on them alongside that on NRT as well. However, an app offering such all-encompassing support would be very complex to develop and assess.

Moreover, smokers who are considering NRT use, or have used it before, tend to rely on informal sources of information and are primarily concerned with the information about harms and side effects rather than with the advice on optimal use. Therefore, promoting such support would be a major challenge requiring new promotional approaches.

Finally, the interviews as part of Studies 2 and 3 showed that even smokers who have used NRT before may have limited insights on the kind of support they would find beneficial and effective for NRT use. Therefore, for certain behaviours, the end-users may not be the experts and thus should not be a sole source of information when developing person-centred interventions. However, other research designs may be more appropriate to use when designing support for NRT use. For example, conducting co-design sessions with smokers who are currently using NRT while quitting may help to create more relevant and acceptable support for this population.

12.5.3. Craving management

Craving management was mentioned as a desired feature in cessation apps in all three qualitative studies on apps, which is in line with many studies on cessation apps research (Herbec et al. 2014a, Ploderer et al. 2014, Hartzler et al. 2016). This seems to have been related to participants' views and beliefs about smartphones and apps in general, and particularly due to viewing them as a source of entertainment and novel

information. Consequently, craving management was often discussed in the context of apps offering a distraction through engaging or novel content (e.g. games), rather than offering advice on avoidance or on alternative, non-app based activities. Taken together, the success of craving management tools in apps may require better harnessing of technology to develop bespoke engaging activities or incorporate some of the existing components in future apps. More research would also be required to identify more effective ways of presenting CMTs to users, including the use of appropriate navigation, or user journeys, within the app.

12.5.4. CO testing and other biofeedback

Personal CO testing emerged as potentially attractive cessation support, also due to its novelty. Participants expected to receive relevant feedback based on their readings, personalised recommendations, and features supporting setting targets and monitoring progress. However, the success and utility of CO monitoring in apps will be closely linked to the quality of the CO monitoring devices, their accuracy, usability and design, as well as the burden of the testing procedures. More research is needed, however, to understand how to best harness the CO data as part of monitoring and feedback, especially as using it could have unintended negative consequences for some smokers (e.g. reassurance in case of low or moderate levels of smoking). Additionally, while many participants in the interview study on the smartphone-based CO monitors (Chapter 11) were interested in using them, posting a similar device to participants in the BupaQuit trial yield poor results (Chapter 9).

Therefore, using CO monitors in future studies should be preceded by feasibility testing of the procedures to ensure sufficiently high acceptability and usability and involve greater communication between the researchers and participants, or their automated substitutes. Although this thesis explored biofeedback from CO testing, some of the insights might apply to other biofeedback mechanisms, such as heart rate monitoring. This would be especially the case if the other methods also rely on external devices or inconvenient procedures (e.g. the heart rate monitoring apps require users to calm themselves down before testing, and ideally carry out multiple tests).

12.5.5. Engagement with apps

The interview studies highlighted the importance of accounting for user behaviour with apps when designing and evaluating them. For example, the behaviour of the interviewees during face-to-face interviews and their interaction with apps were often marked by impatience in exploring the app features, skimming through the materials in the app, and relying on experimenting, or trial and error, to figure out how the app functions, rather than seeking out tutorials or help sections in the apps. Although lab-based setting has limited ecological validity, such behaviour is consistent with the accounts of BupaQuit participants regarding their use of the app during the trial (e.g. not finding craving management aids within the app), and with the findings from other studies and industry reports (Dimensional Research 2015, Sarkar et al. 2016, Perski et al. 2017a, Planet 2017). These insights suggest that designing overly complex apps that require tutorials to use may discourage use and prevent participants from benefiting from all the designed features. However, the apps informed by this thesis would have ended up being complex, suggesting that acceptable tutorials are still needed.

12.6. Insights from the process of app development

12.6.1. The role of end-users' insights

The studies in this thesis drew on three approaches to smartphone app development, the insights from which testify to the important role of incorporating person-centred method. Thus, the development of the novel NRT2Quit app was primarily theory-informed, while BupaQuit was based on an existing app that already had promising usage and self-reported outcomes (Ubhi et al. 2015). However, the potential end-users were not involved in the design of these apps. Subsequent research on these apps showed that while the apps contained features that the participants found beneficial or showed interest in, there were a number of ways in which they could be improved, for example through implementing better user journeys and including additional supportive content. At least in theory, addressing these issues from the start of the projects might have improved the trial outcomes.

In contrast, the research on the CO Monitor app was strongly rooted in the

person-centred approaches that prioritised users' insights and needs as a first step in intervention development. It used a range of stimuli (e.g. existing apps, app prototypes, as well as app design) to collect preliminary feedback in a lab-setting before a more complex app version would be developed and trialled among the users (Murray et al. 2016). The findings from this study, together with the identified technical challenges with the CO devices, informed our decision to pause this research, as it became evident that more formative research would be required to determine (i) the desired functionality of the app, (ii) the target group of smokers that could be the end-users, and among whom the new app could be piloted in the first instance, and (iii) appropriate evaluation methods.

12.6.2. Constraints in app development and the role of the IT teams

Although in theory app development offers almost endless possibilities, in practice the process is limited by several factors, including the resources available. It is also important to note that regardless of the approach adopted to app development, the final versions of the apps assessed in this thesis were heavily influenced by the work and input from the multidisciplinary IT teams who programmed the apps. One the one hand, this is because software development requires specialist knowledge, proficiency in different programming languages and frameworks, and access to relevant technological solutions (i.e. individual developers and designers may differ in skills and resources available to them).

On the other hand, many IT-related decisions are pragmatic and sometimes also reactive (e.g. involve modifications due to technical challenges) and may prioritise solutions known to the team already (e.g. re-use of existing code). They may also be driven by an expert individual who is leading on a given task (e.g. a designer who is responsible for the app's overall look and feel). Similarly, limited skills or resources within the IT team may prevent certain features from being developed or may lead to delays in the wider project. Thus, the skills, knowledge and vision of the individual IT teams may have a 'random' and nontrivial impact on the final app, and thus also on the users' satisfaction, engagement, and its outcomes.

In addition, and in contrast to interventions delivered face-to-face, there may be little scope to make last-minute adjustments to improve participants' experience with the app-based intervention. Introducing even small changes to the final version of the

app (e.g. changing the wording on one screen or fixing bugs) may be difficult, resource intense, or even impossible to implement without risking interrupting data collection or having the new app version being rejected from the app store. This is particularly problematic when a study is already underway. Moreover, in the absence of a person delivering the intervention, the team creating the app has to anticipate and make provisions for the many possible scenarios of app use. Some of these possible scenarios may surface only when the app is used by a large number of users, by which time it might be too late to rectify the shortcomings.

12.6.3. The illusion of standardisation and high fidelity in app-based interventions

One potential advantage of using digital solutions to provide behaviour change interventions is the promise of standardisation of the interventions and their delivery, including the timing and pace. This could help to avoid biases and differences arising from such interventions being implemented by individual advisors or in different settings (West et al. 2013, Brose et al. 2014). However, as the app development and studies conducted for this thesis show, this can be an aspirational goal only.

In reality, many factors affect the delivery and implementation of the support through smartphone apps. These include (i) technological constraints (e.g. speed of internet connection can affect the downloading of additional app content, the model of the phone and operating system can impact usability and app design or navigation, and third-party solutions can affect the performance of individual features within apps, such as app notifications); (ii) app features and qualities (e.g. personalisation and customisability may prevent delivery of intervention as originally intended, such as when participants disable reminders or lead to very different user experiences); as well as (iii) user behaviour (e.g. attrition, experimentation with features and answers provided to explore all functionality within the app).

12.6.4. Challenges to the sustainability of app-based support

Long-term sustainability of smartphone-based cessation interventions remains a major challenge, with one study showing only a few of the apps that have undergone

academic evaluation still being available for the general public to use beyond the trial (Haskins et al. 2017). This was also the case with the apps assessed in this thesis. Bupa owned BupaQuit, and the programme has been terminated with the completion of the data collection. Additionally, some elements of the software used to build NRT2Quit have been terminated. Giving the passing time, both of these apps would likely require some re-programming in order to make them available and usable on the new operating systems and smartphone models.

Changes to app store policies can also pose important barriers to programme sustainability. For example, in April 2015 (i.e. just weeks after BupaQuit and NRT2Quit were accepted on the app stores for the planned trials) the iTunes store introduced a new policy of not accepting new apps that required users to provide personal details in order to function, which was a key feature in both BupaQuit and NRT2Quit. This would have impacted any other studies with a one-step, app-based enrolment involving collecting the contact details. Finally, in the case of the CO Monitor app, any future studies will also be dependent on collaboration with the third parties who manufacture the CO measuring devices (e.g. to obtain source code and support to enable integration of these devices with new apps), as well as on device availability, quality and compatibility with new phone models and software.

12.6.5. Competing interests and needs of the researchers, users and the IT teams

Finally, the development and evaluation of the three apps revealed numerous unresolved tensions from competing interests, preferences or needs of (i) the clinical and research team, (ii) the individual smokers, or target end-users, as well as (iii) the IT teams who were commissioned to deliver the software and service it (see Box 12.5). These tensions will likely not be easily resolved in future interventions, and they may continue to impact on what can be delivered and evaluated, and on the satisfaction among smokers who use our programmes.

Box 12.5. Competing interests, preferences and needs of researchers, participants/users, and IT teams that can impact the development and evaluation of smartphone-based interventions.

Researchers (incl. clinical team members)	Participants / Users	IT teams
Evaluation of evidence-based and theory-informed content and features to incrementally build knowledge-base	A high degree of personalisation and customisability leading to unique experiences	Simplicity of the code and functionality
Research into apps that target specific aspects of quitting (e.g. cravings, medications use, biofeedback)	Multifunctionality and comprehensive support, features found in other liked health apps	Single-purpose apps perform best Use what works elsewhere
Clinically-relevant content (e.g. informative, complex, comprehensive)	Bite-size text, visual, engaging, fun	Use current design, interface and other industry standards; adapt to user preferences.
Evaluation of a quit programme (e.g. with a quit date) for a pre-specified period of time among a sufficiently large sample	Changing the quit date, using app long-term (as a companion) or at relevant to user times	Frequent iteration, bug fixing, upgrades to operating systems
Standardised data collection, i.e. at pre-determined time points (e.g. baseline, follow-up)	Different level of acceptability and interest in data entry	Minimum user burden, minimal data collection; use data from other sources where possible
Expectations for certain engagement levels and patterns	Different preferences for use; use ad libitum	Features supporting frictionless use and different user journeys

12.7. Strengths and limitations of the thesis

An important strength of this thesis is the use of mixed-methods that combined quantitative evaluation of two different apps through pragmatic RCTs, as well as qualitative research combining interview studies with think-aloud procedures about several different apps and app prototypes addressing different aspects of smoking. These studies also enabled assessing some of the key research design elements, and resulted in observations that could inform future app development and the design of the studies to evaluate them.

Although the findings from the studies on individual apps may have limited generalisability, especially if they involved small samples, together they provided an

opportunity for triangulation. Reassuringly, despite the different study aims, foci, and use of different research designs, they brought converging insights regarding app preferences. Additionally, even though the studied samples were self-selected and may be representing a potentially small proportion of smokers in general, this was nevertheless a group that was expressing interest in smartphone-based support, but had not been provided yet with satisfactory support. Finally, the qualitative studies captured a range of views on smartphone apps for quitting smoking and their individual components.

However, the research conducted as part of this thesis had several important limitations. Some of them were discussed in relation to the individual studies in the previous chapters, and others applied across this PhD research. First of all, the pragmatic RCTs were underpowered, and in the case of BupaQuit, relied only on self-reported abstinence, or explored only short-term quit rates (NRT2Quit). Secondary outcome data pertaining to satisfaction from the interventions, medication use and access to other support were completed by a minority of participants in the two trials, which makes interpreting these findings very difficult. Crucially, the follow-up rates were modest.

Additionally, the reported studies had limited generalisability, arising from the characteristics of the sample, as well as the context of data collection. The studies all enrolled adult (aged 18-67), otherwise healthy, UK-based smokers (46.9% women), and in the case of face-to-face interviews, residents of London. All participants were interested in quitting in the near future and in using digital and smartphone-based cessation support. It can also be assumed that they had favourable views on participating in research studies. Therefore, the views and findings emerging from these studies may not generalise to the wider population of smokers in the UK. Additionally, as was discussed in Chapter 1, there are important differences between countries in the prevalence and patterns of smoking, as well as in access to cessation support. Current findings may therefore have less applicability to countries where smokers have different access to the behavioural and pharmacological cessation support.

Furthermore, the data collection for the studies took place between December 2014 and October 2017. This period saw continued development of technology and changes to the cessation behaviours among smokers in England and Europe (e.g. the rise of e-cigarettes use in quit attempts), which might further limit generalisability of the

thesis findings to future circumstances (Beard et al. 2015, Beard et al. 2016b, Filippidis et al. 2018).

In light of the recommended guidelines (Yardley et al. 2015, Murray et al. 2016, Blandford et al. 2018), the initial plans for each of the apps included their iterative development based on the qualitative and quantitative findings from the studies reported in this thesis. Ultimately, however, this was not feasible within the timeline of the PhD programme, as well as given the constraints on the resources and the high costs of sustaining these interventions. It is also important to underline that the development of both NRT2Quit and BupaQuit did not involve inputs from potential end-users during the development stage. Similarly, it was also infeasible to pilot the recruitment strategies and materials, all of which might have impacted on the recruitment, but would require a dedicated programme of research to optimise. On the other hand, however, conducting further formative and usability research would have delayed the launch of the trials, which in turn would have almost certainly led to their cancellation, or at least to re-programming the apps and changing the study designs (this was caused by aforementioned changes to the app store policies, see Chapter 8.4.1. and 12.6.4).

However, a further important limitation of this thesis is that the findings still fall short of providing sufficient guidelines on how to best implement and deliver these desired components in apps. It also remains an empirical question as to whether apps developed in line with the findings would translate into better engagement patterns and cessation outcomes. Indeed, research suggests that end-users may not be able to articulate all of their needs or to understand the subconscious processes that impact on their behaviours (De Ridder 2014), and there is a well-documented gap between the intentions and subsequent behaviour (Armitage and Conner 2001)

12.8. Reflections on the current state of research on stop smoking apps

The field of research on stop smoking smartphone apps has not advanced considerably during the period during which this PhD programme has been conducted. Even though several new evaluation studies have been published (Iacoviello et al. 2017, Garrison et al. 2018, Tombor et al. 2018), the research on apps remains limited and many questions are still unanswered. For example, we still lack well-powered and definite trials of effectiveness, especially those including biochemical verification of

abstinence. Additionally, very few studies use novel research designs (e.g. MOST), sophisticated data collection methods (e.g. GPS or wearables), or report on apps that had undergone several iteration phases.

Limited research on cessation apps is a testimony to the challenges in developing, running, and completing such trials. These include the dynamic and unpredictable research environment (i.e. changes in the app ecosystem and technological solutions), high costs and uncertainty, challenges with recruitment and data collection, changes to policies and laws (e.g. policies of app stores, data protection legislature, new regulations around medical devices), and reliance on third parties. Additionally, further challenges emerge due to the fragmentation of the ongoing efforts, with individual academic teams developing their own programmes, which after their release compete for attention from potential users with commercial apps, with some of the latter being better funded, designed and promoted.

There is also considerable heterogeneity in the studies evaluating apps, but still only a limited range of measures is being assessed, which also limits advances in the field (as presented in Tables 2.2-2.3). The challenges related to running smartphone-based studies lead to pragmatic decisions about study design, inclusion criteria, and follow-ups. For example, regardless of the study design, the recruitment criteria tend to be broad (i.e. low bar to entry) and we can typically only recruit participants who (a) possess a specific smartphone model; and who are: (b) smokers (often daily smokers, min 5-10 cig/day), (c) interested to quit, (d) willing to try using a stop smoking app, and (e) consent to study procedures. Adding further inclusion criteria, e.g. accounting for dependence, motivational factors, or other characteristics that may affect engagement and satisfaction with the programmes, could lead to further under-recruitment.

Additionally, to limit participant burden, the baseline and follow-up surveys tend to be as short as possible, especially if they are delivered through apps. In case of smoking cessation there are a handful of standardised measures assessed at baseline and follow-up (e.g. the Russel Standard), which leaves little scope for additional data collection that may be relevant to assessing engagement with apps and their effectiveness. For example, this thesis suggests that other factors may play a role, e.g. prior experience with apps, expectations, preferences for data entry.

12.9. Future research directions

12.9.1. Improving support with NRT use

During the process of researching potential targets for smartphone-based interventions for NRT use, important barriers to accessing traditional support with NRT use were identified across all COM-B domains (see Study 2 in Chapter 5). Designing interventions based on these findings was beyond the scope of this thesis. The Behaviour Change Wheel (Michie et al. 2014) could be used to identify appropriate intervention functions, policy categories and individual behaviour change techniques for future interventions in the field.

12.9.2. Identifying and evaluating optimal modes of intervention delivery through smartphones

In line with the person-centred and iterative development of complex interventions (Craig et al. 2013, Yardley et al. 2015, Michie and West 2016, Michie et al. 2017, Perski et al. 2017b), this thesis' findings could inform future versions of BupaQuit, NRT2Quit, CO Monitor and other, comprehensive, cessation apps. One line of research could involve developing an app that meets as many of the requirements and preferences of potential users and evaluating its effectiveness, use and satisfaction. However, as explained above in Section 12.7 on limitations, more research is needed to translate these desired features and functionality into effective apps.

Therefore, the field could be advanced through conducting more systematic research into the different ways of implementing the desired intervention components in apps. The specific areas requiring research include: (i) the mode of delivery within the app (e.g. use of different technological solutions, such as wearables), (ii) the design of user journeys, (iii) the frequency and timing of delivery of individual BCTs, as well as (iv) use of visual design elements (e.g. imagery). Once identified, further research would be required to determine how delivery is influencing the outcomes.

Next, it would be important to assess whether dynamically adaptive interventions would really be more effective than minimally personalised interventions that were tested as part of this thesis. Finally, there exist novel technological solutions, such as smart devices and GPS, which at least in principle could improve the richness and

precision of the data collected at relatively low user burden, but effective use cases in smoking cessation still remain limited.

Future research should also make a greater use of other research designs, especially co-design (i.e. collaborative sessions on app development with the researchers, designers, and end-users), research by design (e.g. conducting an observational study of NRT2Quit in the natural environment among smokers who are undergoing quitting with NRT), A-B testing of different versions of the individual features, use of micro-randomisation designs and just-in-time interventions (Klasnja et al. 2015). However, many of these designs rely on users' continuous engagement with the app and the programme of research. Therefore, unless we solve the problem of attrition and low commitment to studies, conducting an ecologically-valid research (i.e. one without incentives and close monitoring by the researchers) may be challenging.

12.9.3. Increasing reach and uptake, also in healthcare settings

An important consideration for research on cessation apps is establishing a feasible recruitment and onboarding process that could increase the reach of the interventions yet still enable scalability and maintain external validity. Recruitment via app stores, and especially through paid social media advertisement, may be the most efficient method now. Another possibility would be to conduct research in collaboration with owners of apps that have a large existing user base. However, such studies would likely be limited to studies that are of interest to both academic and the commercial sector, and which would not carry risks of negatively impacting on the app popularity and ratings.

Moreover, the benefits of smartphone-based support may only be realised fully once such programmes are integrated within the healthcare systems, e.g. as part of hybrid interventions (Pulverman and Yellowlees 2014, Houston et al. 2015), and when they are recommended by healthcare professionals (HCPs) to patients who may benefit from cessation the most, e.g. those with tobacco-related diseases or conditions that are exacerbated by smoking, as well as those from lower socio-economic groups. For this to be materialised, apps would need to be developed in close collaboration with HCPs and patients, and address from the start any challenges to app implementation in the clinical practice.

12.9.3. Accounting for the evolving needs of the end-users

The different interview studies identified a range of factors that may be driving the preferences for apps and engagement with them. These could include smokers' experiences, plans and views on smoking and quitting, such as the perceived role of the strong will or pharmacological support with quitting, understanding of one's barriers to abstinence (e.g. low motivation, high cravings), as well as plans for quitting in terms of the timing and approach (e.g. quitting abruptly, or cutting down across extended periods of time). Additionally, smokers' motivation behind engaging with specific app features (e.g. to record and obtain feedback on successes vs failures at quitting) may impact on their preferences regarding app and the engagement patterns.

Finally, the insights from the interviews also seem to suggest that research with smokers who are at different stages of quitting during the data collection (e.g. not planning to quit in the near future, having just completed a successful attempt, or having relapsed), may result in different recommendations for app development. These observations are line with a recent cross-sectional study among Dutch smokers showing that smoking-related characteristics (e.g. dependence, prior quit attempts) and innovativeness, and not demographic characteristics, were associated with intention to use a stop smoking app (Chevalking et al. 2018).

Systematically assessing these different factors was beyond the scope of this thesis, but the findings suggest that research into what is shaping preferences could help to inform tailoring of apps and be important for their appropriate evaluation. Moreover, an important next research step would be exploring preferences for cessation apps among smokers who are just undergoing a quit attempt to capture more accurately their time-specific needs.

A further, and important finding emerging from each of the qualitative study of apps (Study 6, 10, and 11, captured by themes such as 'experienced appers' and 'preferences for features found in other apps') is that the expectations of smokers for app-based support seems to be influenced by their experiences with other apps, and thus by the contemporary trends in app design. Indeed, evaluations of BupaQuit, NRT2Quit and CO Monitor apps included direct comparisons between these and existing health apps. This introduces a new set of commercial or market standards as benchmarks for the development and evaluation of cessation apps.

Thus, developing acceptable, attractive, and potentially also engaging programmes may require incorporating methodology and approaches from other disciplines and non-academic fields, such as market research and competitor analysis (Bergen and Peteraf 2002) to identify trends that may affect satisfaction, while also drawing more heavily on user experience design and usability principles to increase engagement. However, developing an app that is striking the balance between the clinical and research requirements on one hand, and the commercial and usability pressures on the other, will require an even closer multidisciplinary collaboration.

12.9.4. Implementing new research paradigms

As long as we develop and test apps that are distributed through the same channels as commercial apps, and insofar as our participants consider themselves to be commercial users (as opposed to patients), the researchers within the academic setting is likely to be at a disadvantage due to comparatively limited resources and different skillset within the teams.

A wealth of relevant experience and data on the use of cessation apps (and other digital health) is being accumulated outside of the academic research, although likely much less data is being collected on the actual cessation behaviour. For example, already in 2017, there have been over 350 accelerators or programmes that support emerging companies, and many individual investors in digital health, with the worth of the market for entry-level healthcare software being estimated at over \$5.4 billion (Pohl 2017). Most health apps are developed as commercial products and are financed through a sophisticated financial start-up system, including by large private venture capital funding, as well as healthcare, insurance, tech and consulting companies (Pohl 2017). Many health apps have been shown to have very little clinical input, but on the other hand are likely to have inputs from experts in IT, user experience (UX), public relations and marketing, designers, illustrators, and professional actors and voice-overs (Pohl 2017).

These teams are likely to be shaping the standards for quality and functionality of apps, including best practice on onboarding users onto apps or introducing features supporting engagement. Importantly, insights from work in the private sector are rarely made public, and if yes, are often published in outlets that are not normally used by the

research community, such as blog posts, or video-streaming from conferences. Insufficient access to the industry data and insights is likely stifling the progress in academic research, and possibly also making it less timely and relevant given the dynamic app ecosystem.

Additionally, many of the funding grants, even if they do recognise the importance of the iterative processes, remain too rigid to accommodate the often necessary agile approach to the development and evaluation of apps, and very limited resources exist to support subsequent cycles of re-development of digital programmes. Although there is a growing recognition of the value of utilising a range of expertise and approaches (Murray et al. 2016), there are still insufficient processes and support in place to facilitate efficient multidisciplinary collaborations, including on app development. The situation is further hampered by the challenges to publishing multidisciplinary research, and little recognition of the resource-consuming non-academic work that is required to get an app launched in the first place, and then maintained (Blandford et al. 2018).

Developing research frameworks, processes and tools, to support harnessing the data and the wealth of expertise in digital health accumulated within and outside of the academia to develop and evaluate apps could help advance the field of cessation apps.

12.10. General conclusion

Given the growing pressures on healthcare systems worldwide and the limited availability of smoking cessation support, digital intervention could play an increasingly important role (Pulverman and Yellowlees 2014). However, the interventions evaluated as part of this PhD thesis have not shown an effect. Furthermore, the promise of the wide reach and impact of smartphone-based stop smoking interventions has not materialised yet, possibly curtailed by the challenges to develop and evaluate such programmes.

This thesis identified possible areas for improvement of cessation apps. It also contributes to our understanding of the challenges involved in the development and evaluation of such apps, and offers possible directions for further research. However, while my findings suggest that smokers can articulate a number of desired features in

apps supporting cessation, addressing both the users' and researchers' needs within one app, as well as making such programmes appealing, engaging, and effective, will likely require further intensive and systematic research, and possibly also a shift in the current research paradigms and processes. The field would benefit from developing and implementing frameworks and processes to enable efficient integration of academic and non-academic expertise to efficiently develop and test new interventions and to identify novel channels to implement them.

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Appendices

Appendix for Chapter 3

Appendix 3.1. Results of the behavioural analysis informed by the Behaviour Change Wheel Guide (Michie et al., 2014) and a list of the selected Behaviour Change Techniques (BCTs) to be implemented in the NRT2Quit app.

What needs to change (behaviour influences) (Stage 1, Steps 1-4)				Relevant ⁷ Intervention Functions for app intervention (Stage 2, Step 5)	BCT identified for the final NRT2Quit app (with examples of their application in NRT2Quit) (Stage 3, Step 7)
		The relevance of domain for NRT use (distinguishing between compliance and persistence) ⁸			
COM-B	TDF	Compliance to OTC NRT use (at initiation)	Persistence in NRT use (for at least 8 weeks)		
PHYS-C	Physical skills	<p>[probably low at the start]</p> <ul style="list-style-type: none"> • Taking the selected NRT according to guidelines, i.e. correct: gum chewing, spray and patch application • Sustain any side effects • Modification of NRT use to minimise side effects 	<p>[uncertain if improved with time]</p> <ul style="list-style-type: none"> • Become used to side effects/not experiencing any • Use of any newly purchased NRT correctly 	<p>Ideally training but not feasible through an app; except indirectly through Instructions, i.e. Education</p>	<ul style="list-style-type: none"> • Instruction on how to perform the behaviour (detailed instructions on how to use each NRT) • Behaviour rehearsal (limited via the app: encourage practising techniques for correct use of each NRT, especially at the start) • Behavioural experiments (limited via the app: encourage trying out different patterns of NRT use, and to persist with it for the first few days before deciding to stop taking it)
Psych- C	Knowledge	<p>[probably low at the start]</p> <ul style="list-style-type: none"> • Have correct knowledge of what NRT is, types, its role, and how to use it (e.g. dose, frequency, techniques, length) • Know about side-effects and how to minimise them 	<p>[uncertain if improved with time]</p> <ul style="list-style-type: none"> • Awareness of the importance of continued NRT use (e.g. duration) • Awareness of tempering, if relevant 	<p>Education</p>	<ul style="list-style-type: none"> • Information about health consequences (Inform smokers about the consequences of using NRT and of its discontinuation) • Information about social and environmental consequences (provide information on how else smokers will benefit from using NRT – e.g. easier quit attempt, saving money in the long-term) • Information about antecedents (clarify the origin of urges and side effects)

⁷ Based on APEASE criteria: affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects/safety, and equity (Michie et al., 2014. [109])

⁸ Based on a distinction made by Cramer et al., (2008)

What needs to change (behaviour influences) (Stage 1, Steps 1-4)				Relevant ⁷ Intervention Functions for app intervention (Stage 2, Step 5)	BCT identified for the final NRT2Quit app (with examples of their application in NRT2Quit) (Stage 3, Step 7)
		The relevance of domain for NRT use (distinguishing between compliance and persistence) ⁸			
COM-B	TDF	Compliance to OTC NRT use (at initiation)	Persistence in NRT use (for at least 8 weeks)		
					<ul style="list-style-type: none"> Information about emotional consequences (explain how using NRT could improve withdrawals symptoms and cravings)
	Memory, attention and decision processes	<p>[probably need development]</p> <ul style="list-style-type: none"> Remember to: <ul style="list-style-type: none"> (a) carry or buy NRT; (b) to use enough Decide to use regardless of competing alternatives or other experiences (e.g. side effects, having smoked) 	<p>[probably needs support]</p> <ul style="list-style-type: none"> Remember to carry/buy NRT Remember to use enough of NRT at later quit stages Decide to continue using NRT despite lapsing, or being abstinent, or not experiencing cravings/urges 	Environment restructuring	<ul style="list-style-type: none"> Prompts/cues (reminders about the app together with reminders to take NRT) Restructuring the physical environment (advise on carrying a supply of NRT with them, or keeping some in the car or at work) Habit formation (provide encouragement and tips on how to make NRT taking into a habit, e.g. take it at specific times and places during the day)
	Behavioural regulation	<ul style="list-style-type: none"> Keep track of NRT use across the day / quit attempt Adjust NRT use as needed Create action plans to facilitate the use of NRT 	<ul style="list-style-type: none"> Continue to monitor the amount of NRT used and available 	Enablement	<ul style="list-style-type: none"> Self-monitoring of behaviour (provide tools to monitor NRT use and smoking status and encourage their use) Feedback on behaviour (give feedback on NRT use reported) Discrepancy btw current behaviour and goal (compare reported vs. recommended NRT levels)
Reflect-M	Professional/social role and identity	<ul style="list-style-type: none"> Professional identity not relevant. Developing identity of someone who quits with NRT (thus increasing chances of quitting) 	<ul style="list-style-type: none"> Sustaining an identity of someone who quits with the correct use of NRT 	Education Persuasion	<ul style="list-style-type: none"> Identity associated with changed behaviour (foster an identity of a 'non-smoker who is doing all their best to quit smoking and uses NRT according to recommendations to increase chances of success) Verbal persuasion about capability (use motivational and positive communications when encouraging NRT use)
	Beliefs about capabilities	<ul style="list-style-type: none"> Accept and believe that one can learn how to use NRT correctly to benefit; Believe that one can manage any side effects 	<ul style="list-style-type: none"> Experience regular NRT use as effortless or manageable 	Education Persuasion	<ul style="list-style-type: none"> Credible source (emphasise the expertise of the team behind the app) Verbal persuasion about capability (use motivational and positive communications when encouraging NRT use)

What needs to change (behaviour influences) (Stage 1, Steps 1-4)				Relevant ⁷ Intervention Functions for app intervention (Stage 2, Step 5)	BCT identified for the final NRT2Quit app (with examples of their application in NRT2Quit) (Stage 3, Step 7)
		The relevance of domain for NRT use (distinguishing between compliance and persistence) ⁸			
COM-B	TDF	Compliance to OTC NRT use (at initiation)	Persistence in NRT use (for at least 8 weeks)		
					<ul style="list-style-type: none"> Information about health consequences (Inform smokers about the consequences of using NRT and of its discontinuation)
	Optimism	<p>[likely to be unrealistic at the start – high optimism about effectiveness]</p> <ul style="list-style-type: none"> Hold realistic expectations about the benefits of NRT use Believe that side effects are short-lived and not harmful Believe that they could quit smoking successfully the help of NRT 	<ul style="list-style-type: none"> Hold realistic and supportive expectations about NRT use at long-term Be optimistic about succeeding at quitting 	Education Persuasion	<ul style="list-style-type: none"> Information about health consequences (Inform smokers about the consequences of using NRT and of its discontinuation) Information about social and environmental consequences (provide information on how else smokers will benefit from using NRT – e.g. easier quit attempt, saving money in the long-term) Information about emotional consequences (explain how using NRT could improve withdrawals symptoms and cravings, and thus how one feels) Re-attribution (explain the source of not feeling well – e.g. due to quitting and withdrawals, not NRT use) Credible source (emphasise the expertise of the team behind the app) Verbal persuasion about capability (use motivational and positive communications when encouraging NRT use)
	Beliefs about consequences	<ul style="list-style-type: none"> [likely to Be aware of the consequences for NRT use and non-adherence (e.g. in terms of chances of quitting; lower cravings and withdrawals) Be aware of any side effects being temporary and not harmful 	<ul style="list-style-type: none"> Hold correct beliefs about benefits and harms of extended NRT use (i.e. safety of long-term use of nicotine) Awareness of possible consequences of termination of NRT use (e.g. increased withdrawal symptoms or cravings) 	Education Persuasion	<ul style="list-style-type: none"> Information about health consequences (Inform smokers about the consequences of using NRT and of its discontinuation) Information about social and environmental consequences (provide information on how else smokers will benefit from using NRT – e.g. easier quit attempt, saving money in the long-term) Information about emotional consequences (explain how using NRT could improve withdrawals symptoms and cravings, and thus how one feels) Verbal persuasion about capability (use motivational and positive communications when encouraging NRT use)

What needs to change (behaviour influences) (Stage 1, Steps 1-4)				Relevant ⁷ Intervention Functions for app intervention (Stage 2, Step 5)	BCT identified for the final NRT2Quit app (with examples of their application in NRT2Quit) (Stage 3, Step 7)
		The relevance of domain for NRT use (distinguishing between compliance and persistence) ⁸			
COM-B	TDF	Compliance to OTC NRT use (at initiation)	Persistence in NRT use (for at least 8 weeks)		
Reflec-M (cont.)	Intentions	[Probably high - initially those buying OTC NRT have the intention to use it as part of a quit attempt]	[likely to decrease with time] <ul style="list-style-type: none"> • Intent to continue using NRT regardless of changes to smoking status (relapse or abstinence) • Possibly related to intention to quit successfully 	Education Persuasion Incentivisation	<ul style="list-style-type: none"> • Information about health consequences (Inform smokers about the consequences of using NRT and of its discontinuation) • Information about social and environmental consequences (provide information on how else smokers will benefit from using NRT – e.g. easier quit attempt, saving money in the long-term) • Information about emotional consequences (explain how using NRT could improve withdrawals symptoms and cravings, and thus how one feels) • Behavioural contract (ask the user to ‘sign’ a pledge of taking NRT while quitting)
	Goals	<ul style="list-style-type: none"> • Formulation of specific goals may be needed • Have goals for NRT use that are in accordance with best clinical practice • Have goals to become a non-smoker 	<ul style="list-style-type: none"> • Have goals to continue using NRT according to recommendations (8- weeks) 	Education Persuasion Incentivisation	<ul style="list-style-type: none"> • Goal setting (outcome) (set an outcome for not smoking at all after the quit date) • Goal setting (behaviour) (set a goal of using NRT every day according to recommendations) • Verbal persuasion about capability (use motivational and positive communications when encouraging NRT use) • Action planning (assist with the creation of action plans supporting NRT taking)
Autom-M	Reinforcement	[Normally not part of NRT use]; <ul style="list-style-type: none"> • Potentially receive incentives for taking NRT according to recommendations 	[may not be applicable beyond offering praise] <ul style="list-style-type: none"> • Find NRT use as rewarding • Develop a habit or routine of taking NRT according to recommendations 	Incentivisation	<ul style="list-style-type: none"> • Self-monitoring of behaviour (encourage monitoring of NRT use) • Self-monitoring of outcomes of behaviour (encourage monitoring of smoking status) • Feedback on behaviour (provide feedback on NRT use reported by users) • Feedback on outcomes of behaviour (offer feedback on smoking status reported by users) • Adding objects to the environment (provide tools through NRT2Quit to monitor NRT use and smoking status) • Discrepancy btw current behaviour and goal (compare reported vs. recommended NRT levels)

What needs to change (behaviour influences) (Stage 1, Steps 1-4)				Relevant ⁷ Intervention Functions for app intervention (Stage 2, Step 5)	BCT identified for the final NRT2Quit app (with examples of their application in NRT2Quit) (Stage 3, Step 7)
		The relevance of domain for NRT use (distinguishing between compliance and persistence) ⁸			
COM-B	TDF	Compliance to OTC NRT use (at initiation)	Persistence in NRT use (for at least 8 weeks)		
					<ul style="list-style-type: none"> • Social reward (offer praise for NRT use)
	Emotion	<ul style="list-style-type: none"> • Experience positive emotions concerning initiation of NRT use • Experience few negative emotions in relation to side effects 	<ul style="list-style-type: none"> • Continue to experience positive emotions towards NRT use • May be complicated by any emotions related to the quit attempt (its success / failure) 	Persuasion Incentivisation	<ul style="list-style-type: none"> • Social reward (offer praise for NRT use) • Verbal persuasion about capability (use motivational and positive communications when encouraging NRT use)
Phys-O	Environmental context and resources	<ul style="list-style-type: none"> • [Access not a relevant concern among smokers who already purchase OTC NRT (i.e. in the NRT2Quit trial)] • Purchase or receive at least one NRT product • Obtaining NRT type (e.g. gum, patch) that meets the needs, and results in acceptable experience and few side effects 	[unknown – access to NRT could change with time] <ul style="list-style-type: none"> • Have sufficient supply of NRT for long-term use • Have means to purchase more NRT (including funds and access to a point of sale of NRT, including stop smoking services, or GP) • Have means and opportunities to obtain a different NRT type 	No possibility to directly address it through an app Possibly indirectly: Education (about opportunities in environment)	<ul style="list-style-type: none"> • Restructuring the physical environment (advise on purchasing enough of NRT to last long-term)
Social-O	Social influences	<ul style="list-style-type: none"> • Have social network (including health providers) that approves and is supportive of NRT use • Know of other smokers who have positive views on NRT • Support with reminders to use NRT 	<ul style="list-style-type: none"> • Have social network (including health providers) that approves or supports continued NRT use • Offers assistance with reminders to use NRT, and/or obtaining further or different NRT products 	Difficult to directly address it through an app, unless via a ‘buddy system’ or reliance on social network, etc Possibly indirectly: Education (about opportunities in environment)	<ul style="list-style-type: none"> • Social support (practical) (advise how others in the environment could support NRT taking, e.g. relatives or health providers: GP or pharmacist)


Appendix for Chapter 3

Appendix 3.2. Instruction sheet used during the usability session of NRT2Quit.

NRT2Quit App – User Testing Session

Background to Part 1:

Scenario: Imagine that you are trying to quit smoking and have bought nicotine patches (below). You are ready to quit smoking cigarettes today. You have found a leaflet about the study and want to register.




The image shows a box of Nicotinel 21mg / 24 Hour Patch. The box is blue and white with the brand name 'Nicotinel' in large blue letters. Below it, it says '21mg / 24 Hour Patch'. There is also a small yellow box on the right side of the main box that says 'Step 1 Patch'.

Tasks:

- 1) Register into the study
- 2) Enter information about your patch
- 3) Report taking patch 4 hours after waking up
- 4) Find information on how you should use your patch.
- 5) You're not sure what the dashboard does – you're trying to find information on it.
- 6) Find information on side effects from your patch.
- 7) Find information on how to manage some of the cravings you're experiencing.
- 8) You changed jobs, and now you're waking up at 2pm, so the dashboard doesn't work well any more.

Background to Part 2:

Scenario: Imagine that after few days you decided to use another NRT product – a nasal spray:



The image shows a box of nicorette nasal spray. The box is blue and white with the brand name 'nicorette' in large blue letters. Below it, it says 'nasal spray nicotine'. There is also a small blue box on the left side of the main box that says 'nasal spray'. At the bottom left, it says '10 ml nicotine'. At the bottom right, it says 'helps overcome your urge to smoke'.

Tasks:

- 1) Add your second NRT.
- 2) Report taking your NRT (patch from 4 hours after waking, and now also you applied nasal spray 8 times since the start of the day).
- 3) You want to know if you're using enough of NRT.
- 4) Find information about side effects of this new nasal spray.
- 5) You want to contact the research team – try finding contact details.
- 6) You want to change your Quit Date to a future date.
- 7) You have seen a diary popping out on your dashboard (for now it's in PROFILE>'How are you doing?'). What do you do?

Appendix for Chapter 3

Appendix 3.3. Functionality and behaviour change techniques (BCTs) implemented in the intervention and control versions of NRT2Quit.

Feature and content supporting NRT use	Intervention		Control	
	BCT Smoking Taxonomy ⁹	BCTs V1 Taxonomy ¹⁰	BCT Smoking Taxonomy	BCTs V1 Taxonomy
Registration and Setting of the Quit Date				
Setting up of the quit date	BS4	1.1, 1.3	BS4	1.1, 1.3
Reassuring feedback on NRT purchased	BM7, RC10	2.2, 3.1, 10.4, 15.1	-	-
Making a pledge for not-smoking and NRT use	BM6	1.8, 13.5,	-	-
Features to update the quit date and NRT use	BS4, RC4	1.1, 1.3	BS4	1.1, 1.3
Support with NRT Use				
Brief advice on NRT use	A1	4.1	-	-
Comprehensive advice on NRT and its use	A1, BM5, RC6	4.1, 4.2, 4.3, 4.4, 5.1, 5.3, 5.6, 6.2, 7.1, 8.1, 8.3, 12.1	-	-
Monitoring and feedback of NRT use (Dashboard, daily diary and additional tailored sessions)	A4, BM7, BS6, RD1, R14	1.6, 2.2, 2.3, 3.1, 15.1	-	-
General cessation advice and other information	-			
Monitoring of smoking status (daily diary)	BS6, R14	2.2., 2.3, 2.4, 2.7, 15.1,	-	-
Feedback on smoking status	BM7	1.6, 10.4, 15.1	-	-
Pre- and post-quit daily tips	A2, BM1, BM2, BM8 BM10, BS2, BS3, BS7, BS8, BS10, BS11, RC10,	5.1, 5.3, 5.5, 5.6, 6.2, 7.1, 8.2, 9.1, 11.1, 11.2, 12.1, 12.2, 12.3, 12.4, 13.5, 15.1,	-	
Generic advice on quitting	BS2, BM8, BM1, BM2, BM5, RC6	4.1, 4.2, 4.3, 5.1, 5.3, 5.6, 6.2, 7.1, 8.2, 9.1, 11.1, 11.2, 12.1, 12.2, 12.3, 12.4, 13.5, 15.1	BS2*, BM1*, BM2*, BM5*, RC6*	5.1*, 6.2*, 10.4*, 11.1*
Information on stop smoking medications	A1, RD2	5.1, 5.6, 11.1	-	
Information about the app, study and the team	RC4	9.1	A1*	9.1*
Calendar / Counting days to and from the quit date				
Outline of the quit plan and reminders to obtain NRT	BS3	12.5	-	-
Display the date of the follow-up	N/A	N/A	N/A	N/A
Displaying days to and since the quit date	BS3	12.5	BS3	12.5
Daily reminders to engage with the app and advice	BS6	7.1	-	-

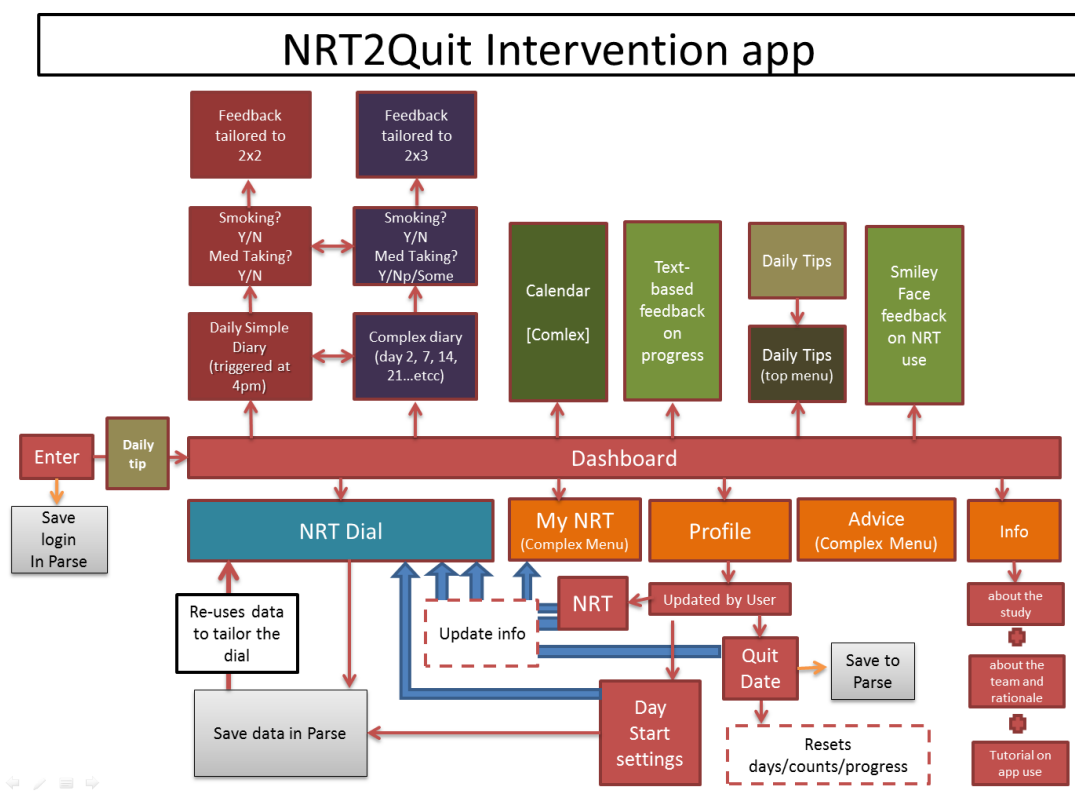
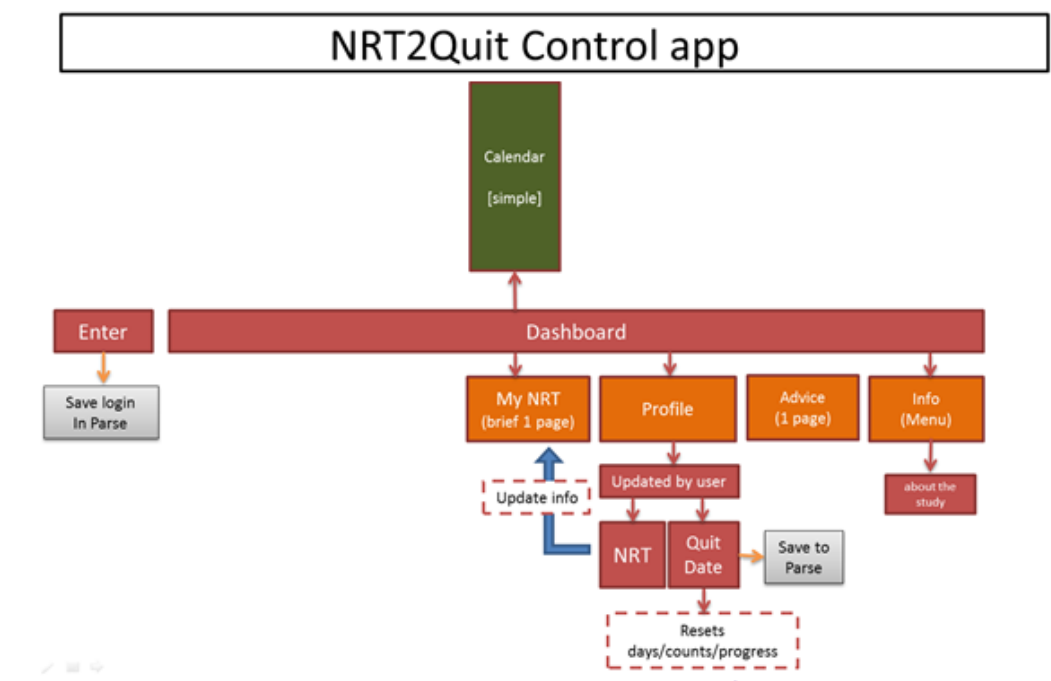
*=brief and simplified

⁹ Michie, S., et al. (2011). Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addictive behaviors*, 36(4), 315-319.

¹⁰ Michie, S., et al., (2013). The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of behavioral medicine*, 46(1), 81-95.

Appendix for Chapter 3

Appendix 3.4. Visual summary of the differences in the architecture and functionality of NRT Control vs. Intervention apps.



Appendix for Chapter 3

Appendix 3.5. Selected screenshots of the intervention version of NRT2Quit

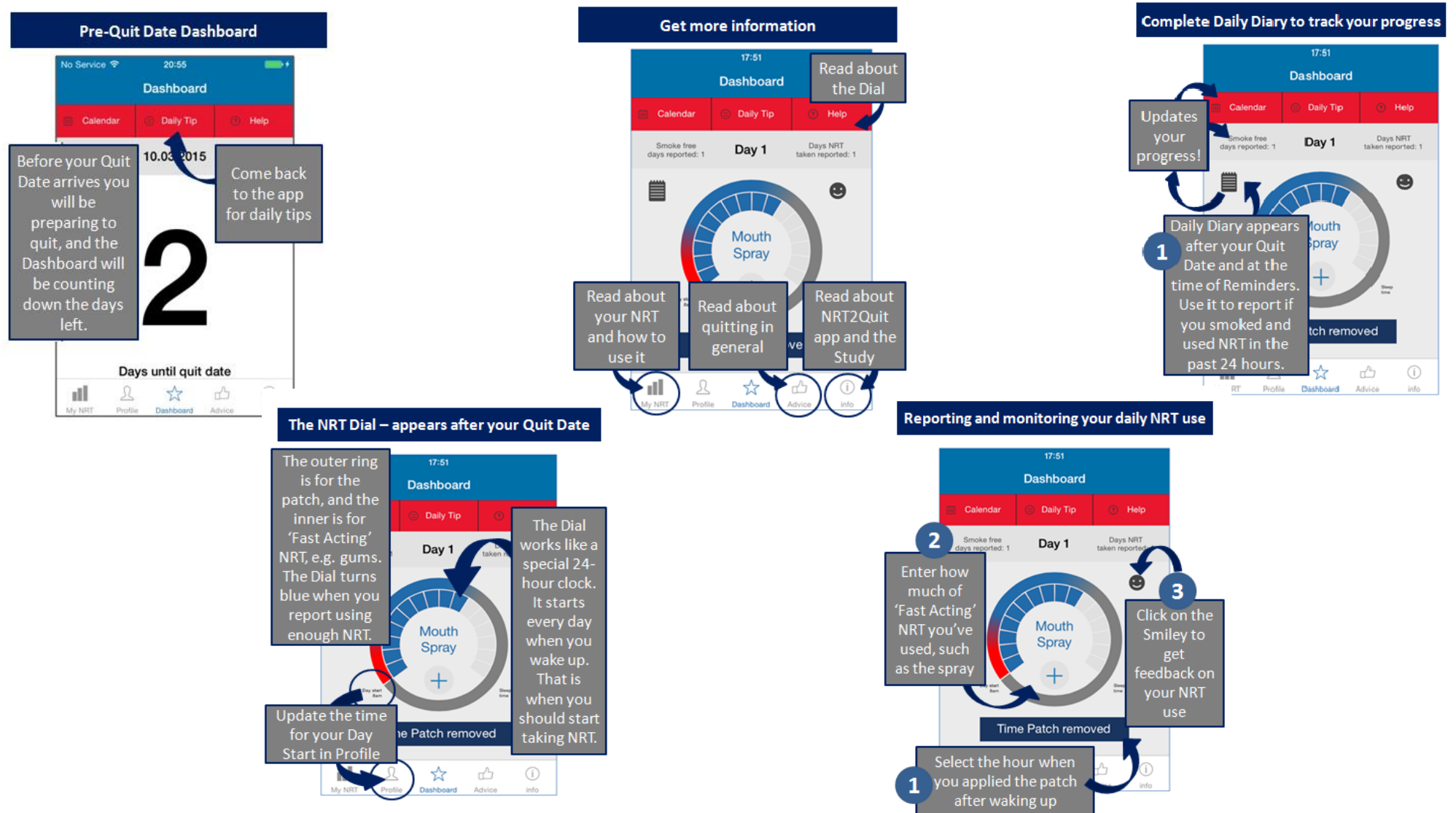
Personalisation: Setting of Reminders and Quit Date, NRT selection

Comprehensive advice on NRT and quitting

Calendar of quit progress & daily tips

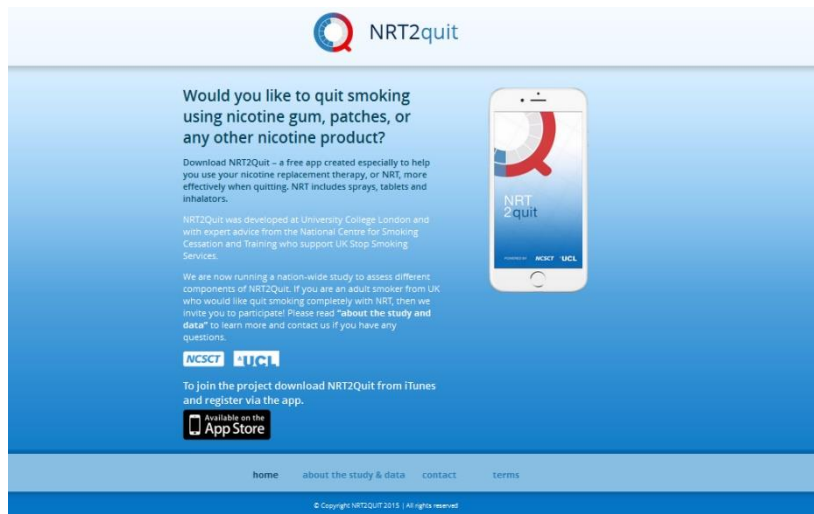
Appendix for Chapter 3

Appendix 3.6. Tutorials about the functionality of the intervention version of NRT2Quit, including the NRT Dial on the app dashboard.

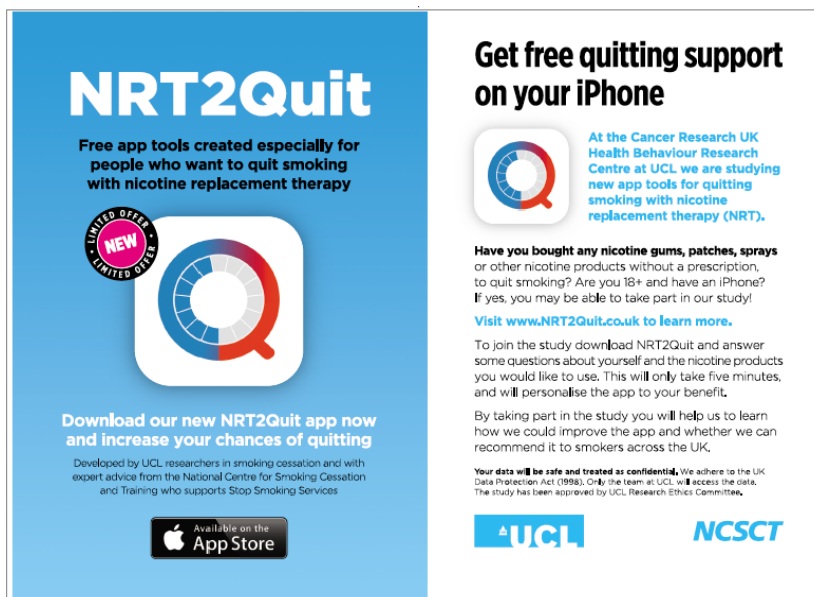


Appendix for Chapter 4

Appendix 4.1. Recruitment materials and the project website for the NRT2Quit trial



The website



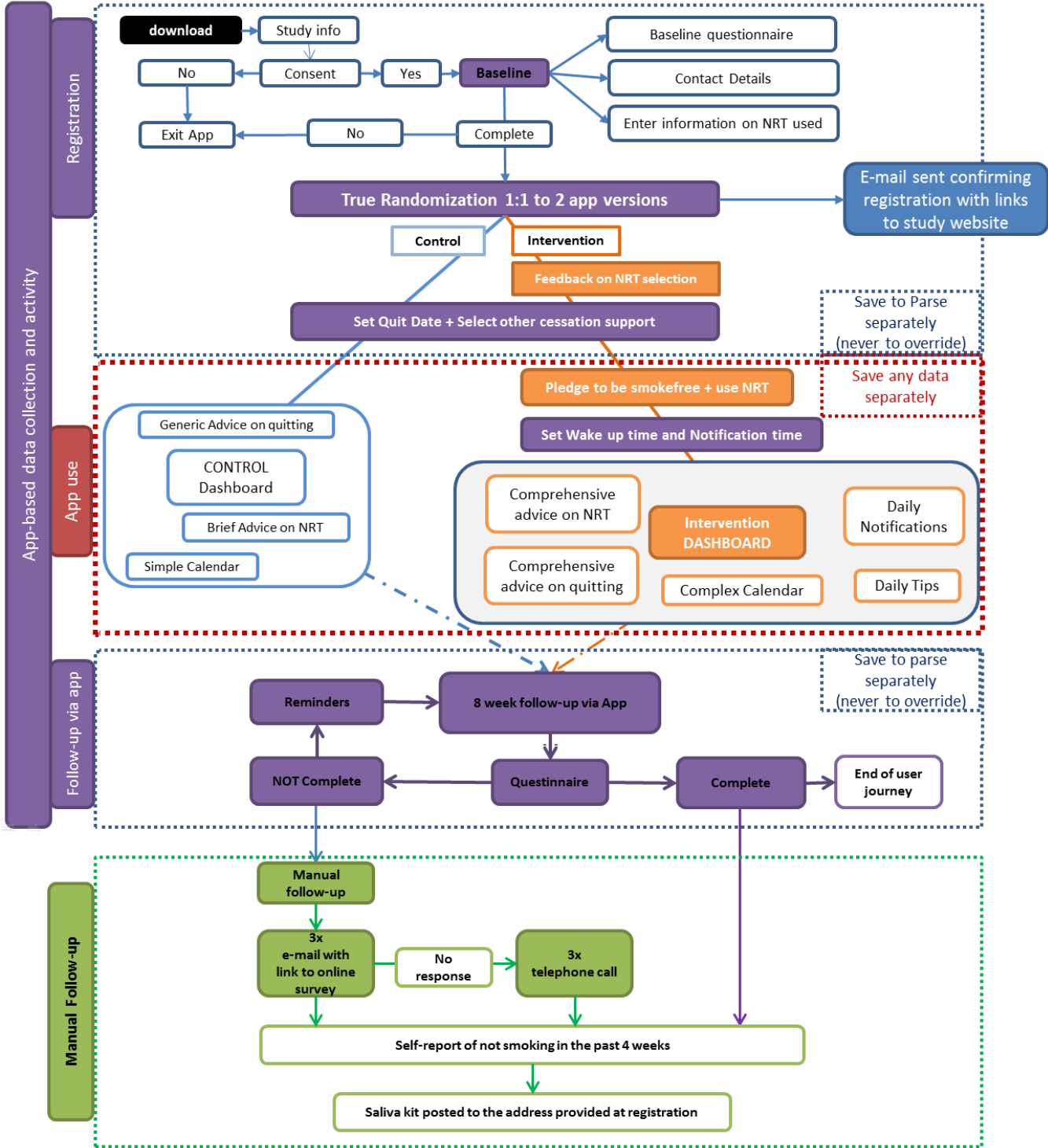
A 2-sided leaflet



On the till advertisement

Appendix for Chapter 4

Appendix 4.2. The flow of trial participants through the intervention and control versions of the app and trial procedures beyond the app.



Appendix for Chapter 4

Appendix 4.3. Procedure and measurement schedule in the NRT2Quit trial.

Procedure and Assessment	Always accessible on the project website	S1: Initial App visit	During the trial	S2: 8-week follow-up
Procedure				
Display complete Information Sheet	X	X		
Display End User Licence Agreement ¹¹	X	X		
Obtain consent		X		
Obtain contact details		X		
Email confirmation of registration		X		
Randomisation		X		
Email reminders				X
Telephone reminders				X
Saliva sample collection				X
Assessment				
Demographic information		X		
Use of NRT		X		X
Smoking history		X		
Dependence levels (HSI)		X		
Smoking abstinence				X
Urges to smoke		X		
Prior use of cessation medication		X		
Prior use of cessation support		X		
Use of other cessation support post-baseline		X		X
Frequency of app use			X	
Satisfaction with the app				X


¹¹ Also accessible through iTunes store

Appendix for Chapter 4

Appendix 4.4. The letter posted to NRT2Quit trial participants who were invited to provide saliva samples

Page 1/2

NRT2Quit App Study
Tel: 02076791258.
Email: quitsmokingapp@ucl.ac.uk
<http://www.ucl.ac.uk/hbrc/>
www.nrt2quit.co.uk



Health Behaviour Research Centre
University College London
1-19 Torrington Place
London, WC1E 6BT

Dear,

Thank you for participating in our university study of NRT2Quit app. Congratulations on having quit smoking! You may recall that you agreed to provide a saliva sample when you joined the study, if selected. Your sample will be analysed for a nicotine by-product to confirm your smoking status.

This test is very important and will let us know whether or not NRT2Quit app should be more widely available to smokers in the UK.

It is important that you complete the test whether or not it was the NRT2Quit app that helped you quit. If you have started smoking since you were in touch with us please still complete the test.

The result will not be linked to your name – it is anonymous and confidential. The sample will be destroyed after testing.

We have enclosed 2x £10 gift vouchers to thank you for your time.

What to do (illustration on the next page):

Inside the tube is a cotton wool swab, like a dental swab. Samples should be taken no earlier than 30 minutes after eating, drinking or taking medication.

- 1-2. Please take the lid off the tube and, without using your fingers, place the swab inside your mouth and under your tongue for 5 minutes
3. Do not swallow or bite hardily on it, and leave swab until it is soggy
4. Without using your fingers, return the swab directly from your mouth back into the same container
5. Replace lid firmly and make sure it is labeled "UCL"
6. If you are using any nicotine replacement therapy (e.g. patches or sprays), or electronic cigarettes, please mark "X" onto the label on the tube.
7. Place inside the bag with the sticky top and seal this bag
8. Place the bag inside the stamped addressed and envelope and post it into a normal post box

If you have any problems please phone us on 02076791258.


Many thanks.

Dr. Jamie Brown and Aleksandra Herbec, MSc
On Behalf of NRT2Quit Study Team

Appendix for Chapter 4

Appendix 4.4.(cont.) The letter posted to the NRT2Quit trial participants who were invited to provide saliva samples


Page 2/2 (the photographs present Dr Jamie Brown, used with his permission)





Health Behaviour Research Centre
University College London
1-19 Torrington Place
London, WC1E 6BT


8 simple steps for sending your saliva sample


Please collect the sample of saliva no earlier than 30 minutes after eating, drinking, or taking medications


- 


1) You can **rub your cheeks** for 30sec to stimulate saliva flow. Take the cap off to open the salivette (keeping inner and outer tubes together).
- 


2) Place the small cotton swab into the cap and then directly into the mouth **without touching** the cotton wool.
- 

3) Keep the swab under your tongue for 5 minutes. Do not swallow or bite hardily on it, and leave swab until it is soggy
- 

3) Without using your fingers, return the swab directly from your mouth back into the same container.
- 

4) Replace the lid **firmly**.
- 

5) If you are now still using any nicotine replacement therapy (e.g. nicotine gum, patches or sprays), or electronic cigarettes, please mark "X" in the box on the container. **Otherwise leave the box empty.**
- 

6) Place inside the transparent bag with the sticky top and seal this bag
- 

7) Place the bag inside the stamped addressed and envelope and post it into a normal post box

Thank you!

Appendix for Chapter 4

Appendix 4.5. Baseline questionnaires in the NRT2Quit trial.

	Question	Answer options
	Part 1	
	Do you smoke now?	<ol style="list-style-type: none"> 1. Yes, daily 2. Yes, but not daily 3. No, I quit already
	How many cigarettes do you smoke per day?	Free text
	How much (in £) do you spend on cigarettes per week?	Free text
	How soon after you wake up do you smoke your first cigarette?	<ol style="list-style-type: none"> 1. Within 5 minutes 2. 6-30 minutes 3. 31-60 minutes 4. More than 60 minutes
	How often did you experience urges to smoke in the past 24 hours?	<ol style="list-style-type: none"> 1. Not at all 2. A little of the time 3. Some of the time 4. A lot of the time 5. Almost always 6. All the time
	How strong were those urges to smoke?	<ol style="list-style-type: none"> 1. Not at all 2. 'slight' 3. 'moderate' 4. 'strong' 5. 'very strong' 6. 'extremely strong'
	When did you last make a serious attempt to quit?	<ol style="list-style-type: none"> 1. In the last 12 months 2. More than a year ago 3. Never
	Have you ever stopped smoking for more than a week?	<ol style="list-style-type: none"> 1. Yes 2. No
	Ever used any of these to try to quit smoking in the past (Select all that apply)	<ol style="list-style-type: none"> 1. Any Nicotine Replacement Therapy 2. Other Medications (e.g. Champix) 3. Stop smoking service 4. Quitline / other counselling 5. Other Apps 6. Websites 7. E-cigarettes 8. Other 9. None
	Part 2	
0	Why joined the study	<ol style="list-style-type: none"> 1. To make a serious quit attempt 2. I'm just testing the App 3. Other
	Confidence to quit this time	Scale from 1-7

1		
2	How did you learn about this study?	<ol style="list-style-type: none"> 1. Leaflet or poster in a pharmacy 2. From the pharmacist 3. Word of mouth (e.g. family, friends) 4. AppStore or Google Search 5. Other
3	Sex	Man / Woman
4	Your Age	Free text
5	Where do you live now	UK / Other
6	Employment Status	<ol style="list-style-type: none"> 1. Employed (Manual job, e.g. mechanic) 2. Employed (Non-manual job, e.g. administrator) 3. Employed (Other) 4. Self-employed 5. Currently unemployed/retired 6. Full-time student 7. Other
1	Do you have a post 16 yrs qualification? (e.g. A-levels, a degree)	Yes/No
Part 3		
	Name & Surname / e-mail Address / Daytime / Evening Telephone	Enter free text
Part 4 (about NRT used)		
	Question	Answer options
	Select Nicotine Replacement Therapy (NRT) that you will use as part of this quit	
	Patch	Yes / No
b	(if applicable) Patch Duration	16hr / 24hr
c	(if applicable) Patch Strength	5-10mg / 11-20mg / 21mg+
	Other NRT	Yes / No
b	(if applicable) NRT Type	Gum / Microtabs / Lozenge / Strips Nasal Spray / Mouth Spray / Inhalator
c	(for Gum/Lozenges) NRT Strength	1-2mg / 4mg
	Why have you decided to use this NRT (Select all that apply)	<ol style="list-style-type: none"> 1. I used it before 2. I wanted to try something new 3. Recommendations from a pharmacist 1. Recommendation from my doctor or GP 2. Recommendation from a stop smoking advisor 3. Recommendation from friends, colleagues or family 4. Advertisement 5. Other

Appendix for Chapter 4

Appendix 4.6. The follow-up questionnaire in the NRT2Quit trial.

The follow-up questionnaire (FU) is administered via the app in the first instance. Participants who do not respond are followed up via e-mail and directed to an online version of the questionnaire hosted on an internal survey engine Opinion available to UCL researchers. Those failing to respond were contacted over the telephone and asked to answer FUQ1

UQ #	Question	Answers
	Did you smoke at all in the past 4 weeks?	Yes / No
2	Which nicotine replacement products did you use at any point in the past 8 weeks (Please select all that apply)	<ol style="list-style-type: none"> 1. None 2. Patch 3. Gum 4. Inhaler 5. Nasal spray 6. Mouth spray 7. Microtab 8. Lozenge 9. Oral strips
3	Which nicotine replacement product are you still using now? (Please select all that apply)	<ol style="list-style-type: none"> 1. None 2. Patch 3. Gum 4. Inhaler 5. Nasal spray 6. Mouth spray 7. Microtab 8. Lozenge 9. Oral strips
4	For how many weeks from the quit date did you use any/all of your NRT in total?	<ol style="list-style-type: none"> 1. Less than 1 week 2. 1–2 weeks 3. 3–4 weeks 4. 5–6 weeks 5. 7-8 weeks 6. More than 8 weeks
5	On how many days in those weeks did you use NRT?	<ol style="list-style-type: none"> 1. 1-2 days per week 2. 3-4 days per week 3. 5-6 days per week 4. Every day
6	Did you use any other support in addition to NRT?	<ol style="list-style-type: none"> 1. None 2. Other stop smoking medication (e.g. Champix) 3. Attended a Stop Smoking Sevices 4. Phoned a Smoking Helpline or attended other counselling 5. Books, booklets or websites 6. Used another smartphone App 7. Used Electronic cigarette 1. Other (please specify)

7	If you used other support, how many weeks did you use it for?	<ol style="list-style-type: none"> 1. Less than 1 week 2. 1–2 weeks 3. 2–4 weeks 4. 4–8 weeks 5. More than 8 weeks
8	Did you find this app helpful with quitting in general?	<p>Yes / No</p> <p>OR scale? (e.g. 1-5)</p>
9	Did you find this app helpful with taking NRT?	<p>Yes / No</p> <p>OR scale? (e.g. 1-5)</p>
10	Did you find this app personally relevant?	<p>Yes / No</p> <p>OR scale? (e.g. 1-5)</p>
QB2	Would you recommend this app to others?	<ol style="list-style-type: none"> 1. Yes 2. No
	Which feature of the app did you find most helpful?	<ol style="list-style-type: none"> 1. Setting up of the quit date 2. The Dashboard and NRT Dial 3. Advice on NRT 4. General advice on quitting smoking 5. Daily Tips 6. Calendar 7. Reminders
QB3	Please provide a star rating for this app.	1-5 rating

Appendix for Chapter 5 and Chapter 6

Appendix 5.1. Questions administered during the interview on NRT use and NRT2Quit.

1. **What nicotine replacement therapy (NRT) product have you used in the past 5 years?**
(please place a ' X ' in the appropriate box)

NRT type	I did not use it	Yes, I used it	
		Used on its own	Used with another NRT product
Patch			
Fast Acting NRT:		Used on its own	Used with the patch
Gum			
Lozenges / minilozenges / Tablets			
Microtabs			
Strips / films			
Mouth Spray			
Nasal Spray			
Inhalator			

2. **How satisfied were you in general with the support you had with using your NRT in the past 5 years?**

1=Not at all satisfied / Rather unsatisfied / Neither satisfied nor unsatisfied / Rather satisfied / 5= Completely satisfied

3. **How would you rate your knowledge of:** (None =1, Satisfactory = 3 Very good = 5)
- what this NRT was?
 - how much NRT you were supposed to be taking, and when?
 - the correct technique or manner in which this NRT should be taken?
4. **Below is a list of potential sources for information on NRT and its use. Please mark the sources that you made use of:**
- Patient Leaflet
 - Advertisements
 - Stop Smoking Services or advisors
 - Quitline
 - GPs
 - Other health providers
 - Pharmacists
 - NHS Websites
 - Other websites
 - Discussion Forums
 - Smartphone Apps
 - Booklets
 - Family, Friends, Colleagues
 - Other

Appendix 5.1 (cont). Questions administered during the interview on NRT use and NRT2Quit.

5. **How many cigarettes do you smoke per day (if you quit already – how many cigarettes did you smoke per day in the past)?**
6. **Gender:** Female / Male
7. **What is your current employment status**
 - (1) Employed (Manual setting, e.g. carpenter)
 - (2) Employed (Non-manual setting, e.g. teacher)
 - (3) Currently unemployed/retired
 - (4) Full-time student
 - (5) Other
8. **Do you have a post 16 yrs qualification? (e.g. A-levels, a degree)** Yes / No
9. **Ever used any of these to try to quit smoking in the past? (select all that apply)**
 - (1) Quitline / other counseling
 - (2) Stop smoking apps
 - (3) Websites
 - (4) E-cigarettes
 - (5) Other
10. **When did you make last attempt to quit smoking?** Never / Last year / Longer than a year ago
11. **Ever stopped smoking for more than a week?** Yes / No

Appendix 5.2. The interview schedule for data collection on NRT use and NRT2Quit

Semi-structured interviews as part of new digital intervention development

The interview will use open-ended questions, flexibly administered, with participants guiding the interview process, and with the researcher using probes to stimulate the discussion further, e.g. “please, could you tell me a bit more about this?” or “why do you think this would be helpful?”, etc.

Depending on the study or participants, ‘stop smoking medications’ will be replaced to focus on specific medications, e.g. one of the over the counter nicotine replacement products.

1. Opening the Interview

- a) Introduce the interviewer and thank participant for participation
- b) Remind participants of the purpose of the interview; expected duration, audio-recording, confidentiality, and voluntary nature of the interview, as well their right not to discuss any topics.

2. Interview topics and example questions

(main questions and example prompts)

Part 1 – experiences and views on quitting and use of stop smoking medications

Experiences with and views on quitting and smoking cessation medications

- a) What are your experiences with quitting smoking to date?
 - What kind of support have you used to quit smoking, if any?
- b) What are your experiences with using stop smoking medications?
 - Tell me about the medications you’re using now?
 - What difficulties have you experienced when using medications?
 - What has motivated you to use any / these medications while quitting?
 - What opportunities did you have to use medications?
- c) Did you get any help with how to use your medications?
 - Where did you look for information? Did you find it helpful? Why? Why not?
 - Was there anything that you found particularly helpful? Why?
 - what did you find useful/unseful about leaflets/printed information or online?
- d) What help with medication taking would you like to have received/ to receive now or next time?
 - What information? / What support? From where? From whom?
 - What skills?
 - What would it take for you to use the medications according to guidelines?
 - What would make you confident / motivated to use medications? / to continue using your medications?
 - What would need to change about yourself, your views or knowledge?
 - What would need to change in your environment, or life in general?

Experiences and views on digital programmes for smoking cessation

- a) What are your experiences and views on using computer, online, or mobile programmes for quitting smoking?
 - What would you expect from such a programme?
 - How do you think such a programme could help you with medication taking?
 - What would you expect from an app that aims to help users with quitting with NRT?

Appendix 5.1. (cont.) The interview schedule for data collection on NRT use and NRT2Quit

Part 2 –Think aloud procedure about NRT2Quit app

Background to the think aloud procedure

“we are developing a novel smartphone app for smokers who want to use stop smoking medications/nicotine replacement therapy to quit smoking. In the first instance the app would be available to people who want to buy nicotine replacement therapy without a prescription. I would like to get your views on the app in general, and also on the specific features and tools that we plan to include. [explanation of the App] Please use it, and share any thoughts or comments out loud.

Example Prompts and supportive questions:

- a) What are your initial thoughts about it in general / layout / looks?
- b) What do you like/dislike about it?
- c) What features do you think are most/least useful?
- d) What do you think about these features / the way we present the advice / the colour scheme used?
- e) How do you feel when using the app?
- f) What other information or tools would you like the app to offer?
- g) Is there anything that you think should be absolutely changed / explained better / presented better?

Task testing; *“I’d like that you imagine you are using the app as part of a quit attempt and you have bought your NRT. There are few things you can do with the app. I’d like that you try completing some of these tasks.”*

Example tasks:

- a) Try to register – how could this be made clearer?
- b) Try to add information about your medications – what other questions should we ask?
- c) Try to find out how to use your NRT correctly
- d) Try to use the calendar to do X/Y/X.
- e) Try to find information about X/Y/Z
- f) Try to set a reminder
- g) Try to find out about the study we are running

Closing the interview

- a) Ask about any additional issues that participant would like to add or emphasize
- b) Debrief and thank the participants
- c) Answer any questions about current research
- d) Offer information about available smoking cessation support to participants still wanting to quit smoking.
- e) Set prototype testing sessions, if relevant, and inform about any other research possibilities
- f) Offer participant the gift voucher

Appendix for Chapter 7

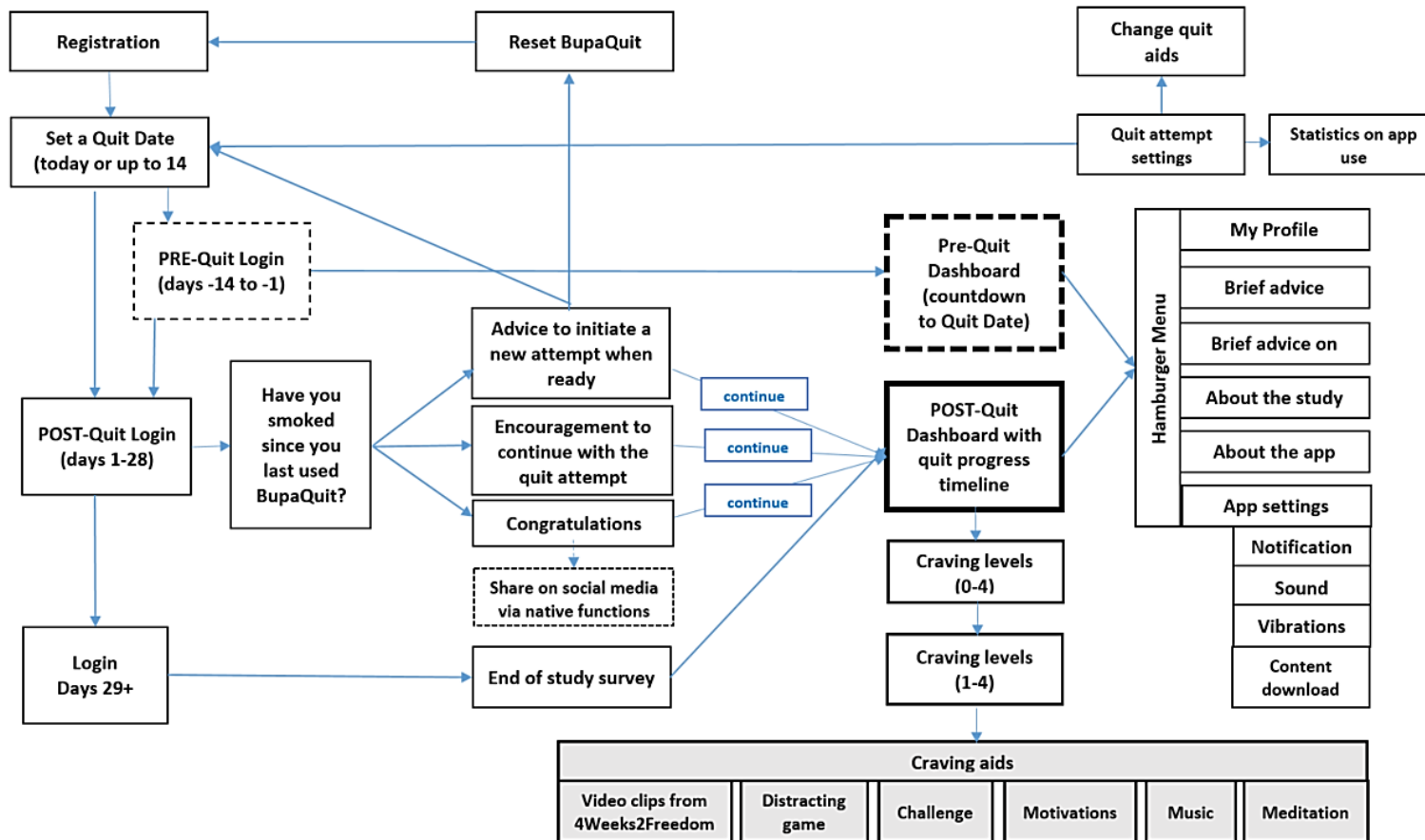
Appendix 7.1. Screenshots of SF28 (left) and the features in the BupaQuit intervention and control app versions.



Appendix for Chapter 7

Appendix 7.2. User Journey through the BupaQuit app for returning users.

(Note: the cravings aids marked in grey were only available for the intervention users, and boxes marked in dashed lines were optional).



Appendix for Chapter 7

Appendix 7.3. Comparison of BupaQuit Intervention, Control, and SF28 apps on functionality and Behaviour Change Techniques (BCTs).

Feature	BCTs from V1 Taxonomy ¹²	BCTs from smoking taxonomy ¹³	SF28	Bupa Quit	
				Inter v	Cont r
Registration and Setting of the Quit Date					
Information about BupaQuit Challenge and app	N/A Information about natural consequences (5.1-5.3)	RC4 (explain expectations regarding treatment programme)	Yes	Yes	Yes
Advice on cessation medication	Pharmacological support (11.1)	A1 (advice on stop-smoking medication)	Yes	Yes	Yes
Identifying / recording the main motivation to quit	Information about social and environmental consequences (5.3)	BM9 (reasons for wanting and not wanting to stop)	-	Yes	Yes
Setting up of the quit date	Goal setting (behaviour 1.1, outcome 1.3) Conserving mental resources (11.3) Commitment (19.1)	BS4 (facilitate goal setting) BS10 (advise on conserving mental resources) BM6 (prompt commitment from the client there and then)	Yes	Yes	Yes
Monitoring of days smoke-free and feedback	Self-monitoring of behaviour (2.2)	BS6 (prompt self-recording)			
Simple positive feedback on not smoking	Feedback on behaviour (2.2)	BM3 (provide feedback on current behaviour) BM2 (boost motivation and self-efficacy), BM7 (provide rewards contingent on effort or progress)	Yes	Yes	Yes*
Daily tips on craving management for non-smokers	Reduce negative emotions (11.2)	BS2, RC6 (provide information on withdrawal symptoms),	Yes	Yes	-

¹² Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, Eccles MP, Cane J, Wood CE. (2013). The Behavior Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions, *Annals of Behavioral Medicine*, 2013;46(1): 81-95. doi: 10.1007/s12160-013-9486-6

¹³ Michie S, Hyder, N., Walia, A. West, R. (2011). Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addictive Behaviors*, 36(4), 315-319

		RC10 (provide reassurance)			
Feedback on smoking (incl. advice to reset quit attempt after the 3 rd lapse)	Feedback on behaviour (2.2) Discrepancy between current behaviour and goal (1.6) Social support (unspecified, 3.1)	BM23 (feedback) BS1 (Facilitate relapse prevention and coping) RC10 (provide reassurance)	Yes	Yes	Yes
Resetting the app after 3 rd lapse into smoking	N/A	N/A	Yes	-	-
Feature	V1 BCT Taxonomy ¹	Smoking BCT Taxonomy ²	SF28	Inter	Contr
Daily reminders to use the app	N/A	N/A	Yes	Yes	Yes
Tracking of money savings	Feedback on outcomes of behaviour (2.7)	BM3 (provide feedback on current behaviour)	Yes	Yes	Yes
Generic Advice					
Pre-quit tips	Information about antecedents (4.2) Restructuring the physical environment (12.1) Restructuring the social environment (12.2) Avoidance/reducing exposure to cues for the behaviour (12.3) Verbal persuasion about capability (15.3) Identity associated with changed behaviour (13.5)	A1 (advice on stop-smoking medications), A2 (advise on/facilitate use of social support), BM1 (provide information on consequences of smoking and smoking cessation), BM2 (boost motivation and self-efficacy), BM8 (strengthen ex-smoker identity), BM10 (explain the importance of abrupt cessation)	Yes	Yes	-
Brief advice on lifestyle changes and social support	Information about antecedents (4.2) Restructuring the physical environment (12.1) Restructuring the social environment (12.3) Avoidance/reducing exposure to cues for the behaviour (12.3) Verbal persuasion about capability (15.3) Information about natural consequences (5.1-5.3)	A2 (advise on/facilitate use of social support), BS7 (advise on changing routines), BS8 (advise on environmental restructuring), BS11 (advise on avoiding social cues for smoking)	Yes*	Yes*	Yes**
Advice to think of oneself as a non-smoker	Identity associated with changed behaviour (13.5)	BM8 (strengthen ex-smoker identity)	Yes	Yes	Yes**
Information on stop smoking medication	Pharmacological support (11.1)	A1 (advise on stop-smoking medication)	Yes	Yes	Yes

About the study and the App	Credible source (9.1)	N/A	-	Yes	Yes
Cravings – monitoring and management					
Tools assessing momentary cravings	Self-monitoring of outcomes of behaviour (2.4)	BS6 (prompt self-recording) R14 (assess withdrawal symptoms)	-	Yes	Yes
Feedback on craving levels	Feedback on outcomes of behaviour (2.7)	R14 (assess withdrawal symptoms) RC6 (provide information on withdrawal symptoms)	-	Yes	-
Brief advice on craving management (use NRT)	Pharmacological support (11.1)	A1 (advise on stop-smoking medication)			
Craving management tools	Reduce negative emotions (11.2)		Yes	Yes [§]	-
Videos diaries of smokers (4Weeks2Freedom)	Reduce negative emotions (11.2) Information about natural consequences (5.1-5.3) Social comparison (6.2)	BM2 (boost motivation and self-efficacy), BM5 (provide normative information about others' behaviour and experiences)	Yes	Yes	-
Relaxation music	Reduce negative emotions (11.2)	BS2 (facilitate relapse prevention and coping)	-	Yes	-
Meditation	Reduce negative emotions (11.2)	BS2 (facilitate relapse prevention and coping)	-	Yes	-
Motivation boosters#	Information about natural consequences (5.1-5.3) anticipated regret (5.5) Information about emotional consequences (5.6) Self-talk (15.4) Verbal persuasion about capability (15.1) Comparative imagining of future outcomes (9.3)	BM1 (provide information on consequences of smoking and smoking cessation) BM2 (boost motivation and self-efficacy) BM5 (provide normative information about others' behaviour and experiences) BM8 (Strengthen ex-smoker identity), RC10 (provide reassurance)	Yes	Yes [¥]	-
'Challenges'##	Distraction (12.4) Avoidance/reducing exposure to cues for the behaviour	BS1 (facilitate barrier identification and problem solving) BS2 (facilitate relapse prevention and coping)	Yes	Yes [¥]	-
Game aiding distraction	Distraction (12.4)	BS2 (facilitate relapse prevention and coping)	Yes	Yes	-
Gamification features	N/A	N/A	-	Yes	Some

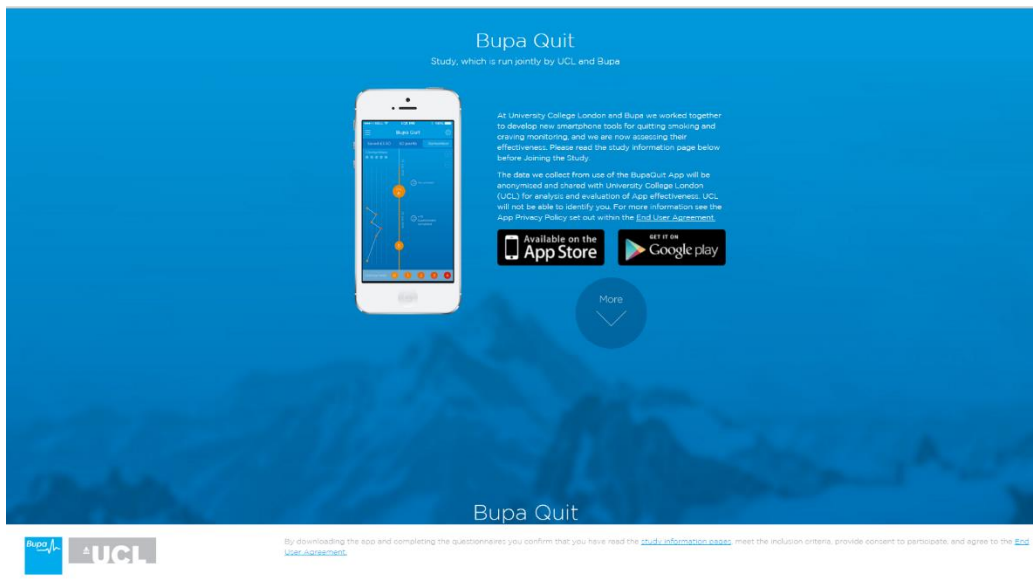
Simple Badges on quit progress	Non-specific rewards (10.3)	BM7 (provide rewards contingent on effort or progress)	-	Yes	-
Collecting points on App use	N/A	N/A	-	Yes	Yes
Points unlocking craving management features	N/A	N/A	-	Yes	-
Statistics on App use with focus on craving aids	N/A	N/A	-	Yes	-
Information about the team behind BupaQuit	Credible Source (9.1)	RC1 (build general rapport)	-	Yes	Yes

*advice updated weekly; **shorted feedback ; ***advice provided for the first week was never updated.; # text-based advice; § content accessible only to those reporting having cravings; ## text-based advice and instructions on physical exercises, muscle tensing, relaxation, distraction; ¥ based on SF28 content and advice, but with modifications and extension

Appendix for Chapter 8

Appendix 8.1. Project website and sample recruitment materials for the BupaQuit trial

BupaQuit project website that included links to the app stores, the complete study information sheet as well as End User Agreement for app use. It was originally available at: www.bupa.com/bupaquit, and was retired on November 1st 2016.



Are you a daily smoker and serious about quitting?

Experts from Bupa and UCL are evaluating a new Smartphone app to help smokers quit smoking.

If you are UK-based, over 18 years old and a daily smoker then we would like to invite you to join our new online study. This study is entirely voluntary, and any information you provide to us will be kept strictly confidential and in accordance with the Data Protection Act 1998.

This study has been approved by the UCL Research Ethics Committee.

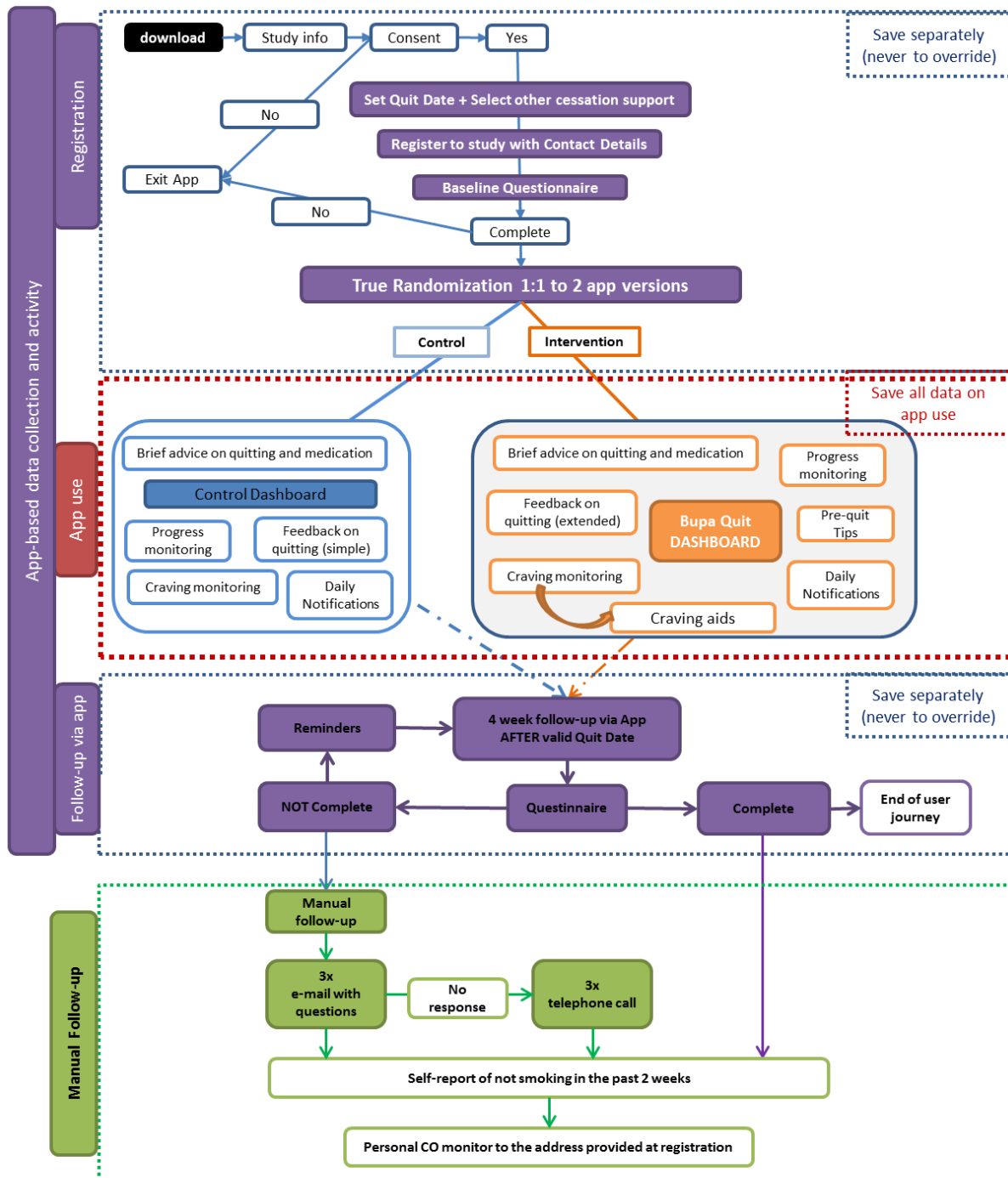
Download Bupa Quit today
Available on iOS and Android

Visit bupa.com/bupaquit

Bupa UCL

Appendix for Chapter 8

Appendix 8.2. Participant flow through the RCT embedded within the BupaQuit app.



Appendix for Chapter 8

Appendix 8.3. Schedule of procedures and measurements in BupaQuit trial.

Procedure/assessment	Always accessible on project website	S1: Initial App visit	S2: 4-week post-quit date follow-up	S4: 6-month post-quit date follow up
Procedures				
Show complete Information Sheet	X	X		
Show End User Licence Agreement	X	X		
Provide contact details to research team	X	X		
Obtain consent		X		
Registration and obtain contact details		X		
Randomisation		X		
Email reminders and follow-up			X	X
Telephone follow-up			X	X
CO personal monitor postage			X	
Assessment				
Demographic information		X		
Smoking history		X		
Dependence levels (HSI)		X		
Smoking abstinence			X	X
Urges to smoke		X		
Prior use of cessation medication		X		
Prior use of additional support		X		
Use of cessation aids		X	X	
CO monitoring test [#]			X	
Time since smoked last			X	
Ease of use of CO monitor			X	
Acceptability of CO test			X	

Appendix for Chapter 8

Appendix 8.4. Baseline questionnaire in the BupaQuit trial.

Q #	Question	Answer options
1	Gender	Man / Woman
2	Age	Enter free text
3	Where do you live now?	UK/ Other
4	Employment status	Manual setting Non-manual setting Currently unemployed/retired Full-time student Other
5	Are you free to use your smartphone throughout the day? (e.g. choose No if work regulations limit your access)	Yes / No
6	Do you have post 16 yrs qualification? (e.g. A-levels, a degree)	Yes / No
7	Ever used any of these to try to quit smoking in the past? (select all that apply)	Medications (e.g. NRT) NHS stop smoking service Quitline / other counselling Other Apps Websites E-cigarettes Other None
8	Made an attempt to quit last year?	Yes / No
9	Ever stopped smoking for more than a week?	Yes / No
10	Do you currently smoke?	Yes, daily Yes, but not daily No, I already quit
13	How often did you experience urges to smoke in the past 24 hours?	Not at all A little of the time Some of the time A lot of the time Almost always All the time
14	Only ask if Q13>0. How strong were those urges to smoke?	(1) 'slight' (2) 'moderate' (3) 'strong' (4) 'very strong' (5) 'extremely strong'
15	How soon after you wake up do you smoke your first cigarette?	Within 5 minutes 6-30 minutes 31-60 minutes More than 60 minutes
16	Why joined the study	To make a serious quit attempt

		I'm just testing the App Other
17	Only ask if Q16=Yes Confidence to quit this time	Scale from 1-7
18	How did you learn about this study?	E-mail or poster about the study Word of mouth (within Bupa) Word of mouth (outside Bupa) App store Other (please specify – free text)
19	Current use of other quitting aids (please select all that apply):	Medications (e.g. NRT) NHS stop smoking service Quitline / other counselling Other Apps Websites E-cigarettes Other None
20	Current number of cigarettes smoked per day:	Enter
21	Weekly spend on cigarettes:	Enter
22	Your main motivation to quit:	(1) To improve my health or fitness (2) To save money (3) For my children or loved ones (4) Not to smell of cigarettes (5) For healthy looking skin and teeth (6) To be less stressed or sleep better (7) Other (free text)

Appendix for Chapter 8

Appendix 8.5. Follow-up questions in the BupaQuit trial

#	Question	Answers
4-week follow-up (Questions asked via the BupaQuit App and e-mail)		
1	Did you smoke at all in the past 2 weeks?	Yes/No
2	How helpful was the App in helping you to manage cravings? (1-not at all, 5- very helpful)*	(1-not at all, 5- very helpful)
3	Would you recommend the App to others?*	Yes/No
4	Would you use the App in the future, if needed?*	Yes/No
6-months follow-up		
5	Have you smoked at all in the past 6 months (except for the first 2 weeks since the quit date)	1)No, not even a puff 2)Yes, between 1 and 5 cigarettes 3)Yes, more than 5 cigarettes
6	Did you smoke any cigarettes in the past 7 days?	Yes/No

(* = questions asked via app and email)



Appendix for Chapter 9

Appendix 9.1. Letter with instructions accompanying CO monitors posted to BupaQuit trial participants

Published as a supplement in (Herbec et al. 2018a)

Page 1/3

Note: After several CO letters were sent, we introduced some small changes to subsequent letters, e.g. wording to emphasise that CO results should be returned even if participants have not used the app much or if they have been smoking.

	
<i>Name and Address</i>	<i>Date</i>
<p>Dear <i>Name</i>,</p> <p>Thank you very much for taking part in BupaQuit study and for responding to our follow-up questions. Congratulations on having quit smoking.</p> <p>Along with this letter, you will find a personal carbon monoxide (CO) testing device. When joining the study you very kindly agreed to take part in this test assessing your smoking status. Please complete it even if you did not use BupaQuit that much, and even if you are still smoking or have quit.</p> <p>You will find instructions on how to use the CO monitor at the bottom of this letter. We would be very grateful if you could follow the instructions to provide a reading as soon as possible, ideally within the next 24 hours.</p> <p>This test is very important, because it will help us decide whether or not BupaQuit app could be recommended more widely. You will also be able to see the progress of your quit and keep the CO monitor for your personal use in the future.</p> <p>Please keep the device, as we may contact you in 6 months time as well.</p> <p>If you have any problems contact bupaquit28support@bupa.com, or phone 02076791258 (to reach Aleksandra at UCL).</p> <p>Thank you for your participation and time!</p> <p>Best wishes, Professor Robert West</p> <p>On behalf of BupaQuit team at Bupa and University College London</p>	
<div style="border: 1px solid black; padding: 5px;"><p>4 Steps to complete the test & send us the results (it should take no more than 5 minutes)</p><ol style="list-style-type: none">1. Connect the monitor using USB to a Laptop or a PC with Windows2. Download the software from http://bupaquit.bupa.com/files/bupaquittest.exe and follow the installation steps (on the back of the monitor you will find the pin number).3. Take the CO test and answer the few questions on the screen.4. On the final screen, click on 'Email Results' to send the results directly to our research team at Bupa.</div>	

Appendix 9.1. (cont.). Letter with instructions accompanying CO monitors posted to BupaQuit trial participants (page 2/3)

Information about Carbon Monoxide and Testing

About the personal CO package, the monitor and software used in the study:

The Package contains 4 different items: (1) CompactUSB monitor, (2) black USB lead (under the packaging), (3) transparent D-piece to be attached to the monitor for the test, (4) 3 sterile SteriBreath mouthpieces in paper packaging - in case other persons would like to use the CO monitor in the future.

Bedfont Scientific Ltd, a company specialising in the development and production of CO monitors, has developed the personal CO monitor and the accompanying software. The CO monitor is a medical device that has been used in smoking cessation to assess smoking status and is used across the United Kingdom by some stop smoking practitioners and smokers themselves.

The software for CO monitor testing has been adapted especially for the BupaQuit study. Bedfont Scientific Ltd will not receive your results.

About carbon monoxide:

Carbon monoxide is a tasteless, invisible gas, which can be lethal in very high concentrations. It is released when a cigarette is lit and enters the body with the cigarette smoke. The more cigarettes smoked, the higher the concentration of carbon monoxide in the body and exhaled air.

Non-smokers and ex-smokers have low levels of carbon monoxide in the air that they exhale. However, carbon monoxide may also be elevated due to faulty gas appliances or environmental pollutants.

About carbon monoxide (CO) testing:

CO testing is used commonly in stopping smoking, and you might have come across it if you have accessed Stop Smoking Services. CO testing is usually used to assess CO levels at the start of stop smoking treatment, throughout the treatment to assess progress, and at the end of the treatment, which we now do in BupaQuit study. The test will allow us to compare the results from this study to other studies in different countries.

Information about the Research Team at UCL

Anonymised findings from BupaQuit study are being analysed independently by researchers and stop smoking experts from Health Behaviour Research Centre at the Research Department of Epidemiology and Public Health, University College London.

Professor Robert West is the Principal Investigator on the study. The lead researcher is Aleksandra Herbec, a British Heart Foundation PhD Student. Visit bupaquit.bupa.com for more information.

Appendix 9.1.(cont.) Letter with instructions accompanying CO monitors posted to BupaQuit trial participants (page 3/3)

The package contains:

- (1) CO monitoring device
- 2) USB lead (under the packaging),
- (3) a transparent mouthpiece in transparent packaging
- (4) two sterile mouthpieces in paper packaging (e.g. in case anyone else would like to use the device in the future).



Appendix for Chapter 9

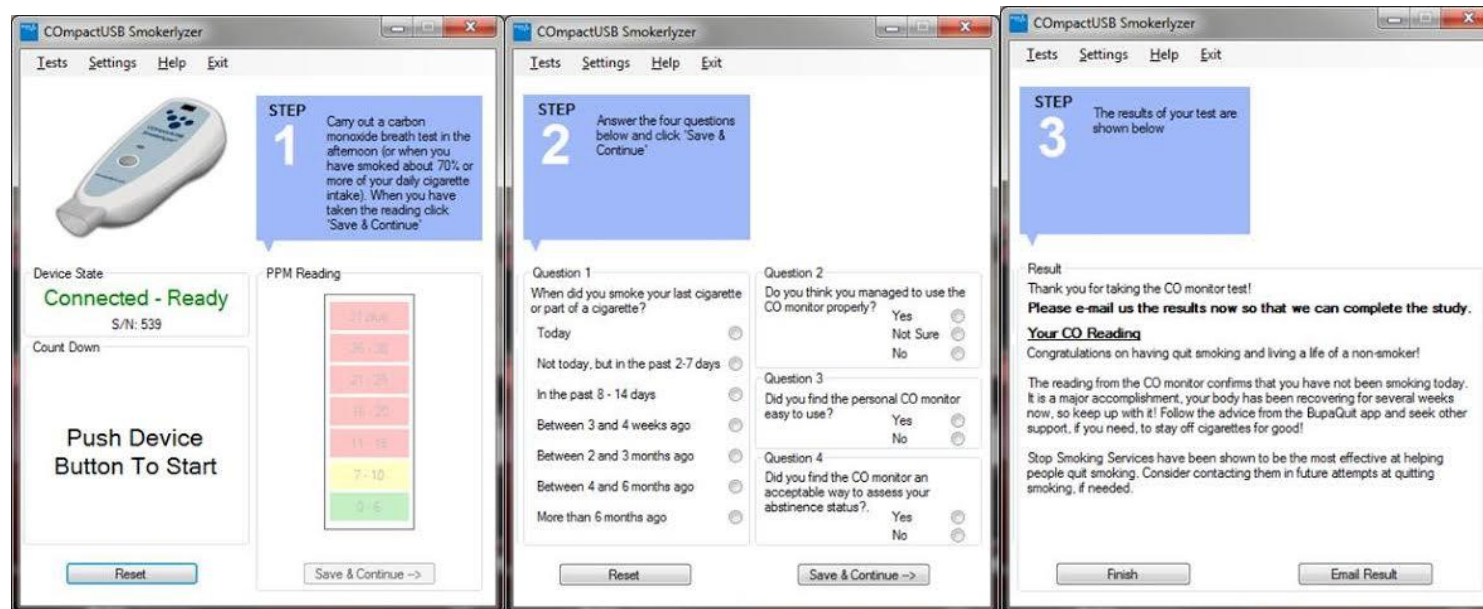
Appendix 9.2. Screenshots of the software accompanying Bedfont® CCompactUSBTM Smokerlyzer® in the BupaQuit Trial

Published as a supplement in (Herbec et al, 2018a)

Screenshots of software accompanying personal CO monitors – the original software accompanying CCompactUSB™ Smokerlyzers® was adapted by Bedfont® for BupaQuit trial. The changes involved:

Step 1: The two original questions comprising Heaviness of Smoking Index (number of cigarettes smoked and time to first cigarette after waking) were replaced with four additional questions that were supporting data collection for the trial and were used to evaluate the use of CO monitor.

Step 2: changing the tailored feedback.



Reproduced with permission from Bedfont® Scientific Ltd

Appendix Chapter 10

Appendix 10.1. Interview guide for the follow-up telephone interviews with the BupaQuit trial participants (conducted by research assistants).

OPENING THE INTERVIEW

My name is Courtney/Georgina and I am calling from the Bupa Quit study – I am part of the team that evaluates the app now. Am I speaking with? Thank you for agreeing to talk to me today!

As we mentioned in the invitations e-mail, we are very interested to learn about your views on the Bupa Quit app and similar support with quitting, so that we could develop better programmes in the future.

To make sure I will not miss any of your comments I would like to record the interview. If you are not happy with this please let me know. Everything you'll say will remain confidential and anonymous. The interview should last around 25min, and I will e-mail you the voucher code soon after to the e-mail address provided. Remember, you don't have to talk about anything you don't want to and you may end the interview at any time, which will not affect the reimbursement for your time.

I would like you to feel comfortable. Because we are interested in your personal opinion, beliefs and experiences, there are no right or wrong answers, and we want to know your honest views. Everything you'll say will be very valuable to us and will help us design better programs.

I will be very happy to answer any of your questions about the study at the end, but is there anything you would like to know about the interview itself before we begin? Are you happy to start the interview?

THE INTERVIEW

Key Open-ended questions.

(1) One important thing we would like to learn a bit more about are your reasons for joining the study and downloading Bupa Quit app. Could you please tell me why did you decide to sign up for this study?

- What were your other reasons and motives for joining?
- What expectations did you have of the app?

(2) What were your experiences with using computer, internet or smartphone programmes with quitting so far?

(3) What did you think about Bupa Quit?

- Do you remember any features or elements that were particularly useful, or not helpful?
- Was there anything you liked particularly? Was there anything you disliked?

(4) What were your experiences with using the app?

- do you remember what was easy / what was difficult / what was confusing / what was clear?
- [good to prompt further about these issues, if they come up: content, trustworthiness, relevance, level of tailoring/personalization, delivery method, ease of following instructions, appearance]

(5) How has using the app affected your smoking and quitting? How? Why/Why not?

Appendix 10.1 (cont.). Interview guide for the follow-up telephone interviews with the BupaQuit trial participants (conducted by research assistants).

(5.1 – for INTERVENTION Only) How has using the app affected your craving for cigarettes? Why/Why not?

- any other (beneficial) impact?

(5.2. – for CONTROL Only) How could we support you better with having cravings for cigarettes?

(6) We are working to improve the app. How could the app be improved to help you quit / manage cravings better? Please be as imaginative as possible - any suggestions about how the app could look or function, or new functions are welcome.

...and how do you think this feature/improvement would help you?

Appendix 10.1.(cont.). Interview guide for the follow-up telephone interviews with the BupaQuit trial participants (conducted by research assistants)

(7) What are your views on using smartphone apps to quit smoking in general?

What is useful or not useful about them?

(8) What are your views on the study we were conducting through Bupa Quit?

Was there anything you'd like us to do differently?

What did you think about being contacted at a follow up?

PROBES:

“This is really interesting...can you tell me more about it... / Could you expand on this.... / Could you elaborate?”

“How / When would this be the case?”

“Could you tell me the reasons for which you..... / for which this happened?”

“What do you mean when you say.....?”

“I am not sure I understand when you say, could you please explain...?”

“How has affected you/your decisions/choices?”

“how would it affect your smoking / quitting?”

“You said that.....”

“Can you give me an example of”

Appendix 10.1.(cont.) Interview guide for the follow-up telephone interviews with the BupaQuit trial participants (conducted by research assistants).

CLOSING THE INTERVIEW

Thank you very much for sharing your thoughts and experiences with me. Is there anything you would like to add or emphasize? Please feel free to e-mail me if you remembered anything or would like to comment on anything else-

- a) I just would like to ask few quick questions about your current smoking, if you don't mind?:

Are you currently smoking any cigarettes? <u>If NOT:</u> Congratulations! What did you find most useful when quitting smoking now?	Y / N
<u>If YES 1:</u> We understand it is very difficult to quit, but every attempt counts! are you smoking daily now?	Y / N
<u>If YES 2:</u> how many cigarettes do you smoke per day?	Number:
Ask these if it's not clear from the above answers:	
<u>Can I just then check/confirm:</u> Have you used any other stop smoking apps to quit since you downloaded Bupa Quit? Do you remember any names?	Y/N Any names? :
Have you used any websites to quit since you downloaded Bupa Quit?	Y/N Any names?
Have you used any medicines, such as nicotine replacement therapy or Champix on prescription?	Y/N Types?
Have you used stop smoking services?	
Age:	

- b) Debrief and thank the participants; Answer any questions about current research
c) My colleague will be sending you a code for the Amazon gift voucher soon.

[STILL WANT TO QUIT?!] You mentioned that you would still like to receive help with smoking? You can access NHS smokefree website, pharmacies or speak with your GP – there are many options available on the NHS that could help you quit.

Appendix for Chapter 11

Appendix 11.1. Wording of questions used in the surveys during the interview on CO Monitors.

CO Monitor App Interview Study Questionnaire

What is your age?

Sex: Male / Female

What is your current employment status

- (6) Employed (Manual setting, e.g. carpenter)
- (7) Employed (Non-manual setting, e.g. teacher)
- (8) Currently unemployed/retired
- (9) Full-time student
- (10) Other

.....

Do you have a post 16 yrs qualification? (e.g. A-levels, a degree) Yes / No

Have you ever used any of these to try to quit smoking in the past? (select all that apply)

- (6) Nicotine replacement therapy (e.g. gum, sprays, patches)
- (7) Medications other than NRT (e.g. Zyban or Champix)
- (8) Stop smoking service
- (9) Quitline / other counselling
- (10) Stop smoking apps
- (11) Websites
- (12) E-cigarettes
- (13) Other

When did you make last attempt to quit smoking? Never / Last year / Longer than a year ago

Ever stopped smoking for more than a week? Yes / No

How many cigarettes per day do you smoke?

Have you ever used a CO monitor?

- No
- Yes – only once to assess smoking status
- Yes – many times to assess progress with quitting

Appendix for Chapter 11

Appendix 11.1. The Interview guide and prompts used in the 2016 and 2017 interviews


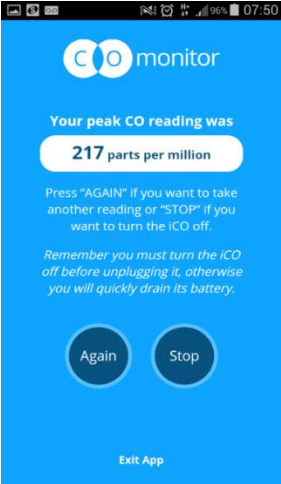
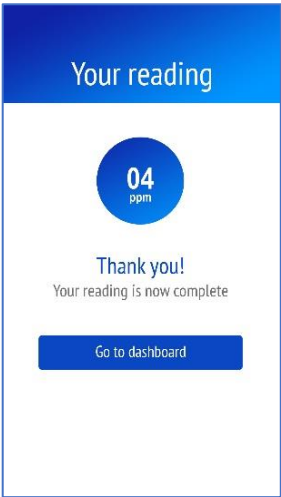
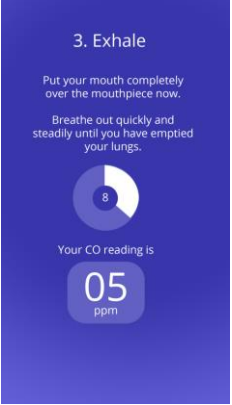

Adapted from: (Herbec et al. 2018b)

	Interview focus and specific topics	Method and prompts
Needs assessment	Part 1: Participant profile and background information (c. 5min) <ul style="list-style-type: none"> - Brief discussion about part and current smoking and quitting history - Prior use of any digital programmes (e.g. apps, devices) - Any experience with CO monitors and testing in the past 	Open-ended questions + prompts <i>No visual materials or prompts</i>
	Part 2: Assessment of needs and expectations for CO testing (c. 10min) <ul style="list-style-type: none"> - Interest in CO testing? Why? - Interested to use CO Smartphone System? Why? - Expectations/general views on CSS - Expectations towards CO monitor and associated apps - Desired functionality / features of CO monitor and associated apps - Expectations for CSS use (When/Where/How?/Why?) - Readiness to share results (With whom? How?) - Reminders (Email, Push notifications, Text) - Expectations for information/advice (topic, location, timing of delivery) 	Open-ended questions + prompts <i>No visual materials or prompts</i>
Demonstration	Part 3: Views and reactions to personal CO monitor <ul style="list-style-type: none"> - General views on iCO Smokerlyzer - Designs/looks - Size - Features and functionality - Battery life (c. 200 tests or 3 years) - Suggestions for improvement 	Open-ended questions + prompts <i>Prompts used: iCO™ Smokerlyzer®</i> <i>No app shown</i>
User testing of apps or functioning app prototypes	Part 4A (only in 2016): Views on, and reactions to, available apps or app prototypes developed to work with a personal CO monitor (c. 15min). <ul style="list-style-type: none"> - Overall impressions (Likes and Dislikes) - Whether would like to use it (when? where? how often?) - User journey through the app - Journey to complete CO testing - Displaying CO results history - Other content, information and advice - Other issues (language, terminology, amount of texts) - Views on ease of use - How to improve? - Discussion of additional suggestions and possible features (e.g. sharing results, using reminders, setting targets, scheduling testing, etc) 	Usability tests (exploring the app naturally, navigating the different content and features) + think aloud procedure <i>Prompts used:</i> <ol style="list-style-type: none"> a) <i>Smokerlyzer® app by Bedfont®</i> b) <i>CO Monitor App prototypes (V1-V2) and designs developed for UCL</i>
	Part 4B: (only in 2017): Usability testing of CO Monitor app (V3) developed for UCL and discussion of piloting use of iCO™ Smokerlyzer® and CO Monitor App V3 at home <ul style="list-style-type: none"> - <i>Specific prompts as in 4A above</i> 	Usability testing and think aloud. <i>Prompts used:</i> <i>CO Monitor app (V3) developed for UCL</i>

Appendix 11.1 (cont.). The Interview guide and prompts used in the 2016 and 2017 interviews

Adapted from: (Herbec et al. 2018b). With permission from Bedfont Scientific Ltd.

The Interview prompts used in the CO Monitor Interviews: example screenshots of existing and prototype apps and designs to work with personal CO monitors

	Bedfont Scientific Ltd app	UCL CO Monitor App (V1)	UCL CO Monitor App (V3)
Think-aloud of functioning apps or app prototypes			
	UCL CO Monitor interactive design (V2)	UCL different CO Monitor designs	
Think-aloud about click-through or static designs of new app			N/A