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**TOBACCO CESSATION
ON PRESCRIPTION -
A primary healthcare intervention
targeting socioeconomically
disadvantaged areas in Stockholm**

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Tobacco Cessation on Prescription – A primary healthcare intervention targeting socioeconomically disadvantaged areas in Stockholm

THESIS FOR DOCTORAL DEGREE (Ph.D.)

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ABSTRACT

Background: In Sweden, the prevalence of tobacco use is higher among socioeconomically disadvantaged groups. Primary healthcare (PHC) has the main responsibility for tobacco cessation treatment in the Swedish healthcare system but relatively few PHC patients are identified as tobacco users and are offered support to quit. Tobacco Cessation on Prescription (TCP) is a new PHC intervention that may facilitate tobacco cessation treatment but this has previously not been evaluated. Thus, the aim of this thesis was to explore and evaluate TCP as a PHC intervention with a focus on socioeconomically disadvantaged areas in Stockholm.

Methods: Study I, III and IV were exploratory qualitative studies based on semi-structured interviews with patients, PHC providers and experts on other lifestyle interventions on prescription that were analysed according to different approaches to qualitative content analysis. Study II was a cluster randomised controlled trial where 18 PHC centres were randomly allocated to provide TCP or standard treatment to their patients. Data was collected through questionnaires and analysed with descriptive statistics and regression models.

Results: In Study I, the informants suggested that TCP should consist of a template with information about the patient, options for evidence-based treatments for tobacco cessation, follow-up, other measures for cessation and support for self-management. TCP was perceived to have an emotional meaning for patients and a practical meaning for PHC providers. Perceived challenges with the method were mainly related to the implementation of TCP.

Study II showed that more patients managed to quit their tobacco use with TCP (38 out of 108 patients) compared to standard treatment for tobacco cessation at 6 months follow-up (4 out of 31 patients). The odds for this were 5.4 times higher in the intervention group compared to the control group when the odds ratio was adjusted for significant covariates. This association was statistically significant.

In Study III, PHC providers perceived TCP to increase self-efficacy to work with tobacco cessation among providers and involvement in the treatment among patients. Perceived barriers to implement TCP included lack of organisational support, resources and differing attitudes among PHC providers to work with tobacco cessation. Long waiting times, costs of treatment and a focus on face-to-face visits limited patients' access to cessation treatment.

In Study IV, patients reported a need for individualised cessation support, taking their individual experiences of tobacco use and cessation into account. They also expressed a need for a supportive environment to quit, including support from the healthcare system, the social environment and other societal structures. The TCP prescription form was perceived as a useful document for PHC providers but counselling from a specialist, an empathetic approach in the counselling and long-term follow-up was considered more important to patients.

Conclusions: PHC providers and patients perceived the TCP prescription form as a tool that could facilitate tobacco cessation treatment from the PHC providers' perspective. TCP may also be effective in decreasing the prevalence of tobacco use among patients in the given setting. It is important that PHC providers adopt an empathetic approach in cessation counselling, taking patients' individual experiences of tobacco use and cessation into account. However, the possibilities to work with tobacco cessation in PHC need to be strengthened in order to improve current cessation treatment and facilitate the implementation of TCP. Tobacco cessation services in PHC likely needs to be reorganised to improve access to treatment for lower socioeconomic groups. Interventions outside the healthcare system are also needed to further support this target group to quit.

Keywords: tobacco use cessation, primary health care, vulnerable populations, Sweden

LIST OF SCIENTIFIC PAPERS

- I. Leppänen A, Biermann O, Sundberg CJ, Tomson T. Perceived feasibility of a primary care intervention for Tobacco Cessation on Prescription targeting disadvantaged groups in Sweden: a qualitative study. *BMC Research Notes* 2016;9(1):151.
- II. Leppänen A, Lindgren P, Sundberg CJ, Petzold M, Tomson T. Motivation 2 Quit (M2Q): A cluster randomized controlled trial evaluating the effectiveness of Tobacco Cessation on Prescription in Swedish primary healthcare. *In manuscript*.
- III. Leppänen A, Ekblad S, Tomson T. Tobacco Cessation on Prescription as a primary health care intervention targeting a context with socioeconomically disadvantaged groups in Sweden: A qualitative study of perceived implementation barriers and facilitators among providers. *PLoS ONE* 14(2): e0212641.
- IV. Leppänen A, Ekblad S, Tomson T. Patients' experiences of tobacco cessation including a prescription approach in Swedish primary health care with a focus on socioeconomically disadvantaged areas. *In manuscript; submitted*.

RELATED WORK

Leppänen A, Lindgren P, Sundberg CJ, Petzold M, Tomson T. A Cluster-Randomized Controlled Trial Evaluating the Effectiveness and Cost-Effectiveness of Tobacco Cessation on Prescription in Swedish Primary Health Care: A Protocol of the Motivation 2 Quit (M2Q) Study. *JMIR Res Protoc* 2016;5(3):e188.

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LIST OF ABBREVIATIONS

CFIR	Consolidated Framework for Implementation Research
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
EMR	Electronic Medical Record
NRT	Nicotine Replacement Therapy
OR	Odds Ratio
PAP	Physical Activity on Prescription
PHC	Primary Healthcare
RCT	Randomised Controlled Trial
RR	Relative Risk
SDG	Sustainable Development Goal
SEK	Swedish Krona
SMS	Short Message Service
SNTQ	Swedish National Tobacco Quitline
TCP	Tobacco Cessation on Prescription
WHO	World Health Organization
WHO FCTC	WHO Framework Convention on Tobacco Control

1 PREFACE

Tobacco use is a multi-faceted phenomenon. Therefore, many perspectives can be applied when researching this topic. Relevant aspects include public health, health systems and policy, healthcare organisation and management, psychology and behavioural change, addiction, physiology and more. Because of my background in public health, this thesis is largely written from the perspective of this field even if other aspects are also discussed. Public health can be defined as the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society (1). In this field, tobacco use is considered one of the largest health threats of all time (2). Tobacco control refers to strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke (3). This thesis investigates a particular tobacco control intervention in the Swedish primary healthcare setting with a focus on socioeconomically disadvantaged areas. The research has a pragmatic approach and concentrates on the real world challenge of tobacco cessation in clinical practice from the perspective of healthcare professionals and patients.

Despite my background in public health, I was not aware of all the consequences of tobacco use when I first became involved in this research project. I still don't think that I have fully grasped them but in my time as a doctoral student I have at least learned more about the many diseases, inequalities in health and sustainability issues that are related to tobacco use. I have developed my understanding of this topic by familiarising with the scientific literature in this field and by conducting the studies included in this thesis but also by continuously discussing the topic in various contexts. In doing so, I have found that most people seem to have a relationship to tobacco, either from personal use, exposure to tobacco from others or experiences of tobacco use and related health problems among patients or loved ones. It appears to be a topic that engages people, regardless of their own tobacco use behaviour, as many have expressed strong feelings about it and spontaneously shared their thoughts on tobacco use with me when I have mentioned my research. This has contributed to my understanding of this complex phenomenon but also to my curiosity and motivation to conduct this research. What I have found particularly valuable was to talk to the patients and others in their situation about their experiences of tobacco and trying to quit. I hope that the thesis in some way can contribute to improved cessation support for them and others who need it.

Anne Leppänen

Stockholm, August 2019

2 RATIONALE FOR THE THESIS

This is a brief introduction to the research problem and the rationale for the thesis. It will be followed by definitions of central concepts that may be helpful when reading the rest of the thesis. A more comprehensive background of the literature in the field will be presented after the aim of the thesis.

Although the prevalence of daily smoking is relatively low in Sweden compared to many other countries in the world (4), inequalities in health due to tobacco use have increased in this setting over time (5). This is reflected in an increasing concentration of smoking, inpatient care and deaths related to smoking among socioeconomically disadvantaged groups (5). Tobacco cessation could improve health and quality of life (6,7) in this population but lower socioeconomic groups have been shown to experience more difficulties in quitting compared to other groups (8).

National treatment guidelines for tobacco cessation treatment have been developed in the Swedish healthcare setting, describing which treatments that are effective (9). These recommend that the healthcare system should offer qualified counselling to all daily smokers in high-risk groups (9) but they do not provide any recommendations for how such services should be organised. There is also a lack of studies regarding the effectiveness of tobacco cessation treatments in disproportionately affected groups such as the socioeconomically disadvantaged (10,11). Thus, more research is needed to identify interventions and strategies with the potential to reduce inequalities in tobacco use that are related to socioeconomic position (12).

Providing cessation treatment as part of routine practice in healthcare has the potential to reach more than 80% of all tobacco users in a country each year (4). In the Swedish healthcare system, primary healthcare has the main responsibility for health promotion (13). Socioeconomically disadvantaged groups also seek care in this setting more often compared to other groups (14). Therefore, primary healthcare can be seen as an important setting in which tobacco cessation support could be offered to this target group. However, relatively few primary healthcare patients in Sweden are identified as tobacco users and are offered support to quit (15). Lack of time, resources, competence and economic incentives have been identified as potential barriers to work with tobacco cessation in this context (16).

Previous studies have shown that Physical Activity on Prescription is an effective intervention in increasing physical activity levels and improving health in the primary healthcare setting in Sweden (17). Similar approaches have been introduced in other countries as well, showing positive patient outcomes (18). Furthermore, other prescription approaches to promote health are used in Sweden (19–21) and elsewhere (22). Therefore, it may also be relevant to introduce a prescription approach to facilitate tobacco cessation in this context but this has to my knowledge previously not been evaluated.

3 DEFINITIONS OF CENTRAL CONCEPTS

3.1 TOBACCO CESSATION

Tobacco cessation refers to the process of discontinuing tobacco use.

3.2 TOBACCO CESSATION ON PRESCRIPTION

Tobacco Cessation on Prescription (TCP) is the intervention that this thesis seeks to study. It is defined as 1) tobacco cessation counselling for at least 10 minutes by a qualified healthcare professional, 2) a written prescription for individualised tobacco cessation treatment and 3) follow-up on at least one occasion.

3.3 SOCIOECONOMICALLY DISADVANTAGED GROUPS AND AREAS

Socioeconomically disadvantaged groups here refer to lower socioeconomic groups, for example those with a lower education and income. In turn, socioeconomically disadvantaged areas refer to geographical areas with a higher concentration of lower socioeconomic groups.

3.4 INEQUALITIES AND INEQUITY IN HEALTH

Inequalities in health are defined as differences in health status or distribution of health determinants between different population groups while inequities in health are defined as health determinants that are unevenly distributed and contribute to unnecessary, avoidable, unjust and unfair differences in health (23).

3.5 PRIMARY HEALTHCARE

In Sweden, primary healthcare (PHC) is defined as healthcare services in which outpatient care is provided without any limitations regarding disease, age or patient group (13). PHC is responsible for basic medical treatment, nursing, prevention, health promotion and rehabilitation that does not require inpatient medical and technical resources or other skills (13).

3.6 PHC CENTRES

PHC centres here refer to the physical units where PHC is generally provided in the Swedish healthcare setting.

3.7 HEALTHCARE PROVIDERS AND STAFF MEMBERS

Healthcare providers can refer to organisations or individuals that provide healthcare. In the context of this thesis, the term refers to individual healthcare professionals that work with patients in the healthcare setting, including physicians, nurses and assistant nurses. Sometimes the term staff member is also used in the thesis. This refers to anyone working at the PHC centres, including administrative staff.

3.8 PATIENTS AND CLIENTS

Patients can be defined as recipients of healthcare. In the context of this thesis, patients mainly refers to persons who use tobacco and seek healthcare in the PHC setting. The term clients was also used in Study I and is here defined in the same way as patients.

3.9 PARTICIPANTS AND INFORMANTS

Participants refer to the individuals that participated in the sub-studies included in this thesis, while the term informants was used specifically for the individuals that participated in the qualitative studies (Study I, III and IV). Further details on the characteristics of the participants and informants are provided in the methods section and in each manuscript.

4 AIM

The overall aim of this thesis was to explore and evaluate TCP as a PHC intervention with a focus on socioeconomically disadvantaged areas in Stockholm. This was done by conducting four sub-studies, each addressing one of the following specific aims with regard to the given setting:

- Study I: To explore the perceived feasibility and optimal design of TCP from the perspective of patients, PHC providers and experts on other lifestyle interventions on prescription
- Study II: To evaluate the effectiveness of TCP compared to current practice for tobacco cessation, measured in 7-day point prevalence of total abstinence from tobacco use at 6 months follow-up
- Study III: To explore PHC providers' perceived barriers and facilitators of implementing TCP
- Study IV: To explore patients' experiences of tobacco cessation and TCP

5 BACKGROUND

5.1 TOBACCO USE

5.1.1 Health consequences of tobacco use

Smoking is the largest preventable risk factor for ill health in the world (24), killing more than 8 million people every year (2). It affects almost all organs in the body and has been established as the cause of more than 60 different diseases, out of which cancers, cardiovascular diseases and pulmonary diseases are the most common (6,25). It reduces physical and psychological wellbeing, health-related quality of life (26) and life expectancy with more than ten years (6,27,28). In addition, smoking has negative effects on the outcome of medical treatments and increases the risk of complications after surgery (6). Second-hand smoke also has negative effects on the health of those exposed (6).

Snus is a smokeless moist tobacco product that is mainly used in Sweden. It is associated with an increased risk of oesophageal and rectal cancer (29,30), type 2 diabetes (31), heart failure (32), fatal myocardial infarction and stroke (33), as well as harm to the fetus (34–38). However, there is less research on snus use compared to smoking and less is therefore known about its health consequences.

5.1.2 Prevalence of tobacco use

There are 1.1 billion smokers worldwide, of which 80% reside in low- and middle-income countries (2). In Sweden, the prevalence and distribution of tobacco use has changed dramatically during the last 50 years. Since the 1960's, the prevalence of daily smoking among men has decreased from approximately 50% (39) to 7% in 2018 (40). The prevalence of daily smoking peaked among women in the mid 1970's and has since then decreased from approximately 30% (41) to 7% in 2018 (40). The prevalence of daily snus use has been stable for the last years and is currently 18% among men and 4% among women (40).

Although the prevalence of daily smoking is relatively low in Sweden (7%) compared to other high-income countries (22%) (4,40), tobacco use has been estimated to cause 8% of the total disease burden in the country (42), including 12 000 deaths and 100 000 new cases of tobacco-related disease per year (25). In addition, the difference in prevalence of tobacco use between different social groups has increased over time, concentrating among lower socioeconomic groups (5). For example, the difference in prevalence of daily smoking between different occupational groups has increased from almost no difference in 1963 (41) to a more than two times higher prevalence among blue-collar workers compared to white-collar workers in 2015 (43). Some of the change can be explained by demographic and socioeconomic changes but it is mostly explained by external factors, such as changing norms, behaviours and policies affecting certain groups more than others (5).

5.1.3 Onset of tobacco use

Almost all smokers try their first cigarette and become daily users before the age of 26 (44). Less than 2% initiate smoking and less than 4% transition to daily smoking later in life (44). However, the vast majority start smoking and become daily smokers already before 18 years of age (44). Risk factors for smoking initiation and use include low socioeconomic status, high accessibility and availability of tobacco products, perceptions that tobacco use is normative, peer influence, lack of parental support, low academic achievement and school involvement, lack of skills and self-efficacy for refusal, previous tobacco use and intention to use tobacco, low self-image and belief that tobacco use is functional or serves a purpose (44). The same factors have been found to predict the use of smokeless tobacco (44). There is also evidence that genes may play an important role in tobacco use behaviours but the presence of genetic risk alone appears to be insufficient and genetic predisposition is likely to interact with other environmental factors (44).

5.1.4 Social determinants of health and tobacco use

Social determinants of health are the conditions in which people are born, grow, live, work and age, that are shaped by the distribution of money, power and resources (45). Examples of social determinants of health are education, occupation and income. Inequalities in these determinants affect health behaviour and can to a large extent explain inequalities in health (46). The social determinants of health and their relationship to tobacco use will here be explained based on a model by Diderichsen et al (47).

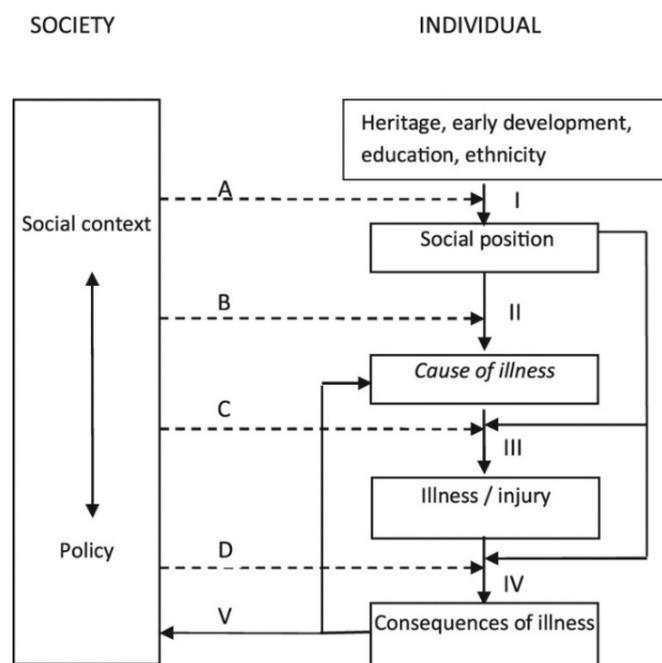


Figure 1. Central mechanisms (I-V) and associated policy entry points (A-D) related to social inequalities in health (47).

I. Social stratification

Economic, social and psychological factors in childhood and early development are important determinants of health (48). Research suggests that parental smoking and socioeconomic status are predictors of tobacco use among offspring in adulthood (49). For example, maternal smoking during pregnancy is higher among socioeconomically disadvantaged groups (50) and has been found to increase the risks of ever-smoking, regular or current smoking, dependence on tobacco as a preadolescent, adolescent and young adult (44). The socioeconomic position of parents and exposure to tobacco at home, in child day care and/or in the school environment can also work as influences in adopting the same behaviour later in life as a result of parents', peers' or other role models' tobacco use during this period (46).

II. Differential exposure

Differential exposure to risk factors can be explained by differential working and living conditions, economic conditions and physical environments between different socioeconomic groups (48). For example, the exposure to tobacco use is disproportionately high among socioeconomically disadvantaged groups. The prevalence of daily tobacco use (cigarettes and snus) in Sweden is 24% among those with the lowest education compared to 14% among those with the highest education (43). There is also a social gradient in the prevalence of tobacco use - the higher the educational level, the lower the prevalence (43). The same pattern can be seen for occupation and income (43). The difference is particularly prominent in daily smoking where the prevalence is more than three times higher among those with the lowest compared to those with the highest education (40).

In addition to high prevalence of tobacco use, tobacco cessation rates are also lower among socioeconomically disadvantaged groups (46). This could be explained by psychosocial factors such as lower motivation, self-efficacy and social support to quit but also by targeted marketing from the tobacco industry (8). Furthermore, nicotine dependence seems to be higher among tobacco users in lower compared to those in higher socioeconomic groups (8). This could be explained by higher levels of psychosocial stress due to poorer living and working conditions in this group and tobacco being used as a coping strategy for stress management (although it is a stressor and withdrawal relief is likely to be confused with calming effects) (46).

Exposure to second-hand smoke and prenatal exposure to tobacco is also higher in this group compared to higher socioeconomic groups (50,51), particularly affecting the health of children with smoking parents but also others present in the same environment as smokers (52).

III. Differential vulnerability

Since causes of illness can interact with each other and those with low socioeconomic status are more often exposed to several risk factors at the same time compared to those with a higher socioeconomic status, these groups are considered more vulnerable (48). This means that two persons from different socioeconomic groups that use the same amount of tobacco can have different risks of developing a disease from their use (48). For example, interaction between smoking, hypertension and low socioeconomic status can increase the incidence and mortality of tobacco-related disease (53) .

IV. Differential disease consequences

Diseases can also have different consequences depending on socioeconomic status (48). For example, care seeking behaviour and access to treatment differs between socioeconomic groups (54–56). This could be explained by lower health literacy and ability/willingness to pay for healthcare services in socioeconomically disadvantaged groups (57,58). Harmful effects of tobacco use can also be understood differently by those with a lower socioeconomic status (8). In addition, the awareness of available tobacco cessation treatment options is lower in this group, as is the use and effectiveness of such services (58). Furthermore, costs of seeking and completing treatment for tobacco cessation may present particular difficulties for this target group to quit (58,59). Those with low socioeconomic status generally have a greater need for care but refrain or wait longer to seek care compared to their counterparts (55) and may therefore suffer more consequences from their tobacco use and related diseases. In addition, several studies have found that disadvantaged groups perceive a lack of support from healthcare providers to quit, which may limit access to tobacco cessation treatment for this target group (54).

Lower cessation rates among low socioeconomic groups can also influence the effectiveness of treatments for other diseases. For example, tobacco use is associated with higher rates of complications after surgery (6). Disease can also affect ability to work and thus income, particularly among manual workers who generally have a higher physical workload compared to non-manual workers and may not be able to work to the same extent if they are affected by a disease (46).

V. Disease consequences for the individual and for society

Disease consequences of tobacco use can be observed at many different levels. At the individual level, social consequences of tobacco-related disease can affect the future course of disease and contribute to further inequalities in health (48). For example, absenteeism and unemployment due to tobacco-related disease can lead to increased risks of adverse health outcomes (46). At the societal level, tobacco use is associated with increased costs of illness

and productivity loss, affecting individuals, employers, the healthcare system and society as a whole (60).

In Sweden, the societal costs associated with tobacco use have been estimated to 31.5 billion Swedish Krona (SEK) per year, out of which 16 billion SEK are due to productivity loss, 10 billion SEK are due to healthcare costs and 5 billion SEK are due to other indirect costs (61). For employers, the cost is approximately 45 000 SEK per employed smoker and year (62). At the individual level, costs for tobacco products and income loss are estimated to 13 500-18 000 SEK per person and year (63).

In addition to these costs, the environmental consequences of tobacco use have been given increased attention in recent years (64). Tobacco growing, manufacturing and distribution all have severe environmental consequences, contributing to deforestation and emissions of greenhouse gases and other waste into nature (64). Tobacco use can also lead to poverty and food insecurity in countries where tobacco is grown and to ill health among farmers that are exposed to nicotine and pesticides involved in the growing and handling process (64). Tobacco consumption further contributes to air pollution and toxic waste from millions of kilograms of non-biodegradable butts that are discarded every year (64). Cigarette butts are the most common type of litter by count (65), comprising 67% of all litter in urban areas in Sweden (66). Tobacco use can thus be considered a threat to sustainability from both a local and global perspective, directly or indirectly affecting many of the United Nations' Sustainable Development Goals (SDGs) (67). The SDGs 1, 3, 5, 10, 12 and 17 that are related to poverty, health and wellbeing, gender equality, inequality, responsible consumption and production and global partnerships are considered particularly relevant for tobacco control (67).

5.2 TOBACCO CESSATION AND TREATMENT

5.2.1 Tobacco cessation

Tobacco cessation has been found effective in improving health and quality of life (6,7). Physiological changes can be observed within hours of quitting and quitting before the age of 30 can reduce the risk of tobacco-related mortality to a similar level to that of never-smokers (28). However, health benefits of tobacco cessation can be observed at all ages (6,28).

High nicotine dependence is associated with a lower likelihood of attempting to quit and a higher likelihood of relapse following a quit attempt (68,69). Younger smokers and smokers with no history of psychiatric disease, anxiety or depression are more likely to attempt to quit and succeed in quitting (70–74). This could be explained by a lower nicotine dependence in these groups (70,72). Female gender, previous quit attempts and motivational factors such as intention to quit have been identified as predictors of making quit attempts but not of

successful cessation (68,69,71,75). Self-efficacy to quit however, is associated with both attempting to quit and succeeding in quitting (68).

Most tobacco users want to quit but several quit attempts and support is often needed to succeed. Population estimates suggest that approximately 70% of smokers and 40% of snus users in Sweden want to quit their tobacco use (76). However, the success rate of unaided quit attempts is only 3-5% after 6-12 months (77). Most tobacco users manage to quit on their own after many attempts (78) but approximately 30% express a need for support to succeed (76). Treatment for tobacco cessation can markedly increase the success rate (79).

5.2.2 Behavioural and pharmaceutical treatment for tobacco cessation

Since tobacco use is a combination of habits and social, psychological and physiological dependence, both counselling and pharmacotherapy play important roles in the treatment process. Counselling can vary depending on the mode of administration (individual or group, face-to-face, telephone or internet-based), duration, frequency and the resources and qualifications of the provider (79). In general, more intensive counselling has been found more effective than less intensive counselling (80). Individual and group counselling have similar effectiveness (81). Face-to-face counselling and telephone counselling also appear to have similar effectiveness (82).

Pharmacotherapies available for tobacco cessation in the Swedish setting include nicotine replacement therapy (NRT), which is sold over the counter, and bupropion and varenicline, which are prescribed (83). All three options have been found effective compared to placebo (79). NRT is available in different dosage forms including nicotine patch, gum, oral tablet, lozenge, inhaler, oral spray and oral powder (83). Most NRT dosage forms have similar effectiveness (84). However, combination treatment with NRT has been found more effective than single form NRT and bupropion (79). Single form NRT and bupropion have similar effectiveness but varenicline has been found superior to both single form NRT and bupropion (79). Pharmacotherapy combined with counselling produces higher cessation rates compared to usual care (85). The relative risk (RR) of successful quit attempts (usually measured as point prevalence of 7-day abstinence from tobacco use at 6 or 12 months) for different treatment options is presented in Table 1.

Less is known about the effectiveness of cessation treatment for snus use. However, counselling methods similar to those for smoking cessation are used in practice and there are indications that varenicline may be effective in supporting snus users to quit (86).

Table 1. Effect size of treatments for tobacco cessation.

Treatment	RR	Reference
Behavioural therapy vs no advice		
Minimal intervention	1.66	(80)
Intensive intervention	1.84	(80)
Pharmacotherapy vs placebo		
NRT (all)	1.60	(79)
Nicotine gum	1.49	(84)
Nicotine patch	1.64	(84)
Nicotine oral tablet/lozenge	1.52	(84)
Nicotine inhaler	1.90	(84)
Nicotine oral spray	2.48	(84)
Bupropion	1.62	(79)
Varenicline	2.27	(79)
NRT combination treatment vs single form NRT	1.34	(87)
Combined behavioural and pharmacotherapy vs usual care in healthcare setting	1.97	(85)

5.2.3 Other treatments for tobacco cessation

There is some evidence that electronic cigarettes may be effective in achieving smoking cessation when compared to placebo electronic cigarettes but the confidence in this result is rated as low and the long-term safety of electronic cigarettes is unknown (88). It has also been suggested that snus could be used for smoking cessation purposes but there is limited evidence of its long-term effectiveness when compared to placebo (89,90) and NRT (91). In Sweden, snus and electronic cigarettes are not approved as tobacco cessation products and clinical guidelines recommend that other cessation treatments with scientific support should be prioritised (15).

5.2.4 Cost-effectiveness of tobacco cessation treatments

In addition to clinical trials that have evaluated the effectiveness of various tobacco cessation treatments, health economic evaluations have been conducted to compare costs and benefits of these relative to each other and to other interventions in healthcare (10). This input can inform allocation of scarce resources and help policy makers decide whether a particular treatment is worth implementing or not (92). Across various methods and settings, tobacco cessation treatments have been found cost-saving or cost-effective (10). Head-to-head comparisons have found that varenicline is less costly and more effective than NRT and bupropion (10). The most cost-effective behavioural therapy has not been established due to large variations in treatment components, settings and evaluation methods used (10). Due to the high benefits and relatively low costs of tobacco cessation treatments, these interventions are considered some of the most cost-effective in the healthcare setting (10).

5.3 POLICY AND PRACTICE

5.3.1 Tobacco control from an international perspective

As a response to the globalisation of the tobacco epidemic, the World Health Organization (WHO) developed the WHO Framework Convention on Tobacco Control (WHO FCTC) (3). It is an international evidence-based treaty, committing parties to reduce the demand and supply of tobacco products (3). It was developed in 2003 and currently has 181 parties, covering 90% of the world population (93). Research suggests that decreases in tobacco consumption have accelerated in high-income and European countries following the introduction of the WHO FCTC, while tobacco consumption has increased in low- and middle-income countries (94). This could be explained by uneven implementation of the WHO FCTC in high- and low-income countries (94). A key target for Goal 3 in the SDGs is to strengthen the implementation of the WHO FCTC in all countries, as appropriate (95).

Article 14 in the WHO FCTC specifically covers demand reduction measures concerning tobacco dependence and cessation (96). Guidelines for the implementation of Article 14 have been issued (96). They focus on infrastructure and funding, population-based approaches such as brief advice and quitlines, as well as more intensive individual approaches such as accessible, available and affordable medications and support from specialised healthcare providers to quit (96). The guidelines also stress that measures for tobacco cessation should be combined with other tobacco control policies to maximise effects (96). Proven policies include monitoring tobacco use and prevention policies, protecting people from tobacco smoke through smoke-free air laws, warning about the dangers of tobacco use through media campaigns and pictorial health warnings, enforcing bans on tobacco advertising, promotion and sponsorship and raising taxes on tobacco (24). The latter is considered the single most effective strategy in decreasing tobacco use (24) and related inequalities in health (97). Implementing large increases in cigarette and snus taxes is expected to decrease the burden of disease from tobacco use in Sweden, particularly if combined with other policies (98).

5.3.2 Tobacco control and national treatment guidelines in Sweden

Due to the health and economic consequences of tobacco use and the inequalities it causes, tobacco control is a prioritised area in Swedish public health policy (99). Sweden ratified the WHO FCTC in 2005 (100) and the Swedish Government has since then adopted a goal to eliminate the preventable inequalities in health within a generation (101). The government has also adopted a "Tobacco Endgame" approach, aiming to reduce the prevalence of daily smoking to less than 5% by the year 2025 (102).

In 2011, the National Board of Health and Welfare issued national guidelines for disease prevention methods, describing which treatments that are effective in changing health-related behaviours and should be given priority for different patient groups in the healthcare setting

(103). The guidelines were updated in 2018 and recommend that the healthcare system should offer qualified tobacco cessation counselling to support daily smokers to quit (9). They also state that cessation support to high-risk groups, such as the socioeconomically disadvantaged, should be prioritised (9). Qualified counselling is defined as structured and person-centred counselling for at least 15 minutes by a healthcare professional trained in tobacco cessation, sometimes combined with follow-up sessions and pharmacotherapy (NRT, varenicline or bupropion) if needed (9). Motivational strategies are often used and the counselling is theory-based, for example on cognitive behavioural theory or stages of change (9). Less intensive counselling alternatives are also mentioned in the guidelines but these are given a lower priority due to lower effectiveness (9).

In addition to the recommendations for smoking cessation treatment, the guidelines state that the healthcare system should offer counselling for snus cessation to pregnant women (9). However, counselling and varenicline treatment for other snus users are given a lower priority (9).

5.3.3 Swedish healthcare and tobacco cessation in clinical practice

The overall goal of Swedish healthcare is good health and healthcare on equal terms for the entire population (13). Healthcare should be provided with respect to the equal value of all people and the dignity of the individual (13). Furthermore, those with the greatest need for healthcare should be prioritised (13). The healthcare system also has an obligation to work with disease prevention (13).

The Swedish healthcare system is highly decentralised and mainly publicly funded by local taxes even if there are healthcare facilities that are both publicly and privately owned (104). There are 21 regions that are responsible for the funding and provision of healthcare services to their populations and 290 municipalities that are responsible for care and housing of elderly and people with disabilities (104). PHC is responsible for basic medical treatment, nursing, prevention and rehabilitation that does not require inpatient medical and technical resources or other skills (13) while more advanced care is provided at regional hospitals (104). PHC is considered the basis of the Swedish healthcare system and also has the main responsibility for health promotion (13).

In Sweden, cessation counselling is partially cost-covered and available in more than 50% of PHC facilities and hospitals (4). NRT is included in the essential medicines list and pharmacotherapies for tobacco cessation are partly subsidised (4). Cessation counselling is provided at different levels by different healthcare professionals depending on e.g. time constraints and the qualifications of the provider (105). Brief advice (usually up to 5 minutes) can be given by all providers with basic knowledge in tobacco cessation but more advanced counselling should be given by a provider with more expertise in tobacco cessation (105).

There is a national standard for specialist education of health professionals in tobacco cessation (16) but reimbursement schemes and other factors differ between regions and it is currently up to each PHC centre to decide for themselves how their tobacco cessation services should be organised. The support offered can therefore differ depending on which region, PHC centre or even provider a patient visits. The decentralised healthcare system in Sweden offers particular challenges to standardise tobacco cessation services in PHC but the lack of clear responsibilities of different professional groups may also contribute to differing practices (106).

Population estimates from Sweden suggest that 87% of patients are positive towards receiving advice on lifestyle changes in the healthcare setting (107). However, only 2.5% of all PHC patients in Sweden are identified as daily smokers (15) compared to 7% in the general population (40). In addition, only 0.5% of all patients in PHC are offered qualified counselling to quit (15). This could be explained by underreporting but also by a lack of time, resources, competence and economic incentives to work with tobacco cessation (16). Similar provider behaviour and barriers to work with tobacco cessation in the healthcare setting have been reported in other European countries (108).

Some of the challenges that Swedish PHC is currently facing are described in two recent investigations of the Swedish healthcare system (106,109). Challenges include an increase in responsibilities and administrative burden in PHC over the years, a lack of specialised providers in PHC and an imbalance in the resources allocated to PHC compared to hospital care (106). The investigations stress the need for a strengthened PHC with a focus on patient-centred, evidence-based and preventive care (106,109). The recently updated guidelines for tobacco cessation treatment further recommend that the healthcare system should increase the provision of qualified counselling to 36 000 patients per year with a particular focus on high-risk groups (9). To achieve this, more time and financial resources to work with tobacco cessation are needed (9).

In addition to treatment in PHC, cessation support is provided by the Swedish National Tobacco Quitline (SNTQ), a toll-free telephone-based counselling service, and through mobile applications, web-based counselling and various inpatient settings. Cessation support is to some extent also provided in the dental care setting, at pharmacies, through school health services and employers (63).

In Stockholm, 57% of the PHC centres report that they have routines for tobacco cessation (110). Of these, 90% report that they follow the routines they have established (110). The most common practice is to refer patients to a tobacco cessation specialist at the PHC centre (78%) or to the SNTQ (60%) (110). Approximately 65% of the PHC centres report having one to two employees with a specialist education in tobacco cessation (110).

5.4 PRESCRIPTION APPROACHES TO IMPROVE HEALTH

5.4.1 Physical activity on prescription schemes

Prescriptions are traditionally used in the healthcare setting to prescribe pharmacological treatment. However, prescriptions can be used for other purposes as well. For example, prescription approaches have been introduced in more than ten countries to promote physical activity among patients in the healthcare setting (18), including Sweden, Norway, Finland, Denmark, Spain, the UK, USA, New Zealand and Australia (111–116). Physical Activity on Prescription (PAP) is the Swedish version of prescribed physical activity (117). It is delivered by registered healthcare professionals and consists of patient-centred counselling on physical activity, an individualised prescription for physical activity, cooperation between healthcare and physical activity providers, follow-up of the prescription and comprehensive prescription guidelines (117). The method has been found effective in increasing physical activity levels and improving health and quality of life (17). The adherence to PAP is similar to that of other medical treatments for chronic diseases (17,118).

Prescription approaches to improve health can have several functions. They can facilitate access to services and/or be used as a complement to counselling. Clinical experience suggests that PAP can help providers to structure their counselling on physical activity (117). The PAP prescription form can also be used as a summary of the counselling session or as a written agreement between the provider and the patient regarding the treatment (117). It may also serve as a reminder and a tool for documentation that can be used during follow-up (117,119). In addition, it can affect how advice is perceived by the patient (117). Advice to change health-related behaviour may be taken more seriously and be prioritised differently by patients and their families if the advice is complemented by a prescription compared to counselling alone (117,120). Receiving an individualised prescription, taking patient preferences and previous experiences into account, with professional counselling and follow-up by an expert may also lead to increased patient involvement in the treatment and increased motivation to change behaviour (119,120).

Although there is support for PAP, both in the scientific literature and in treatment guidelines for physical activity (9,103), there seems to be scepticism towards the evidence for the method among healthcare providers (118,121,122). A report suggests that the method is underutilised in practice and not used as intended (118). Physical activity counselling is considered important but perceived lack of time, competence, experience, routines and guidelines, collaboration and interest among colleagues to prescribe PAP have been identified as potential barriers to use the method (119,121,122). Heavy workload and other priorities have also been identified as barriers to implement PAP in Sweden (121,122) and health promoting activities in various PHC settings (123). Personal commitment may also explain differences in use of PAP among healthcare providers (122). Similar results have been found regarding PHC providers' perceptions of physical activity counselling in general (124). In contrast, support from colleagues and managers, clear routines, responsible staff and

allocated time to work with health promotion have been identified as facilitators to implement PAP in Sweden (119,121,122).

5.4.2 Other prescription approaches in healthcare

Since PAP was introduced in 2001 (117), other prescription approaches to improve health in the Swedish healthcare setting have emerged. Prescription approaches that have been introduced in different regions include Culture on Prescription, Dietary Advice on Prescription and Therapy Dogs on Prescription (19–21). The concept of prescriptions for other treatments than pharmaceuticals is thus familiar to many patients and providers in Swedish healthcare setting.

A before and after study has shown that Culture on Prescription improves self-rated health and reduces symptoms of anxiety, depression and stress, as well as absenteeism (19). Similar approaches exist in Norway, Denmark and the UK (125). This type of social prescribing is defined as referral of patients from PHC to services commonly provided by the voluntary and community sector (22). Social prescribing is being widely advocated and implemented in the UK but there is limited evidence regarding the effectiveness of such approaches due to poor quality of studies (22).

5.5 INTERVENTION AND IMPLEMENTATION RESEARCH IN PHC

Research on the organisation and delivery of health services is conducted to inform how such practices can be optimised to improve the health of the population (126). Research in this setting is often based on a multidisciplinary approach using both qualitative and quantitative methods (126). These methods can be viewed as complementary to each other (127,128) and helpful to use when conducting research on complex public health problems (129).

Intervention research can be defined as the systematic study of purposive change strategies, including the design, development and evaluation of interventions (130). Pragmatic randomised controlled trials (RCTs) may be used to quantitatively evaluate whether interventions are effective in routine practice compared to current treatment (126). Pragmatic approaches are recommended to maximise applicability and generalisability under real life circumstances (131). However, such trials are costly and time consuming (132). They also require involvement from patients, providers and organisations (132). Patient recruitment and retention has been identified as one of the greatest challenges with this type of research (133).

Qualitative methods may be used alongside clinical trials to inform intervention design or to explore contextual factors and processes such as how, where, when and by whom an intervention is delivered and received (132). They may also be used to increase understanding of how and why an intervention works.

Implementation research is a related research field, defined as the scientific study of methods to promote the systematic uptake of research findings into routine practice to improve the quality and effectiveness of health services and care (134). In this field, theory may be used to understand and explain influences on implementation outcomes (135). Determinant frameworks are considered particularly useful in identifying barriers and facilitators to implementation from a systems perspective, stressing the importance of context (135).

Research in the Swedish PHC setting is considered of increasing importance (106,109) and is currently expanding (136). However, RCTs evaluating non-pharmacological interventions are relatively rare in this setting. Therefore, PHC staff generally has little experience in participating in this type of research. In addition, the reimbursement system does not include well-defined incentives for research in PHC (136).

6 METHODS

6.1 RESEARCH STRATEGIES

Research paradigms are basic belief systems or worldviews that guide researchers in the choice of research methods but also in ontologically and epistemologically fundamental ways (137). Ontology here refers to the “reality” that is being investigated, while epistemology describes the relationship between this reality and the researcher (138). Methodology in turn refers to the techniques that researchers use to investigate reality (137).

Quantitative methods are closely related to the positivist research paradigm where the underlying assumption is that one true reality exists independently from its surroundings (realist ontology) and can be objectively observed by the researcher without influencing or being influenced by it (dualist and objectivist epistemology) (137). In this research paradigm, experimental methodologies are often used to test hypotheses in order to generalise the results to larger populations (137). Random sampling is recommended to obtain representative samples of the target population (139). Quantitative data is usually presented in numbers, collected through standardised measures and analysed with statistical methods (140). The advantage of quantitative methods is that they can be used to measure the reactions of many individuals to a limited set of questions, while the advantage of qualitative methods is that they can produce a wealth of detailed information about a smaller number of individuals (140).

Qualitative methods are often associated with the constructivist research paradigm where the underlying assumption is that there are multiple realities that are socially constructed, context dependent (relativist ontology) and created in the interaction between the researcher and the informants (transactional and subjectivist epistemology) (137). In this research paradigm, hermeneutical and dialectic methodologies are commonly used to reconstruct previously held

constructions (137). Purposeful sampling is usually applied in this type of research to gather data from those with the most relevant experience of the phenomenon under study (141). Qualitative data is often presented in text, collected through interviews, field observations or documents and analysed to identify patterns that are context-specific but possible to extrapolate to other settings (140). Qualitative data can be analysed in different ways, for example inductively (based on patterns found in the data) or deductively (based on a pre-defined theory) (142).

Even if quantitative and qualitative methods produce what may be viewed as opposing forms of knowledge, they are increasingly mixed and considered complementary to each other (127,128). The primary philosophy of mixed method research, which combines quantitative and qualitative research methods, is that of pragmatism (143). According to the pragmatist position, knowledge is viewed as a tool for action, focusing on concrete problems in society and on people's everyday experiences (144). A research method in itself is not considered better than another one but dependent on the interest (144). Different methods are not in competition with each other, because they each serve a different purpose (144).

This thesis applies both quantitative and qualitative research methods in a set of related studies, complementing each other to explore and evaluate different aspects of TCP. The methods have been chosen based on the interest of each study to increase knowledge but also to inform policy and practice regarding tobacco cessation and related inequalities in health. The studies have been conducted from the perspective of individual patients and healthcare providers, rather than on the perspective of organisations or society even if implications have been identified on multiple levels. Therefore, this thesis is considered well-aligned with the pragmatist position.

6.2 OVERVIEW OF STUDIES

The thesis consists of four sub-studies that are based on different study designs and methods. All studies were conducted in the same setting. In Study I, patients, PHC providers and experts were interviewed to inform the design of TCP. After the intervention was developed, its' effectiveness was evaluated in Study II. In Study III, PHC providers that participated in Study II were interviewed to explore their perceived barriers and facilitators of implementing TCP. In Study IV, patients that participated in Study II were interviewed about their experiences of tobacco cessation and TCP. An overview of the sub-studies and how they are linked to each other is presented in Figure 2. Further details on the study characteristics in Study I-IV are presented in Table 2.

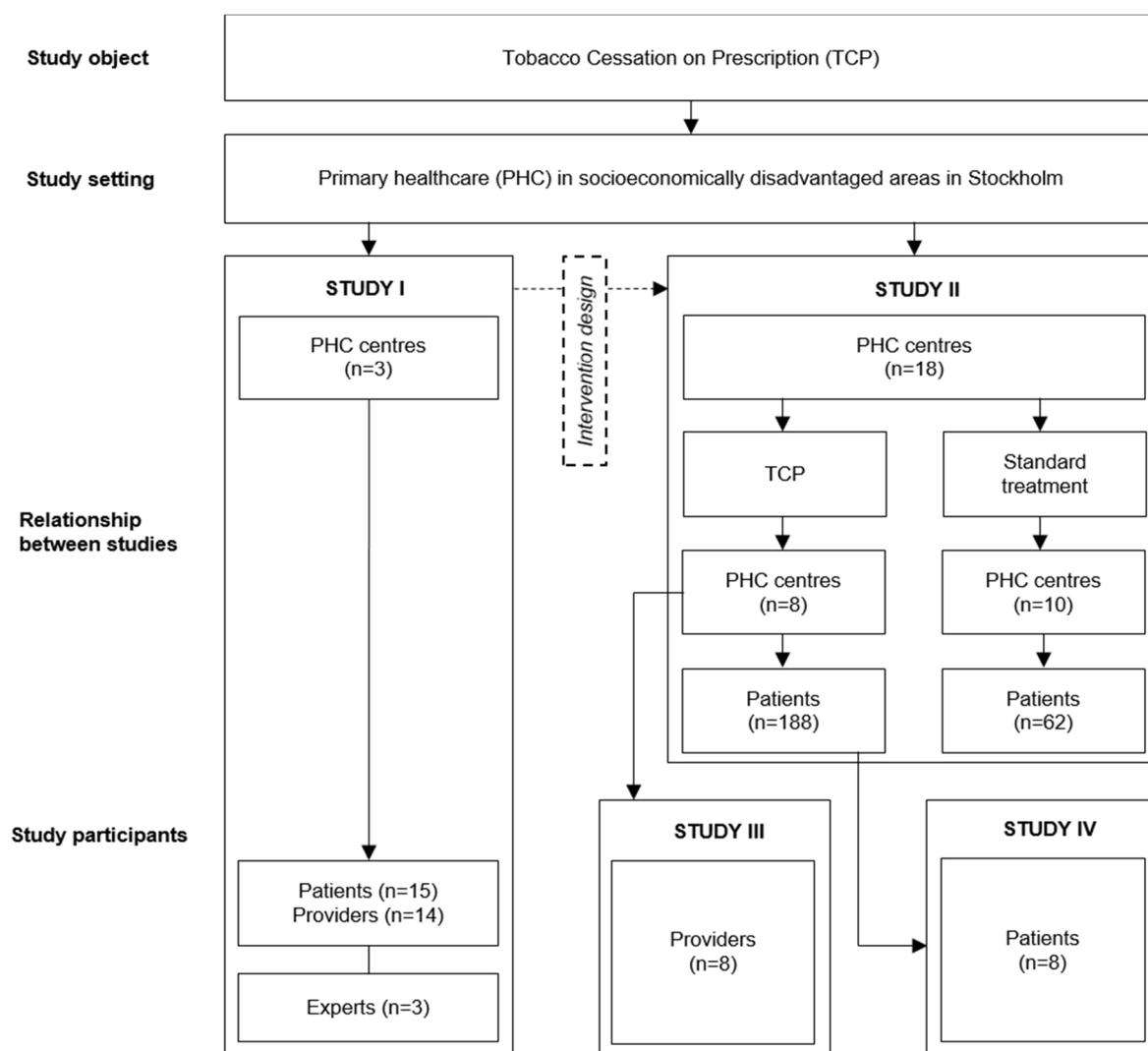


Figure 2. Overview of Study I-IV.

6.3 STUDY SETTING

All sub-studies were conducted in the PHC setting in Stockholm with a particular focus on PHC centres located in socioeconomically disadvantaged areas. This setting was chosen since the majority of the population has regular contact with PHC and socioeconomically disadvantaged groups more often seek care in PHC compared to other groups (14). The prevalence of tobacco use is also higher among lower socioeconomic groups (40) and therefore expected to be higher in this setting compared to more affluent areas. In addition, previous studies have shown that individuals are more likely to smoke in more deprived neighbourhoods even after adjustment for individual socioeconomic factors (145–148). Place of residence has also been identified as a contributor to health inequality in itself (149).

There are 215 PHC centres in Region Stockholm (150), out of which approximately 70% are privately operated (151). The PHC centres that participated in the sub-studies were purposefully sampled based on an index that was originally developed to inform resource

allocation in this setting (152). The index is calculated based on factors that explain differences in health status between areas, including the income, educational level, and ethnicity of the population (152). This approach was chosen since it is recommended to focus on areas rather than communities (153) or individuals when trying to reach disadvantaged populations (154).

Table 2. Study characteristics.

	Study I	Study II	Study III	Study IV
Study focus	Perceived feasibility and optimal design of TCP	Effectiveness of TCP	Perceived barriers and facilitators of implementing TCP	Experiences of tobacco cessation and TCP
Study design	Exploratory qualitative study	Pragmatic cluster RCT	Exploratory qualitative study	Exploratory qualitative study
Study participants	Patients, providers and experts on other lifestyle interventions on prescription	Patients* from randomised PHC centres	Providers with personal experience of TCP from Study II	Patients with personal experience of TCP from Study II
Data collection	Semi-structured individual interviews	Patient questionnaires, documentation protocols and informal interviews with staff members	Semi-structured individual and focus group interview(s)	Semi-structured individual interviews
Data analysis	Conventional content analysis (inductive)	Descriptive statistics, regression modelling	Directed content analysis (deductive)	Inductive content analysis

*Daily tobacco users >18 years with Swedish social security numbers and permanent resident permits, fluent in Swedish or Arabic without ongoing treatment for tobacco cessation and cognitive impairment affecting voluntariness to participate

6.4 STUDY I

6.4.1 Study design

Study I was an exploratory qualitative study based on interview data from three informant categories. The aim of this study was to explore the perceived feasibility and optimal design of TCP from the perspective of patients, PHC providers and experts on other lifestyle interventions on prescription.

6.4.2 Sampling and recruitment

In Study I, patients (in the paper referred to as clients) and providers from three PHC centres and experts on other lifestyle interventions on prescription with willingness to participate were purposefully sampled and invited to take part in the study. Eligible patients included daily tobacco users over 18 years of age. These were identified and recruited by providers at the participating PHC centres. Eligible providers included licensed healthcare professionals that were identified and recruited by the researchers. Eligible experts were identified and recruited by the researchers based on their previous involvement in research projects on other lifestyle interventions on prescription. In total, approximately 50 informants were invited and 32 agreed to participate, out of which 15 were patients, 14 were providers and three were experts.

6.4.3 Data collection

Data in Study I was collected in February to May 2014 through 32 individual semi-structured interviews. The interviews were based on interview guides that were specifically developed for each informant category. Patients and providers were asked about their experiences of tobacco use and cessation, and their perceptions of TCP, including its optimal design. Patients were also asked about their health. Experts were asked about their experiences of other lifestyle interventions on prescription and how these could inform the design of TCP.

Twenty-eight of the interviews were conducted face-to-face, out of which 26 were conducted in private rooms at the PHC centres. One patient interview was conducted in a waiting room at one of the PHC centres and one provider interview was conducted at the interviewer's workplace. In addition, two patient interviews and two expert interviews were conducted via telephone. The location of the interviews was based on the informants' preferences.

The interviews in Study I were on average 30 minutes long. All but one was conducted in Swedish. This was conducted in Arabic in collaboration with a translator. All interviews were audio-recorded and transcribed verbatim. The interview in Arabic was transcribed and translated by a professional language agency. Field notes were also collected but not included in the data analysis.

6.4.4 Data analysis

Data in Study I was collected until no more emergent patterns were found (155) and analysed according to a conventional approach to content analysis (156). This approach was chosen since it is recommended when existing theory or research literature on the phenomenon of interest is limited (156). The transcripts were read several times to get an overview of the data. Text passages on TCP-related issues were then extracted and put together to constitute the unit of analysis. Meaning units were identified based on the manifest content of the transcripts (what was explicitly stated), abstracted inductively and labelled with codes (157). Differences and similarities between the codes were then analysed and combined to create sub-categories and categories. The credibility of the analysis was enhanced by random checks of the codes by another member of the research team and an independent researcher experienced in qualitative methods. Contradicting opinions were discussed until consensus on the final codes and categorisation of these was reached. The credibility of the analysis was also enhanced through member checking with two patients and three providers.

6.5 STUDY II

6.5.1 Programme theory

The programme theory of TCP is described below according to the first steps of intervention research as proposed by Fraser et al (130). The logic model of TCP is presented in Figure 3.

6.5.1.1 Outcome measures

The primary outcome of TCP was measured in self-reported point prevalence of 7-day abstinence (abstinence from all tobacco use during the 7 days preceding follow-up) and the secondary outcomes in prevalence of 3-month continued abstinence (abstinence from all tobacco use during the 90 days preceding follow-up), daily tobacco consumption (number of cigarettes per day during the last 7 days) among non-quitters, any cigarette quit attempt (total abstinence for at least 24 hours) among daily smokers and change in health-related quality of life (based on a weighted index value from 0 to 1 where 0 represents death and 1 represents perfect health) at 6 months after the intervention.

6.5.1.2 Mediators

Based on experiences of PAP and the results in Study I, TCP was expected to contribute to a more structured approach to tobacco cessation counselling among healthcare providers (117,158). Patients were also expected to feel more involved in their treatment with TCP (158). Furthermore, advice was expected to be taken more seriously by patients and their social environment when prescribed, potentially increasing patients' motivation, self-efficacy

and social support to quit (117,158). These mediators could in turn lead to a reduction in tobacco use and improve health and quality of life.

6.5.1.3 Materials, activities and inputs

TCP was inspired by PAP but adjusted to the tobacco cessation context. The original TCP prescription form was designed based on the national guidelines for tobacco cessation treatment in the Swedish healthcare setting (103) and on the results from Study I. The prescription form was then adjusted based on feedback from patients, healthcare providers, researchers and experts on tobacco cessation and other lifestyle interventions on prescription in Sweden. Minor revisions were also made to it after it was pilot tested for six weeks at a PHC centre located in a socioeconomically disadvantaged area in Stockholm. Further details on the development of TCP are provided in the study protocol for Study II (Appendix A).

TCP consisted of three core components; 1) person-centred tobacco cessation counselling from a qualified healthcare professional for at least 10 minutes, 2) an individualised prescription of tobacco cessation treatment and 3) follow-up on at least one occasion. The TCP prescription form included options for further counselling (individual, group or telephone-based counselling in PHC, dental care or at the SNTQ), pharmacotherapy (NRT, varenicline, bupropion), other measures for cessation (physical activity and other strategies to cope with withdrawal symptoms), follow-up (by telephone or revisit) and support for self-management and empowerment (questions for self-reflection and reference to mobile applications and websites). The prescription form was available on paper and electronically as a PDF-file that could be edited but it was not incorporated into the electronic medical record (EMR). The idea with TCP was that healthcare providers could use the prescription form as a basis for tobacco cessation counselling with the patient, discussing available treatment options and deciding together what option(s) that would suit the patient best. It was recommended that the patients in the study were given a copy of the filled out prescription form but the PHC providers were free to use the prescription form as they liked.

Inputs needed to provide TCP included financial resources and experts that could educate healthcare providers in tobacco cessation counselling and TCP. Before TCP was delivered, responsible PHC providers received three hours of training by representatives from the SNTQ and Region Stockholm in tobacco cessation treatment and 30 minutes of training by the researchers in the TCP method. A manual that described how the prescription form should be filled out and how it could be used in tobacco cessation counselling was also distributed in connection with the training of PHC providers.

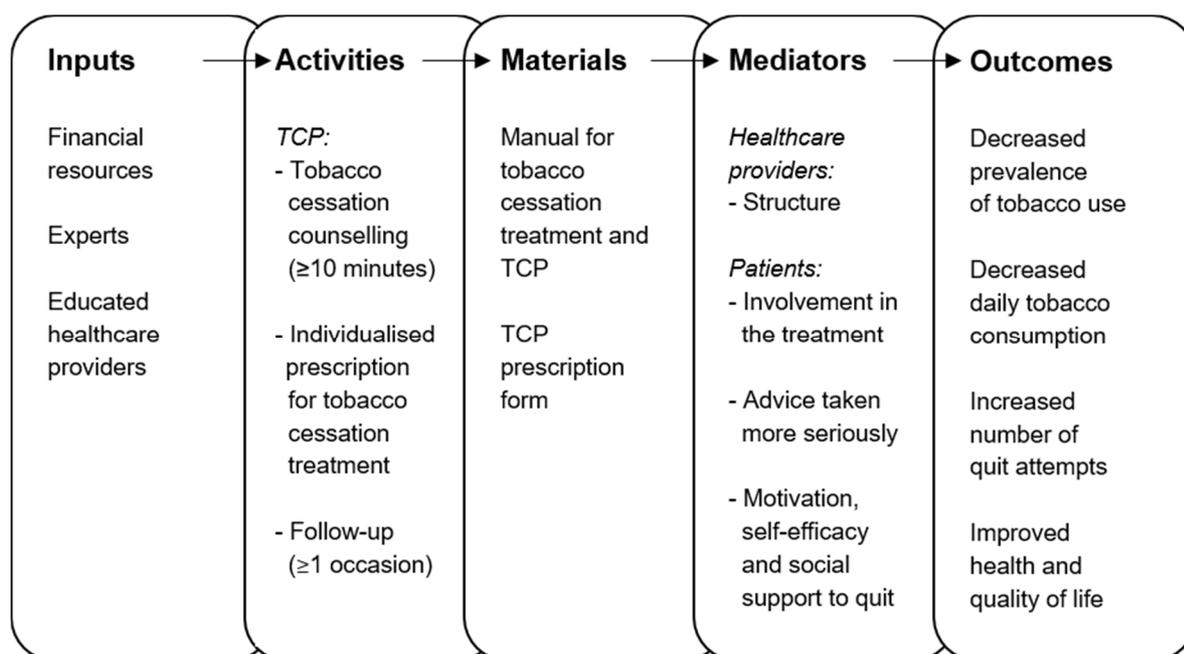


Figure 3. Logic model of TCP.

6.5.2 Study design

Study II was a two-armed pragmatic cluster RCT, evaluating the effectiveness of TCP compared to current practice for tobacco cessation treatment. The participating PHC centres were randomised with a computer-generated random allocation sequence at the cluster level to either the intervention group or the control group. The PHC centres were randomised in two sets with the first set of PHC centres paired based on their socioeconomic index and allocated to the study arms with a 1:1 ratio. In the second set, pairing was not possible as the allocation had to be adjusted for a higher attrition rate among PHC centres in the control arm. All patients that were recruited by PHC centres in the intervention group were offered TCP and all that were recruited by PHC centres in the control group were offered treatment according to their current practice for tobacco cessation. The minimum intervention in the control group was brief advice (<5 minutes of tobacco cessation counselling) but the PHC providers were free to offer whatever treatment they wanted as long as this was documented. The PHC providers in the control group also received a written manual and three hours of training in tobacco cessation treatment, but without any information about TCP, before their involvement in the study. The main difference between the treatment arms was whether a prescription form was used (intervention) or not (control). Outcomes were measured at baseline and after 6 months. Patients, PHC providers and researchers were not blinded to the treatment allocation but the patients were not informed about the treatment options in the study arms until after the study. The estimated sample size required was 464 participants per arm or 928 in total. Further details on the sample size calculation are provided in the study protocol (Appendix A) and manuscript for Study II.

6.5.3 Sampling and recruitment

Patients that were eligible to participate in Study II included daily tobacco users over 18 years of age with Swedish social security numbers and permanent residence permits that were fluent in Swedish or Arabic. Patients with ongoing treatment for tobacco cessation and cognitive impairment that could potentially affect the voluntariness of their participation, were excluded from the study.

Eligibility was assessed using a short screening questionnaire before patients were invited to participate. The patients were recruited by one to three appointed PHC providers at each PHC centre that were responsible for the treatment of patients in the study. Appointed PHC providers were mainly female nurses, specialised in diabetes or asthma/chronic obstructive pulmonary disease (COPD). Other staff members at the PHC centres could also screen patients and/or refer them to the responsible PHC providers for more information about the study. Staff members were informed about the recruitment procedure before their involvement in the study.

6.5.4 Data collection

In Study II, data on patients' sociodemographics, tobacco use, experiences of cessation and health was collected through paper-based questionnaires. The questionnaires were based on questions from the Swedish Public Health Survey 2014 (159), a questionnaire used in a previous study that evaluated the effectiveness of brief advice for tobacco cessation in Swedish dental care (160) and the Swedish and Arabic (Lebanon) version of EQ-5D-5L (161). The questionnaires were pilot tested in Swedish before the start of the study. They were also translated to Arabic and pilot tested before recruitment of Arabic speaking participants. The Swedish version of the questionnaires is presented in Appendices B and C (excluding the EQ-5D-5L due to copyright).

Measurements were conducted at baseline and 6 months after the intervention. In the follow-up questionnaires, the patients were also asked about the tobacco cessation support they had received during their participation in the study. The baseline questionnaires were administered by the appointed PHC providers at the participating PHC centres. The responsible PHC providers also documented the cessation treatment they provided in the EMR and in documentation protocols. The appointed PHC providers received written information and training in the documentation procedures before their involvement in the study. The researchers also conducted scheduled follow-up visits at the participating PHC centres every three to four months throughout the study to collect data and provide research support.

The follow-up questionnaires were sent to the participants via mail. Reminders were then sent every ten days. The first reminder was sent via mail with a new follow-up questionnaire

attached. The second reminder was sent via mail without any questionnaire attached. The last two reminders were sent via e-mail and Short Message Service (SMS) with the option to answer the questionnaire in a telephone interview. All follow-up questionnaires and reminders were sent by the researchers. Data on baseline characteristics of the participating PHC centres was also collected by the researchers through informal interviews with staff members.

6.5.5 Data analysis

Baseline characteristics of the treatment groups were analysed with descriptive statistics at the cluster and individual level. The results are presented as proportions for categorical variables and as mean values with standard deviations (SDs) for continuous variables. The binary outcomes point prevalence of 7-day abstinence, 3-month continued abstinence and any cigarette quit attempt among daily smokers at 6 months follow-up were analysed with logistic regression models and presented as odds ratios (ORs) with 95% confidence intervals (CIs). The continuous/count outcomes cigarettes per day among non-quitters and change in health-related quality of life were analysed with multiple linear and Poisson regression models. All analyses were conducted according to the intention-to-treat concept (139). Inference was targeted at the individual level and hierarchical models were used to account for clustering.

Model covariates at the individual level were defined before the start of the study and included age, gender, educational level, chronic disease diagnosis, nicotine dependence, previous quit attempts, ever-use of pharmacotherapy and importance and intention to quit (162). All baseline characteristics at the cluster level were also included. Non-significant covariates were excluded from the final models. The results from the hierarchical models were confirmed in non-hierarchical models without any material effects on the results. A sensitivity analysis was also conducted on the primary outcome, assuming that all non-respondents had continued their tobacco use at 6 month follow-up. The descriptive statistics were analysed in IBM SPSS Statistics 25 and the regression models were analysed in Stata 15.1.

6.6 STUDY III & IV

6.6.1 Study design

Study III and IV were both exploratory qualitative studies based on different approaches to content analysis of transcripts from semi-structured interviews with individuals that had personal experience of TCP. The aim in Study III was to explore perceived barriers and facilitators of implementing TCP from the perspective of PHC providers while the aim in Study IV was to explore patients' experiences of tobacco cessation and TCP.

6.6.2 Sampling and recruitment

The informants in Study III and IV were purposefully sampled from the intervention group in Study II. In Study III, eligible informants were PHC providers with willingness to participate that had at least 6 months experience of TCP and that actively worked at the PHC centres in Study II at the time of data collection. They were informed about the study during a routine follow-up visit in Study II and received written information about it before being invited to participate. In total, eight informants were invited to participate in Study III and all agreed to participate.

Patients that had responded to the 12 month follow-up in Study II (results not included in the thesis) in May 2018 to January 2019 with willingness to participate were eligible for inclusion in Study IV. They were sent an information letter via mail and followed up with telephone calls, voice mail and text messages, to invite them to participate. In total, 23 patients were contacted and eight agreed to participate.

6.6.3 Data collection

All data in Study III and IV was collected through semi-structured interviews in conversational form based on interview guides specifically developed for each study. In Study III, PHC providers were asked about their experiences and views on TCP to explore perceived implementation determinants of TCP. The questions were based on an Interview Guide Tool covering the constructs of the Consolidated Framework for Implementation Research (CFIR) (163) and freely adapted to the TCP context before being translated to Swedish. CFIR is a determinant framework, listing factors that have previously been identified as influential to implementation (135). It is based on 19 implementation theories and consists of 26 constructs and 13 sub-constructs divided into five domains (intervention characteristics, outer setting, inner setting, characteristics of individuals involved and process of implementation) (163). Because of the comprehensiveness of CFIR, it was not possible to ask the informants about all constructs included in the framework. The choice of CFIR constructs that the informants were asked about was therefore informed by the results from Study I.

In Study III, eight individual interviews and one focus group interview was conducted in September to October 2017 and April to May 2018. The individual interviews were conducted face-to-face in private rooms at the informants' workplaces, while the focus group interview with four of the informants was conducted face-to-face in a private room at the researchers' workplace. The interviews were on average 70 minutes long. Data on PHC provider characteristics was also collected in connection with their training in Study II and confirmed in connection with the individual interviews in Study III.

In Study IV, eight individual interviews were conducted to ask patients about their experiences of tobacco cessation and TCP. The interviews were conducted in December 2018 to January 2019. Four of them were conducted face-to-face in private rooms at local libraries close the informants' homes and four were conducted via telephone based on the patients' preferences. The interviews in Study IV were on average 42 minutes long. Questionnaire data from Study II was also used to present patient characteristics in Study IV.

All informants in Study III and IV but one patient that was interviewed via telephone were provided with a copy of the TCP prescription form during the interviews. All interviews in both studies were conducted in Swedish, audio-recorded and transcribed verbatim. Field notes were also taken during each interview to facilitate the transcription process, document the interview situation and methodological considerations but these were not included in the data analysis for either study.

6.6.4 Data analysis

When analysing the data in Study III and IV, both the manifest (explicit) and latent (implicit) content of the transcripts was taken into account (164). The transcripts from all interviews in each study were considered in the analyses with a focus on text passages that were related to the aim of the studies. In both studies, the transcripts were first read several times to get an overview of the data. Data was then coded independently by two researchers and compared with random checks to enhance credibility. Member checking was also conducted in both of the studies to further strengthen the credibility of the analyses.

In Study III, a directed content analysis was applied (156). This analysis was theory-driven and informed by CFIR. First, the constructs in CFIR were operationalised, then data was coded by identifying and labelling passages in the text describing barriers and facilitators of TCP. Next, the codes were deductively assigned to the constructs of CFIR. Member checking of the preliminary results from the individual interviews was conducted with four of the eight informants in a focus group interview. The data from the focus group interview was included in the final analysis by repeating the procedure above.

In Study IV, an inductive content analysis was applied (142,157). This analysis was data-driven and based on patterns found in the transcripts. First, passages in the text that were related to the patients' experiences of tobacco cessation and TCP were analysed by identifying meaning units (parts of the text that were related to each other through their content and context). The meaning units were condensed, abstracted (described and interpreted on a higher logical level) and labelled as codes. The codes were then grouped into sub-categories, categories and themes. Member checking of the preliminary results was conducted through individual interviews with two representatives of the target group.

6.7 ETHICAL CONSIDERATIONS

The studies included in this thesis all follow the ethical principles for medical research involving human subjects (165). All studies have also been conducted and reported according to best practice guidelines for qualitative research (Study I, III and IV) and RCTs with relevant extensions (Study II) (166–169). Ethical considerations of the studies are reflected upon below according to the Declaration of Helsinki (165).

6.7.1 Vulnerable groups and individuals

Ethical guidelines state that research on vulnerable and disadvantaged populations should be avoided if the knowledge can be obtained by conducting research on other populations (170). Studies I, II and IV involved patients that were recruited from PHC centres located in socioeconomically disadvantaged areas with the intention to reach tobacco users with a lower socioeconomic status. This was motivated by a lack of knowledge regarding the effectiveness of treatment and experiences of tobacco cessation in this target group and setting which could not be addressed if the research was conducted on other groups. Ethical guidelines also state that there should be a clear benefit and minimised risk to participate in research, particularly if the target group is already disadvantaged (170). A clear benefit was seen for all participants in Study II since they were offered support for tobacco cessation that could help them to quit their tobacco use and improve their health. Participation in Study I and IV was also perceived as beneficial as patients from a socioeconomically disadvantaged setting were given the opportunity to share their experiences and opinions regarding tobacco cessation and TCP. This is well-aligned with the notion that groups underrepresented in medical research should be provided appropriate access to participate in research (165). Patients that otherwise would not have been able to participate were also included in Study I and II by providing study materials and translation services in Arabic and in Study IV by offering telephone interviews as an option to face-to-face interviews.

6.7.2 Risks, burdens and benefits

There is a risk that the data collection process in the studies may have been perceived as intrusive since personal and sometimes sensitive information was collected (171), for example on tobacco use, health-related issues and work environment. All patient questionnaires and interview guides in Study I-IV were therefore pilot tested prior to the start of data collection on representatives from each target group and consulted with experts experienced in similar research to ensure appropriateness in language, content, sensitivity, time constraint, etc. The process for data collection was also designed to minimise the burden of participation, for example by scheduling interviews at a time and place of the informants' convenience (Study I, II and IV) and by sending follow-up questionnaires via mail with

prepaid envelopes to return them in and an option to answer in a telephone interview (Study II). All participants were also offered a 100 SEK gift certificate as an incentive to participate.

Participants in Study II were subjected to additional risks because of the experimental design of this study. Patients were expected to seek care for other reasons than tobacco cessation when they visited the PHC centres and were invited to participate. In this situation, offering support for tobacco cessation could be perceived negatively. This was minimised by providing information about the study and seeking informed consent to participate before treatment was initiated.

Despite many short- and long-term benefits of tobacco cessation, it may also cause temporary discomfort and withdrawal symptoms, including irritability, sleeplessness and cravings for tobacco (172). To minimise this, some patients in Study II were offered approved pharmacotherapies for tobacco cessation. Common side effects of NRT include skin irritation from patches and irritation to the inside of the mouth from gum and tablets (84), while side effects of bupropion include sleeping difficulties (173). Common side effects of varenicline include nausea, headache, abnormal dreams and sleeping difficulties (174). There are no serious side effects associated with NRT (84) and the prevalence of serious side effects is less than 1% for varenicline and bupropion (173,174). Despite some risk for side effects, these pharmaceuticals are used for a relatively short time period and the intake of chemicals is much lower during pharmacotherapy compared to during tobacco use. Thus, the benefits of using pharmaceuticals are considered to exceed the risks. Risks were also minimised in Study II by providing training and written information to PHC providers responsible for the treatment of patients in how to use these pharmaceuticals in accordance with existing recommendations and guidelines (9,103).

Since all tobacco use is harmful, support to quit should be offered to all tobacco users. However, Study II only focused on tobacco users at PHC centres located in socioeconomically disadvantaged areas. This was motivated by a higher expected prevalence of tobacco use and need for support in these areas compared to more affluent areas. Although patients that visited the participating PHC centres were expected to have a lower socioeconomic status, eligibility criteria on socioeconomic status was not be applied at the individual level due to ethical reasons. However, data on socioeconomic status was collected at the individual level to evaluate whether the intended target group was reached.

6.7.3 Informed consent

All participants received written and verbal information about the studies, ensuring that participation in the research was voluntary and that they had the right to refuse or withdraw their consent to participate at any time without reprisal. The participants were also given the opportunity to ask questions about the studies and have them answered before consent to

participate was obtained. In Study I, written informed consent to participate was obtained before the start of each face-to-face interview and verbal informed consent to participate was obtained before the start of each telephone interview. In Study II-IV, written informed consent was obtained from all participants before the start of data collection.

6.7.4 Privacy and confidentiality

Recruitment of patients in Study I and II, and part of the data collection in Study II was conducted by staff members at the participating PHC centres. Responsible staff in Study II received training and written information in the recruitment and data collection procedures prior to their involvement in the study to ensure proper data management. Data collected by the PHC providers in Study II was physically collected by the researchers during regular visits at the participating PHC centres to subsequently be handled and stored by the researchers together with all data from the other studies. Quotes presented in Study I, III and IV were de-identified and approved by the informants to ensure their confidentiality. Furthermore, participant characteristics in all studies and data in Study II was presented on an aggregate level for the same purpose.

6.7.5 Research Ethics Committee

Ethical approval to conduct this research was obtained from the Regional Ethical Review Board in Stockholm [ref: 2013/2264-32/2, 2015/207-31, 2015/1226-32, 2016/2080-32].

7 RESULTS

7.1 STUDY I - PERCEIVED FEASIBILITY AND OPTIMAL DESIGN OF TCP

In Study I, four categories and thirteen sub-categories were identified. The categories are presented in the subheadings below and the sub-categories are highlighted in italics in the subsequent paragraphs.

7.1.1 The prescription

Regarding the *content* of the TCP prescription form, the informants suggested that it could include information about the patient and contact person at the PHC centre, options for pharmacotherapy (NRT, bupropion, varenicline), counselling (via telephone or by referral to the SNTQ, support groups, tobacco cessation courses, lifestyle clinics) and physical activity/PAP. Information about the health benefits of tobacco cessation, support for self-management and empowerment were also suggested to be included. In addition, the

informants suggested that some non-evidence-based cessation support ideas could be included (e.g. eating fruit, engaging in cultural, outdoor and other activities, using self-help books or electronic cigarettes).

The *design* of TCP was often compared to the design of PAP. Furthermore, most of the informants described the TCP prescription form as paper-based as opposed to electronic.

7.1.2 Usage

Providers had different ideas about the perceived *target group* of TCP from including all tobacco users to focusing on those with smoking-related health problems like asthma/COPD and diabetes.

Patients suggested different time points for *when to receive TCP* from “whenever” or “as soon as possible” to once their health status worsens, improves, or when a decision to quit has been made.

Follow-up of the prescription was considered important by both patients and providers. Patients could be followed up face-to-face at the PHC centres, via telephone or by the SNTQ, at a time point suitable for the patient.

Providers had different perceptions regarding the *responsibility* for TCP from being a shared responsibility between everyone to being a specific responsibility of managers, certain occupational groups or clinics, such as physicians, nurses, occupational therapists, physiotherapists, dieticians or asthma/COPD clinics.

Moreover, practical *guidelines* for tobacco cessation treatment and for how to use TCP were requested by providers.

7.1.3 Expected results

Advantages of TCP were often related to a positive emotional meaning for patients. TCP was perceived to increase patients’ motivation to quit and emphasise the health consequences of tobacco use. For providers, TCP had a more practical meaning as it was seen as a tool for documentation and planning that could facilitate a more structured and standardised approach to tobacco cessation treatment. It was also perceived as a sign of support from the healthcare system.

For patients, *disadvantages* of TCP were related to a perceived lack of self-efficacy to quit their tobacco use. Providers reported more concerns about the prescription approach itself, worrying that TCP would be complicated, that they would use it in the wrong way and that

they would forget, or not follow-up TCP. They also reported insecurities about TCP's content, lack of evidence for the approach and accessibility for non-Swedish speakers. Other disadvantages mentioned by the providers were potential barriers to integrate the prescription into the EMR and a perceived lack of time and human resources to work with TCP.

Adherence to TCP was expected to be influenced by the self-efficacy of patients to quit their tobacco use and of providers to use TCP.

The informants expected the *perceptions of others* regarding TCP to vary from negative to more neutral and positive attitudes toward TCP.

7.1.4 Feasibility

To facilitate the *implementation* of TCP, the informants suggested that it would consist of a "package" of multiple components, linked to the EMR, counselling, additional information and relevant collaborators. It was considered important that the TCP prescription form was adaptable to the individual patient and that providers took patients' cessation preferences and goals into account before deciding together which treatment option(s) to choose, thereby increasing patients' involvement in the treatment. Other important implementation prerequisites mentioned were that TCP should be simple, structured, easily accessible and usable.

Regarding *organisational aspects*, the informants reported a need for time, resources, infrastructure, teamwork, motivation and competence among PHC providers to work with TCP. A good introduction to TCP for providers was also considered a facilitator. In addition, economic benefits of using TCP were considered beneficial for both patients and providers. Barriers mentioned were perceived difficulties in reaching the intended target group and in introducing new methods in PHC.

7.2 STUDY II - EFFECTIVENESS OF TCP

In Study II, 77 PHC centres were invited and 18 agreed to participate. The PHC centres were contacted from April 2015 to August 2016. Reported reasons for non-participation included high workload, staff turnover and lack of resources. Due to recruitment challenges, the PHC centres were randomised in two sets with a total of eight PHC centres randomly allocated to the intervention group and ten PHC centres allocated to the control group. More PHC centres were allocated to the control group in the second randomisation to account for uneven drop-out rates between the treatment groups after the first randomisation.

From February 2016 to August 2018, 311 patients were screened for eligibility and 250 were included in the study. From August 2016 to March 2019, the patients were sent the 6 month follow-up questionnaire. In total, 140 patients (56%) responded. The number of PHC centres recruited and retained, and the number of patients screened for eligibility, recruited and retained, was higher in the intervention group compared to the control group. An overview of the PHC centre and participant flow in Study II is presented in Figure 4. More details about the differences between excluded and participating PHC centres and patients are provided in the manuscript for Study II.

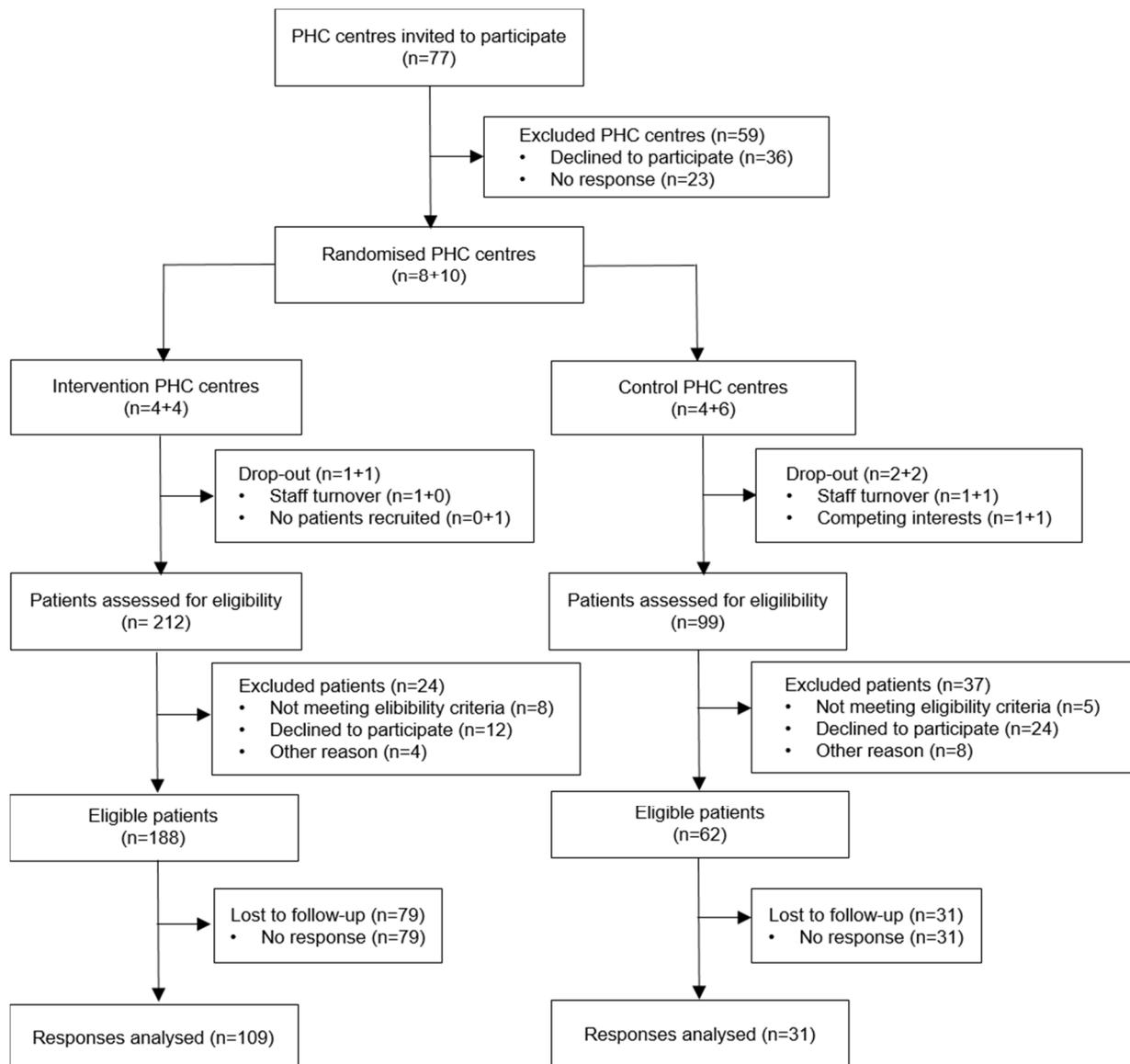


Figure 4. Overview of PHC centre and participant flow.

At the start of the study, PHC centres in the intervention group had fewer patients, more employees, lower socioeconomic index (more affluent) and were more often privately operated compared to those in the control group.

The mean age of the patients in Study II was 54.4 (SD 14.5) years. The majority of the patients had a chronic disease (70%), used cigarettes on a daily basis (98%), had attempted to quit in the past (77%) and had previous experience of pharmacotherapy (70%). Most of the patients also reported a high importance to quit (88%) and an intention to quit within 6 months (82%). The patients were similar in the treatment groups but patients in the intervention group were more often female, born in Sweden, had more previous quit attempts, experience of pharmacotherapy and lower prevalence of chronic disease compared to the control group.

According to the documentation protocols in Study II, patients in the intervention group received more counselling (mean number of sessions 2.6, SD 1.8 and mean number of counselling minutes 105, SD 56) compared to the patients in the control group (mean number of sessions 2.4, SD 1.5 and mean number of counselling minutes 89, SD 51). The general content of the counselling was similar in the treatment arms but there was a higher proportion of patients that were provided information about pharmacotherapy for tobacco cessation in the intervention group (87%) compared to the control group (67%). A lower proportion of communication problems was also reported in the intervention group (9%) compared to the control group (23%).

In addition, a higher proportion of patients in the intervention group reported use of prescription drugs for tobacco cessation in the questionnaire at 6 months follow-up (47%) compared to the control group (23%). A higher proportion of patients in the intervention group also reported that the support they had received was considered sufficient (71%) when compared to the control group (52%). In total, 38 of 108 patients in the intervention group and 4 of 31 patients in the control group reported total abstinence from tobacco use during the 7 days preceding follow-up 6 months after the intervention. The crude OR for 7-day abstinence was 3.5 (95% CI 1.06 to 11.90). When adjusted for significant covariates, the OR for 7-day abstinence increased to 5.4 (95% CI 1.57 to 18.93). Both associations were statistically significant. The crude OR for 3-month continued abstinence was 3.4 (95% CI 0.96 to 11.98). This association was not statistically significant. In the adjusted analysis, the OR for 3-month continued abstinence increased to 6.4 (95% CI 1.30 to 31.27). This association was statistically significant.

There were no statistically significant differences between the treatment groups in the other outcomes (any cigarette quit attempt among daily smokers, number of cigarettes per day among non-quitters and change in health-related quality of life) at 6 months follow-up.

The sensitivity analysis of 7-day abstinence produced a similar crude OR (3.6, 95% CI 1.20 to 10.95) but a lower adjusted OR (3.5, 95% CI 1.18 to 10.30), both with statistically significant associations.

7.3 STUDY III - PERCEIVED DETERMINANTS OF IMPLEMENTING TCP

The results from Study III are presented below according to the pre-existing domains, constructs and sub-constructs of CFIR. The domains in CFIR are used as subheadings, while the constructs and sub-constructs are emphasised in italics in the subsequent paragraphs. Since the study was conducted prior to any formal implementation of TCP in standard practice, the process of implementation domain in CFIR was not represented in the data.

7.3.1 Intervention characteristics

Regarding *evidence strength and quality*, the informants mainly reported positive outcomes of TCP among their patients even if relapse and inability to quit was also mentioned. Reported *relative advantages* of TCP included perceived increased self-efficacy in working with tobacco cessation among providers and involvement in the treatment among patients, more comprehensive counselling and advice being taken more seriously by patients with TCP. TCP was also considered flexible as it was *adaptable* to the individual patient and could be used in many different ways.

TCP was not perceived as *complex* even if time and experience was needed to learn the method. Furthermore, the *design quality and packaging* of TCP was perceived positively. However, which parts of TCP that were found valuable differed between the informants.

It was considered beneficial to use the TCP prescription form and Motivational Interviewing as a basis for the counselling, and to connect it to the patient's health status, tobacco use and previous experiences of tobacco cessation. Waiting room advertisement, guidelines for TCP and integration of the TCP prescription form into the EMR was also considered positive.

TCP was not perceived as costly but the *cost* of educating PHC providers in how to use TCP was considered a potential barrier to implementation. At the same time, tobacco cessation was perceived as cost-effective and important to allocate resources to, including the implementation of TCP.

7.3.2 Outer setting

Regarding *patient needs and resources*, the informants perceived tobacco use and the need for cessation support among patients in the given target group as high. Access to treatment was facilitated by regular contact with the target group, awareness of treatment options among patients and offered support from providers. Access could be further improved by providing information in different languages, reducing the cost of treatment and offering different types of counselling according to the patients' needs. A long-term perspective, positive attitude towards treatment and motivation, self-efficacy and social support to quit

among patients was considered beneficial. Experienced consequences of tobacco use, a positive experience of the treatment and a good relationship between the provider and the patient was also perceived positively.

TCP was perceived as a patient-centred approach that could support patients in quitting. However, the informants reported that some patients found TCP repetitive and difficult. The informants were also concerned that the TCP prescription form could be perceived as either demanding or redundant for patients depending on their motivation to quit.

The informants also reported several barriers for patients to quit their tobacco use, including lack of motivation and self-efficacy to quit, lack of knowledge about health risks of tobacco use and benefits of quitting, negative attitude and experiences of treatment, lack of knowledge and trust in treatment and low adherence to treatment. Long-term tobacco use, lack of consequences from tobacco use and weight gain were also mentioned as barriers to quit.

Lack of cessation support from providers and fear of disappointing or being judged by a provider were other perceived barriers. Access to treatment was further limited by costs of treatment, long waiting times and a focus on face-to-face counselling. Peer pressure, exposure to tobacco in the social environment and other health and social problems were also perceived as barriers for patients to quit.

Regarding *cosmopolitanism*, the informants were externally linked to colleagues at other PHC centres and in dental care, pharmacies, the pharmaceutical industry and municipalities. Some patients were also referred to the SNTQ for further treatment. Miscommunication and underutilisation of these collaborations were mentioned as barriers.

External policies and incentives that were perceived as facilitators included societal and political support, clinical guidelines and quality performance indicators for tobacco cessation, as well as financial reimbursement for related activities. Barriers included restrictions for nurses to prescribe some pharmacotherapies for tobacco cessation, lack of reimbursement for telephone counselling and longer patient visits.

7.3.3 Inner setting

Structural characteristics that were perceived to facilitate the implementation of TCP included continuity and some autonomy in the work with tobacco cessation. Lack of these and staff turnover were identified as barriers to implement TCP. Regarding *networks and communications*, clear responsibilities, routines, communication and collaboration with colleagues to work with tobacco cessation were considered facilitators. To have responsible staff for this work was considered particularly important but support from colleagues,

redistribution of competing work tasks and an active discussion about tobacco cessation in PHC was also considered helpful. Unclear responsibilities, routines, communication, collaboration and lone responsibility for tobacco cessation were seen as barriers.

The *culture* at the PHC centres was that mainly nurses worked with tobacco cessation. The informants considered it important that all providers at the PHC centres worked with this but it appeared to be less common for other professions to do so at some of the PHC centres. The curative (rather than preventive) tradition in PHC was also mentioned as a barrier.

Regarding the *implementation climate*, the informants reported a *tension for change* as they expressed a need for more tools, routines, continuity, networks and collaborations to work with tobacco cessation. They also expressed a need for more action, experience and knowledge regarding tobacco cessation among providers and more time and resources allocated to work with this in PHC. TCP was considered *compatible* with the increasing focus on health promotion and disease prevention in PHC. It was also considered well-aligned with previous working methods without increasing workload. Tobacco cessation and related work was described to have a high *relative priority* in PHC but appeared to have a lower priority among colleagues. Quality improvement work and research at the PHC centres were perceived as facilitators to a positive *learning climate*.

Regarding *readiness for implementation*, *leadership engagement* was facilitated by support from managers to work with tobacco cessation but this varied between PHC centres. At the same time, the lack of *available resources*, including allocated staff, time, physical space and financial resources to work with tobacco cessation appeared to be the main barrier for implementing TCP.

Access to knowledge and information about tobacco cessation and TCP was also considered important. This included relevant competencies among providers, training in tobacco cessation and experience in working with behavioural change. Documentation and follow-up of tobacco use and cessation in the EMR was also considered a facilitator. Lack of staff specialised in tobacco cessation and lack of experience, knowledge and education in tobacco cessation were considered barriers, particularly among colleagues.

7.3.4 Characteristics of individuals

Knowledge and beliefs about TCP were mostly positive as TCP was seen as a support and a tool for providers. Most of the informants expressed trust in the TCP components pharmacotherapy and counselling. Lack of experience with TCP among colleagues was perceived as a barrier as this was often associated with a lower *self-efficacy* to use TCP among informants and their colleagues. In contrast, experience and prolonged use of TCP was perceived to promote self-efficacy in using TCP.

Most of the informants were enthusiastic about TCP and had implemented it in their daily practice. They intended to continue to use TCP and spread it to colleagues. However, some informants had discontinued their work with TCP due to external factors and were thus in earlier *individual stages of change*. High workload, stress and poor working environment had negative effects on the informants' *individual identification with organisation*.

Regarding *other personal attributes*, all informants expressed a personal interest and motivation to work with tobacco cessation. They promoted a non-judgmental approach in the counselling and described a personal routine for tobacco cessation treatment. They mentioned personal abstinence from tobacco use and experience of tobacco cessation as facilitators for working with TCP. In contrast, tobacco use among providers and a judgmental approach in the counselling were seen as barriers. Lack of motivation and interest among some colleagues to work with tobacco cessation were also perceived as barriers to implement TCP.

7.4 STUDY IV - PATIENTS' EXPERIENCES OF CESSATION AND TCP

In Study IV, two themes were identified; 1) *Needing individualised support to quit, taking differences in patients' experiences of tobacco use and cessation into account*, which focused on individual factors of tobacco cessation and TCP and 2) *Needing a supportive environment to facilitate tobacco cessation*, which focused more on contextual factors. In addition, six categories and eighteen sub-categories were identified. The categories are presented in the subheadings below and the sub-categories are emphasised in italics in the subsequent paragraphs.

7.4.1 Impact of health and wellbeing on tobacco use

The informants' *knowledge and attitudes towards health risks of tobacco use* revealed that tobacco-related health problems were a motivation for them to quit, particularly if they were aware of and afraid of falling ill from these diseases. Health benefits of quitting were also mentioned as facilitators to quit.

Informants that had *experienced consequences of tobacco use* were generally more motivated to quit. At the same time, some of the informants perceived that it could be too late to quit if they became seriously ill. Still, several informants reported health-related events as reasons for quitting.

Furthermore, *life stress and other health problems* were perceived as reasons for both using tobacco and for not being able to quit. Stress was also reported as a reason for increased tobacco use. Examples of stressors included loneliness, loss, illness or death among friends and family, mental illness and pain. Wellbeing was thus considered an important facilitator for cessation.

7.4.2 **Contradictory attitudes and experiences regarding tobacco use**

The informants viewed *tobacco use as the individual's responsibility*, saying that it was up to each person to decide if and when to quit their tobacco use. At the same time, tobacco use was described as highly addictive and comparable to other substance abuses. *Tobacco use* was also viewed *as an addiction manifested in different ways*, for example as a habit, a situation-specific behaviour or a way of coping with stress.

Furthermore, the patients reported *predominantly negative feelings about tobacco use*, expressing disgust with the smell and taste of tobacco, inconvenience or dissatisfaction with being a smoker, self-anger, self-blame, shame and guilt even if it was also acknowledged that tobacco could taste good.

7.4.3 **Differing attitudes and experiences of tobacco cessation**

As attitudes, motivation and self-efficacy to quit varied among the informants, they reported *differing readiness to change*. They also reported *differing knowledge and attitudes toward cessation support*. Informants with high awareness of treatment options, high perceived need of support and trust in treatment appeared to be more open to engage in treatment in order to quit their tobacco use. Trust in pharmacotherapy was generally high even if some concerns about adverse events were reported. Trust in counselling was expressed by fewer informants. Some patients also expressed interest in the use of electronic cigarettes. Treatment preferences were perceived as individual.

Moreover, the informants reported *different experiences of tobacco cessation*. Most informants had personal experience of pharmacotherapy and counselling but use of electronic cigarettes and self-help materials were also mentioned. Some informants had decreased or quit their tobacco use while others had continued their use. Registration of tobacco use, followed by a stepwise decrease was considered helpful by many. Behavioural replacement strategies and pharmacotherapies were also considered useful but prescription drugs were often associated with nausea.

Regarding TCP, most of the informants could not remember if they had received the prescription form or not. However, they recognised the majority of its content. Different attitudes were reported toward TCP, with more negative attitudes if the purpose of the prescription form was unclear. Most of the informants reported that they perceived TCP as a form that could be helpful for providers rather than for them as patients.

7.4.4 **Professional cessation support from the healthcare system**

The informants reported that *well-organised cessation support from the healthcare system* was considered important and particularly helpful if provided frequently and regularly with

long-term follow-up by a tobacco cessation specialist. Collaboration and communication between different healthcare providers was also perceived as beneficial for patients as this increased formal support and follow-up.

Trust in the healthcare system also appeared to be important as this was reported to affect the informants' willingness to seek care for tobacco cessation. Different expectations between patients and providers was perceived to lead to disappointment and loss of trust. Trust in the tobacco cessation specialist was considered particularly important. This was facilitated by the competence, experience, enthusiasm, commitment, encouragement and empathetic approach of the provider and by prolonged contact with the same provider. However, the informants recommended to have more than one provider with this competence at each PHC centre since lone responsibility and lack of a substitute could lead to an interruption in the treatment and to negative outcomes for patients.

Most of the informants reported a *positive experience of cessation support* from PHC. Staff was considered friendly and the informants were generally satisfied with the support they had received. Many informants reported that they felt involved in their treatment and stated that the support they had received had helped them to reduce or quit their tobacco use. Still, some informants perceived the support as insufficient, particularly regarding long-term follow-up.

7.4.5 High impact of social environment on tobacco use

The informants perceived a *change in social norms regarding tobacco use* as tobacco use was described as a less acceptable behaviour now compared to before. This was reported to increase motivation to quit among some informants but also contribute to social isolation for those who were unable to quit their tobacco use. The informants also described the *impact of tobacco use in the social environment* on their own tobacco consumption. Tobacco use was described as a social activity, associated with a sense of community among smokers that was facilitated by exposure to tobacco through friends and family. At the same time, *social support in quitting* in the form of encouragement, quit attempts among friends and family and quitting together with someone else, were perceived as facilitators for the informants to quit.

7.4.6 Supportive societal structures facilitating tobacco cessation

The *availability of tobacco products and cessation support* was perceived to have an impact on the informants' tobacco use as this decreased when availability of tobacco was restricted. Use of cessation support was in turn promoted by high visibility and availability of NRT through marketing and over-the-counter sales.

The *affordability of tobacco products and cessation support* was also perceived to have an impact as the cost of tobacco products was reported as a motivation for some patients to quit.

Pharmacotherapies for tobacco cessation were also perceived as expensive. However, subsidies could encourage patients to use them.

Moreover, the informants reflected on the role of *legislation promoting tobacco cessation*, saying that comprehensive smoke-free air laws and pictorial health warnings on tobacco products led to inconvenience and could increase their motivation to quit.

8 DISCUSSION

To my knowledge, the studies included in this thesis are the first scientific studies to explore a prescription approach to tobacco cessation in the PHC setting in Sweden. The thesis contributes to the understanding of TCP, how it influences patients and providers and how it is perceived by these stakeholders in PHC with a focus on socioeconomically disadvantaged areas in Stockholm. In a wider sense, the thesis also explores general barriers and facilitators for PHC providers to work with tobacco cessation and how patients in this setting experience tobacco use and cessation. Here, influential factors are identified and discussed at the individual, social, organisational and societal level.

8.1 IMPACT OF TCP ON PATIENTS AND PHC PROVIDERS

The thesis found that TCP likely has an impact on PHC providers and patients, including their behaviour. For example, more patients in Study II were given advice about pharmacotherapy and to some extent also received more counselling with TCP compared to standard treatment. PHC providers also reported communication problems to a lesser extent with TCP. This could potentially be explained by an increased self-efficacy to work with tobacco cessation among PHC providers with TCP, as reported in Study III. In addition, Study I, III and IV found that TCP was perceived as a helpful tool for PHC providers that could support them in planning, providing and following up treatment, possibly offering a more structured approach to tobacco cessation in PHC. Similar findings have been reported in a recent study, where clinicians found that a lifestyle prescription form was a useful addition to verbal advice, supporting patient interaction and improving clinicians' confidence in giving lifestyle advice (175).

Patients in Study II also reported that they had used prescription drugs for tobacco cessation (mainly varenicline) and had managed to quit their tobacco use to a greater extent with TCP compared to standard treatment. Moreover, a higher proportion of patients reported that they were satisfied with the support they had received with TCP. As suggested in Study III, this could be explained by an increased involvement in the treatment among patients that made them perceive and respond to the advice they were given in a different way with TCP. These

factors may also explain the higher recruitment and retention rate of PHC centres and patients in the intervention group in Study II.

Previous research shows that tailored behavioural support and treatment with varenicline may be particularly useful in supporting socioeconomically disadvantaged groups to quit smoking (176). This, since nicotine dependence is generally higher in this target group compared to more affluent groups and varenicline is not used or offered to the same extent to these patients (176). This supports the idea that improved cessation outcomes with TCP may have been mediated by an increase in the use of varenicline among patients as a result of PHC providers offering this treatment to a greater extent or communicating it in a different way with TCP.

Regarding the intervention components of TCP, the PHC providers in Study III perceived TCP as a person-centred approach, appropriate for the target group and appreciated by the patients, while patients in Study IV mainly perceived the TCP prescription form as a document for PHC providers. Patients in Study IV also expressed uncertainty as to whether they had received the TCP prescription form or not, even if filled out prescription forms were documented in Study II for all but one of these informants. This suggests that the TCP prescription form itself did not have a direct impact on tobacco cessation from the patients' perspective. Instead, patients in Study IV stressed that counselling from a specialist and long-term follow-up was considered important. The importance of these components were also emphasised by the informants in Study I and III. Thus, the counselling and follow-up components of TCP appear to be the most important to patients. This is well-aligned with previous research on PAP, showing that the prescription form was forgotten by patients and mainly had a symbolic value compared to the subsequent support provided (120).

PHC providers in Study III generally had a positive attitude towards TCP. This could be explained by the involvement of relevant stakeholders when designing TCP, including the input provided by patients, PHC providers and experts in Study I. This is supported by previous research, stating that community involvement in intervention design has a positive impact on intervention uptake (154). However, scepticism toward the method was also expressed by some of the informants, particularly by PHC providers in Study I. At the time of Study I, TCP was still a hypothetical concept, while all PHC providers in Study III had at least 6 months personal experience of working with the method. Scepticism towards TCP could therefore be connected to a lack of experience, knowledge and self-efficacy to work with TCP, as reported by the informants in Study III. Differences in PHC provider attitudes towards TCP in Study I and III could also be explained by different compositions of PHC providers in these studies as the informants in Study I represented several different medical professions while the informants in Study III only included female nurses responsible for tobacco cessation treatment in Study II.

Lack of experience, knowledge and self-efficacy to work with TCP could be addressed by providing training and guidelines for how to use TCP to PHC providers, as suggested in Study I and III. Integration of the TCP prescription form into the EMR was also highlighted in these studies as a facilitator to implement TCP.

Furthermore, Study IV found that patients' attitudes toward the TCP prescription form were dependent on its perceived purpose as patients expressed a more negative attitude when the purpose of the TCP prescription form was unclear to them. This could be addressed by clearly communicating the purpose of the TCP prescription form to patients in the counselling. However, most of the perceived barriers to implement TCP were not related to TCP specifically but to working with tobacco cessation in PHC in general.

8.2 TOBACCO CESSATION IN THE PHC SETTING

The thesis further found that there appears to be a discrepancy between existing guidelines and policy goals to work with tobacco cessation and the resources that are allocated to do this in clinical practice. The PHC providers in Study III described a perceived societal and political support to work with tobacco cessation and that TCP was well-aligned with current changes and working methods in PHC. At the same time, they described a lack of organisational support, resources and mixed attitudes among colleagues to work with tobacco cessation. Lack of time was reported as the single most important barrier to work with tobacco cessation. This is supported by a study on tobacco cessation specialists in Sweden and Denmark, showing that most tobacco cessation specialists spend 0.5 to 2 hours per week on tobacco cessation, treating 0 to 2 new patients every month with varying support from managers and other colleagues (177). More than half of tobacco cessation specialists also report that they work alone (177). This is well-aligned with my experience that much of the tobacco cessation treatment in the study setting appears to be dependent on the efforts of individual PHC providers. This was first noticed when conducting Study II, as the participating PHC centres themselves suggested that a few selected individuals at each PHC centre should attend the training and be responsible for the recruitment and treatment of patients in the study. The responsible PHC providers were interviewed in Study III, showing that these were individuals with a personal interest and motivation to work with tobacco cessation. These individuals could be described as champions (in Swedish "eldsjälar").

Champions can be defined as people who 1) are internal to an organisation; 2) generally have an intrinsic interest and commitment to implementing a change; 3) work diligently and relentlessly to drive implementation forward, even if those efforts receive no formal recognition or compensation; 4) are enthusiastic, dynamic, energetic, personable and persistent; and 5) have strength of conviction (178). Champions have previously been identified as important facilitators to implementation (178). The patients and PHC providers in Study III and IV reflected on the benefits of having a person responsible for tobacco

cessation at the PHC centre, saying that this facilitated trust and a good relationship between the patient and the provider. However, they also reflected on the vulnerability of only having one PHC provider with this competence at each PHC centre since this person's absence could limit access to cessation treatment and lead to negative outcomes for patients. From the PHC provider perspective, lone responsibility to work with tobacco cessation was considered a barrier because colleagues often had limited possibilities to act as substitutes for responsible providers due to lack of knowledge, experience, motivation and self-efficacy to work with tobacco cessation. This also had implications for the sample size in Study II since responsible PHC providers were continuously changed due to staff turnover, sickness absence or competing priorities at the PHC centres, resulting in major challenges to recruit and retain the estimated number of PHC centres and patients in the study.

Previous studies have found that it is possible for single well-placed champions to implement new interventions within their own sphere of influence (179). Indeed, most of the responsible PHC providers that were interviewed in Study III reported that they were enthusiastic about TCP and that they had implemented it as part of their daily practice. These are trademarks of successful champions, as these tend to be intrinsically motivated and enthusiastic about the practices they promote (179). However, research shows that more than one champion is needed when new practices involve behavioural change or teamwork in inter-professional groups (179). This is consistent with the findings from Study III, where the informants reported that they were dependent on referrals from colleagues and that there was a need for more networks and collaborations to work with tobacco cessation. They also expressed a need to provide more tobacco cessation counselling to patients and a need for more tools, routines, continuity, experience and knowledge among providers and time, resources and attention to work with this in PHC. These organisational barriers need to be addressed to strengthen tobacco cessation services in PHC and to facilitate the implementation of TCP.

8.3 CESSATION SUPPORT FOR LOWER SOCIOECONOMIC GROUPS

The thesis identified several barriers and facilitators for patients to quit their tobacco use. For example, Study III found that access to treatment for patients was partly limited by how tobacco cessation services were currently organised in PHC with long waiting times, costs of treatment and a focus on face-to-face visits. These barriers may pose specific challenges for patients in disadvantaged populations to engage in treatment. Such barriers are particularly important to address since increased access to treatment can compensate for lower quit rates among lower socioeconomic groups (180).

The cost of treatment has previously been identified as a barrier to cessation in this target group (58,59) and was also mentioned by the patients in Study IV. A report from the OECD has shown that the proportion of lower educated individuals that refrain to seek medical care or retrieve prescribed medications due to financial reasons in Sweden is 2.3 times higher

compared to more affluent groups (181). Thus, a similar pattern could be assumed for tobacco cessation treatment among lower socioeconomic groups in this setting. To address this, subsidised treatment may be offered, as suggested by the informants in Study I, III and IV. Removing financial barriers by providing free or subsidised cessation treatment to disadvantaged populations has previously been recommended as an intervention to reduce tobacco-related inequalities in health (182).

Study IV further found that there was a need to individualise tobacco cessation treatment in PHC, taking patients' health status, life situation and various experiences of tobacco use and cessation into account. The importance of individualising TCP was also stressed in Study I and III. This is well-aligned with previous studies, emphasising the importance of individualised cessation support for socioeconomically disadvantaged groups to quit (12,58,183), acknowledging that most barriers to quit in this group are related to individual circumstances (176). Individualised support can be defined as support provided according to the patients' needs and preferences. However, the PHC providers in Study III reported that most of the tobacco cessation treatment in PHC was focused on individual face-to-face counselling even if other types of counselling may have been more suitable for the patients. Face-to-face counselling was prioritised since this was what the PHC centres were reimbursed for. Alternative forms of counselling could be provided to a greater extent to better meet the needs of this patient group. For example, telephone counselling was perceived as more convenient for the patients since this was free of charge and did not require any traveling on their behalf. Toll-free telephone counselling is already provided in several different languages by the SNTQ (184). Referrals to this service could improve access to treatment by reducing cost and language barriers. However, some patients may prefer telephone counselling with a cessation specialist at the PHC centre if a relationship has already been established with such a person. In this case, reimbursement may be needed to facilitate telephone counselling in PHC since there is a risk that other activities that are reimbursed otherwise will be prioritised (185) even if these are not the most relevant for patients.

8.4 NEED FOR INTERVENTIONS OUTSIDE THE HEALTHCARE SYSTEM

The thesis further found that there was a need to complement tobacco cessation treatment with interventions outside the healthcare system. This became clear in Study III and IV, where it was shown that tobacco users in socioeconomically disadvantaged groups face many barriers to quit that cannot be addressed by tobacco cessation treatment alone. This included factors like high availability and affordability of tobacco products, tobacco use and support to quit in the social environment and stress related to their life situation. Examples of policies that could address some of these issues include tax and price increases on tobacco products, advertising, promotion and sponsorship bans, anti-tobacco advertising and smoke-free legislations (24).

A new legislation in tobacco control recently came into force in Sweden, introducing licenses for retailers and increased coverage of smoke-free air laws to include bus stops, platforms, play grounds, sports facilities, etc (186). The patients in Study IV reflected on the influence of such policies on their tobacco use, saying that they could decrease their use due to inconvenience and motivate them to quit. Media reports show that the new legislation appears to have had an immediate effect on tobacco users as calls to the SNTQ increased by 24% and sales of NRT increased by 8 to 12% in the month following the introduction of the new legislation compared to the same time period the year before (187). Still, it is unclear how this will affect cessation outcomes and equity aspects in the long term. The patients in Study IV also stated that the cost of tobacco products was a motivation for them to quit. Previous studies have shown that tobacco users in lower socioeconomic groups are particularly sensitive to price increases when compared to other groups (12). Therefore, price increases via tax raises on tobacco products have been found to have a positive equity effect on socioeconomic disparities in smoking (12). Revenues from tax may also be used to fund cessation services and other tobacco control. However, tax increases were not included in the new legislation even if cigarettes are more affordable in Sweden compared to most other countries in the world (188).

Although the above mentioned policies all have the intention to reduce tobacco use, it is also important to consider the unintended consequences of such policies, including additional financial burden and increased stigma among those who are already disadvantaged and who are unable to quit (189). The patients in Study IV reported negative feelings about their tobacco use, expressing feelings of shame, guilt and self-blame towards this behaviour and avoiding smoking in public or in some social settings, indicating that they were subjected to tobacco-related stigma. Previous studies have shown that this can increase intention to quit (190,191) but also decrease self-efficacy (192). Therefore, it is important that policies that de-normalise tobacco use are combined with appropriate access to treatment. At the same time, it should be noted that stigma can be a barrier for patients to engage in cessation treatment (193,194). Thus, it is important that PHC providers apply an empathetic approach when working with tobacco cessation. This was highlighted by both patients and PHC providers in Study III and IV.

Another important determinant that was mentioned by the informants in Study III and IV was the social aspect of tobacco use. Patients in Study IV reported that their tobacco use was increased by exposure to smoking among friends and family and that social support to quit, either by encouragement or by quitting together with someone else, was a facilitator to tobacco cessation. Thus, it could be relevant to provide social support as an intervention to help tobacco users to quit. While there is some indication that this could be useful for disadvantaged groups in the short-term perspective (195), the evidence for this approach is relatively limited and more research is needed to inform how such interventions should be designed and evaluated (196).

8.5 METHODOLOGICAL CONSIDERATIONS

An overall strength of the thesis was that it included multiple perspectives of TCP, including those of patients, PHC providers and experts on other lifestyle interventions on prescription. Including the patient perspective in Study IV was considered particularly important since this was the intended target group of TCP. The studies also showed that there was a discrepancy between patients' own perceptions of TCP in Study IV and PHC providers' perceptions of how patients experienced the intervention in Study III. It was also considered a strength that the thesis applied both quantitative and qualitative methods to investigate different aspects of TCP.

In quantitative research, quality is often assessed using the concepts of validity, reliability and generalisability (197). Internal validity refers to whether a study investigates what it is meant to, while external validity or generalisability refers to whether the findings are applicable to other contexts (128,197). Reliability can in turn be defined as the consistency or stability of a measure (197). These concepts will be discussed below with regard to Study II.

Methodological considerations of Study I, III and IV will then be discussed according to quality criteria for qualitative research.

8.5.1 Considerations of the quantitative study

A strength of Study II was that it focused on tobacco cessation among socioeconomically disadvantaged groups who have a higher prevalence of tobacco use and need for support to quit. To reach this target group, several strategies were applied. These included patient recruitment by staff members at PHC centres located in socioeconomically disadvantaged areas, incentives to participate to both PHC centres and patients, study materials in several languages and access to bilingual staff members and translators (154). However, it should be noted that all patients in Study II did not have a low socioeconomic status. Still, the sample represented a twice as high proportion of lower educated and foreign born individuals compared to the general population in Sweden (198). Furthermore, patients in this study had a similar educational level but a higher proportion of individuals without employment (53%) compared to the participants in a study conducted in Swedish dental care (28%) (160). This could partly be explained by a higher proportion of older individuals in Study II. However, area deprivation has also been identified as a contributor to increased tobacco use, even after controlling for individual socioeconomic status (145–148). Therefore, this approach was considered relatively successful in reaching the intended target group.

A limitation of Study II was that it was not blinded. This was not possible as the responsible researchers had regular contact with the participating PHC centres throughout the study and also managed the data collected manually. However, the patients were not informed about the treatment options in the study arms until after the study in order to reduce the risk of biased psychological or physical responses to the treatment (199).

A possible threat to reliability was that all study outcomes were based on self-reports as opposed to biochemical verification. Biochemically verified outcomes are considered the golden standard in tobacco cessation research since there is a risk of underreporting tobacco use due to social desirability bias (200). However, a recent Delphi study among experts in the field found that self-reported outcomes are considered reliable and sometimes preferable to use (201). In Study II, self-reported data was considered more appropriate since biochemical validation would have required a physical visit to the PHC centre at 6 months follow-up, which was expected to have negative consequences on recruitment and retention of PHC centres and patients (162). In addition to cessation outcomes, health-related quality of life was measured with the generic instrument EQ-5D-5L. However, no clinically relevant changes were observed at 6 months. This may have been explained by the sensitivity of the instrument as EQ-5D-5L is more sensitive than the EQ-5D-3L (202) but most likely less sensitive compared to a condition-specific instrument (203). In addition, the follow-up period may have been too short to capture some of the greater health benefits of tobacco cessation.

Regarding external validity, this was facilitated by the pragmatic approach applied in Study II, where efforts were made to reflect real world conditions in the setting under study (131). Therefore, the results may be generalisable to similar settings, such as other regions in Sweden. However, a relatively large number of PHC centres and patients that were invited, declined to participate in Study II, increasing the risk of selection bias. Reported reasons for non-participation among the PHC centres were lack of organisational stability and resources to participate, indicating that the participating PHC centres may have had better prerequisites to work with tobacco cessation. Furthermore, most of the patients that participated in Study II reported a high importance and intention to quit their tobacco use, suggesting that they may have been more motivated to change behaviour and receive cessation support in the PHC setting compared to those who declined to participate. This and other recruitment challenges resulted in a much smaller sample size than anticipated. The attrition rate was also relatively high with a difference between those who dropped out and those who continued in the study, suggesting that the external validity of the findings may have been compromised (204).

8.5.2 Considerations of the qualitative studies

In qualitative research, a different terminology is often used to assess quality. Here, trustworthiness is a central aspect that is commonly presented based on the concepts of credibility, dependability, conformability and transferability (141). Credibility refers to the accurate identification and description of those participating in the research, while dependability can be defined as the stability of data over time and under different conditions (141). Conformability on the other hand, refers to the objectivity of the data's accuracy, relevance or meaning, while transferability refers to the potential for extrapolation of the findings to other settings or groups (141). These concepts will be discussed below in relation to Study I, III and IV.

Several strategies were applied to enhance credibility, dependability and confirmability in the qualitative studies. Multiple data collection methods, study sites and informant categories with different characteristics were used to obtain a broad understanding of TCP. The interview guides that informed the data collection were reviewed by experts in the field and pilot tested on representatives of the target population to ensure their appropriateness before the start of data collection. In the analyses, data was independently coded by several researchers and discussed until consensus was reached. The analyses were also reviewed by multiple researchers. Furthermore, member checking was conducted with representatives of each target group (except experts in Study I) to deepen the researchers' understanding of the data. Here, analysed data from each sample was used to explore whether the findings had resonance with the representatives' experiences (205). In Study III and IV, this was done by presenting the preliminary results to the target group representatives and asking them to reflect on their personal experiences related to the results. They were also asked to address unfamiliar or unclear findings, to elaborate on important aspects that may have been missed and to prioritise what aspects of the findings that they considered were the most important. The latter partly informed the interpretation of the results, for example that lack of allocated time to work with tobacco cessation was considered the most important barrier to implementing TCP in Study III.

A possible limitation in Study I was that it only considered the manifest (explicit) content of the transcripts in the analysis. This appears to have resulted in a more superficial analysis compared to Study III and IV where the latent (implicit) content was also considered. Furthermore, Study I only included accounts that were directly related to TCP in the analysis, possibly disregarding the influence of context and other aspects of tobacco cessation that could have been important to consider when designing the intervention. An increased understanding of these aspects was however explored in Study III and IV.

Study I and IV applied an inductive approach in the data analysis. This was considered appropriate since TCP is a new phenomenon that to my knowledge has previously not been explored. In Study III however, a deductive approach was used where both data collection and analysis was informed by CFIR. This was considered a methodological strength since the application of a theoretical framework that had identified important determinants to implementation in the past allowed for many barriers and facilitators of TCP to be captured that otherwise could have been missed. This could also enhance the transferability of the results in Study III to other settings. A limitation of CFIR was that it did not take the interaction between the constructs into consideration. There was also some perceived overlap in the constructs of CFIR when conducting the analysis. This was addressed by operationalising the constructs before the data analysis was initiated and by involving several researchers in reviewing the analysis.

Regarding transferability, the context and the informants have been described in detail for all studies to enable extrapolation of the findings to other settings. The informants' reports

regarding TCP may be relatively context-specific but some of the other experiences that the informants reported regarding tobacco cessation and determinants to implement tobacco cessation treatment and health promotion in PHC were similar to those reported in previous studies. This suggests that part of the findings in these studies could be transferable to similar settings, such as other regions in Sweden. At the same time, it should be noted that the views of the informants in Study I and IV may have been different from the views of those who declined to participate in these studies. For example, the informants may have had a more positive attitude towards TCP and tobacco cessation in PHC. The risk for this was avoided in Study III since all PHC providers that were invited, agreed to participate in this study. The informants in Study III share many characteristics with tobacco cessation specialists in Sweden and Denmark (177), wherefore the results from this study may be transferable to this target group. However, the PHC providers in Study III may be different from PHC providers in general as they were all female nurses with a personal conviction to work with tobacco cessation, reporting differences in attitudes toward this among their colleagues. Furthermore, smokers' experiences of tobacco use and cessation in Study IV may be different from those of snus users. Tobacco users in Sweden may also experience more stigma compared to other settings where this behaviour is more socially accepted.

8.5.3 Reflexivity

Reflexivity refers to an attitude of attending systematically to the context of knowledge construction at every step of the research process with a particular focus on the effect of the researcher (128). This includes identifying the researcher's beliefs, experiences and preconceptions and reflecting on their potential influence on the research (128). I have a background in public health with a specialisation in health promotion from my bachelor's degree and a specialisation in health economics, policy and management from my master's degree. This perspective and other background characteristics, such as being female, Swedish born and highly educated, may have influenced the interaction with the informants, as well as the data collection and analysis. For example, I had a more positivist approach to knowledge when I first started my doctoral studies. This is partly reflected in the wording in Study I where the terms respondent, participant and informant are used inconsistently and some of the results are reported as the number of informants that made a particular statement, etc. However, my approach to knowledge has changed over time as I have gained more experience and familiarity with qualitative research methods. My preconceptions regarding tobacco use have also broadened from mainly viewing this as an individual health behaviour to better understand the contextual factors related to tobacco use, including the sustainability and inequity issues that it causes.

The informants that I interviewed in Study III and IV included patients that were daily tobacco users and PHC providers that worked with tobacco cessation in the PHC setting with a focus on socioeconomically disadvantaged areas. I do not have any personal experience of

tobacco use or of working with tobacco cessation. Therefore, I could not personally relate to the experiences that the informants shared regarding tobacco cessation. At the same time, this meant that I did not have any preconceived ideas about what the informants would report based on my own experiences. However, differences between myself and the informants in age, gender, socioeconomic status, cultural background and language may have introduced misunderstandings or misinterpretations when collecting and analysing the data (206).

I do not have a clinical background or experience in working in PHC. However, I familiarised with the study setting in my role as project coordinator in Study II by conducting regular follow-up visits at the participating PHC centres every three to four months throughout the course of the study to collect data and to monitor the research progress. Therefore, I had a relatively good understanding of the PHC context when I conducted the interviews in Study III and IV. At the same time, my presence may have affected the results in Study II as the PHC providers may have modified their behaviour as a result of being observed (Hawthorne effect). However, this effect should have been similar in the intervention group and the control group since attempts were made to give the same amount of attention and support to all PHC centres in both study arms.

Furthermore, it is important to state that I was involved in the development of TCP. This may have caused me to subconsciously interpret findings regarding TCP more positively. With this in mind, I have been particularly careful to also acknowledge scepticism and disadvantages of the intervention and I have continuously tried to present TCP from the perspective of the informants while being mindful of my own preconceptions. I recorded field notes during the interviews to critically reflect on this and other methodological considerations. The data collection and analysis procedures were also reviewed and discussed with other researchers experienced in the study setting and not involved in the development of TCP to address this.

My involvement in Study II meant that I had established a relationship with the informants in Study III before conducting these interviews. This may have facilitated trust and openness in the interview situation that otherwise would not have been achieved. At the same time, the informants in Study III were aware of my role in the development of TCP. I had also instructed them in how to use TCP prior to their involvement in Study II. Thus, the informants in Study III may have been less inclined to report perceived disadvantages with TCP due to social desirability bias (207). However, I did not have an established relationship with the informants in Study IV when they were interviewed. The informants in this study were also unaware of my role in the development of TCP to minimise the risk for social desirability bias regarding TCP. Still, there was some risk for social desirability responses in this study due to the potential power imbalance between myself and the informants and due to the sensitivity of the topic (208).

8.6 IMPLICATIONS FOR RESEARCH

This thesis provides an initial understanding of TCP in the PHC setting with a focus on socioeconomically disadvantaged areas in Stockholm. However, more research is needed to evaluate the long-term effectiveness of TCP in the given setting. The cost-effectiveness of TCP may also be relevant to evaluate to inform proper allocation of society's scarce resources. Future studies should also evaluate the effectiveness of TCP in other settings. Adaption of TCP to the local context should then be considered. It is also recommended that more implementation research is conducted on TCP and that the perspectives of other stakeholders in tobacco control are explored in relation to this intervention.

Future research should also evaluate the equity impact of tobacco control interventions in Sweden and how they affect tobacco use in different socioeconomic groups. This is important to address inequalities in health caused by tobacco use. For evaluation of tobacco cessation treatment in the PHC context this includes assessment of tobacco use, access to treatment, use of services and cessation outcomes. The equity impact of national policies, such as smoke-free air laws and tax increases should also be evaluated.

8.7 IMPLICATIONS FOR POLICY AND PRACTICE

TCP is an intervention that is intended to be delivered in the PHC setting after exposure to daily tobacco use, either to prevent disease or minimise harm among tobacco users who are already experiencing health problems from their use (policy entry points C and D in Figure 1).

TCP appears to produce relatively large effect sizes with regard to cessation outcomes when compared to other tobacco cessation interventions (see Table 1). This is achieved with relatively small means as TCP consists of counselling for a minimum of 10 minutes, an individualised prescription for tobacco cessation treatment and follow-up on at least one occasion, and does not differ greatly from standard practice. TCP also appears to be acceptable, feasible and appropriate from the perspective of PHC providers responsible for tobacco cessation treatment in the given setting. In addition, patients were generally positive toward the tobacco cessation counselling and follow-up components of TCP. Thus, it may be relevant to implement TCP in the study setting. At the same time, some scepticism was reported when the patients did not understand the purpose of the TCP prescription form. Therefore, it is important if the prescription form is used with patients that its purpose is clearly communicated to them.

Suggested implementation strategies include development and distribution of guidelines and training for PHC providers in how to use TCP and integration of the TCP prescription form into the EMR. General education of PHC providers in tobacco cessation treatment may also be needed to address differences in attitudes and skills to work with tobacco cessation in

PHC. This is aligned with the WHO recommendation that training in tobacco cessation should be part of all healthcare professional training curricula and part of a mandatory training programme across healthcare professions (4). Increased funding, financial incentives and formal requirements to work with tobacco cessation could also increase the status of tobacco cessation in PHC and possibly have a positive impact on PHC provider behaviour.

Increased funding and organisational support could further strengthen the implementation of TCP and tobacco cessation treatment in general in the PHC setting in Stockholm. To fund cessation services and other tobacco control, it is recommended that taxes on tobacco products should be raised and increasingly allocated to such measures. A tax increase is also likely to have a pro-equity impact. However, it is important that such policies are combined with improved access to treatment for lower socioeconomic groups, for example by providing subsidised treatment and alternative forms of counselling to a greater extent. This suggestion is supported by previous research, showing that reimbursement can have a significant impact on the uptake and adherence to cessation treatment (209). Reimbursement can also increase the number of people who attempt and manage to quit (210). For example, provision of subsidised NRT has been shown helpful in supporting disadvantaged smokers to quit (211).

Lastly, it should be emphasised that no policies to address tobacco use will succeed in reducing inequalities if the social factors that breed these inequalities are not addressed (212). Effective policies to reduce tobacco use should therefore be supported by social and economic policies (policy entry point A in Figure 1) (212). This includes efforts to reduce poverty and social exclusion and to increase social protection and levels of education (182).

9 CONCLUSIONS

The thesis concludes that TCP may be effective in decreasing the prevalence of tobacco use in PHC with a focus on socioeconomically disadvantaged areas in Stockholm. PHC providers and patients in this setting perceive the TCP prescription form as a tool that can facilitate tobacco cessation treatment from the PHC providers' perspective, which in turn may help patients in this target group to quit their tobacco use. Since socioeconomically disadvantaged groups may experience specific barriers to quit, it is important that PHC providers adopt an empathetic approach in cessation counselling, taking patients' individual life situation, health status and experiences of tobacco use and cessation into account. However, the possibilities to work with tobacco cessation in PHC need to be strengthened in order to improve current cessation treatment and facilitate the implementation of TCP. PHC likely needs to reorganise their tobacco cessation services to improve socioeconomically disadvantaged patients' access to tobacco cessation treatment and better meet their needs. Other interventions outside the healthcare system are also needed to further support socioeconomically disadvantaged groups to quit their tobacco use.

10 SAMMANFATTNING PÅ SVENSKA

10.1 BAKGRUND

I Sverige är förekomsten av dagligt tobaksbruk ojämnt fördelad med en mer än tre gånger så hög förekomst av dagligrökning bland de som har lägst utbildning jämfört med de som har högst utbildning. Socioekonomiskt utsatta grupper påverkas även mer negativt av sitt tobaksbruk och har svårare att sluta med tobak jämfört med andra grupper. Tobaksavvänjning har visat sig förbättra hälsa och livskvalitet. Därför har man i Sverige tagit fram Nationella riktlinjer för sjukdomsförebyggande metoder som beskriver vilka behandlingar som är effektiva. Dessa rekommenderar att hälso- och sjukvården bör erbjuda alla dagligrökare med särskild risk behandling för att sluta röka men de beskriver inte hur detta arbete ska organiseras.

Primärvården kan ses som ett naturligt sammanhang där man kan erbjuda stöd för att sluta med tobak då primärvården har ett uttalat uppdrag att förebygga ohälsa. Majoriteten av befolkningen har dessutom regelbunden kontakt med primärvården och personer med låg socioekonomisk status söker oftare vård i primärvården jämfört med andra grupper. Dock visar utvärderingar att relativt få patienter som besöker primärvården identifieras som dagligrökare och erbjuds stöd för att sluta. Hög arbetsbelastning, brist på personal, tid och resurser har identifierats som hinder för att arbeta med levnadsvanor i primärvården.

Tidigare forskning visar att Fysisk aktivitet på recept (FaR) är en effektiv behandlingsmetod för att öka fysisk aktivitet och förbättra hälsa. I denna avhandling undersöks om en liknande metod skulle kunna användas för att främja tobaksavvänjning i primärvården med fokus på socioekonomiskt utsatta områden i Stockholm. Metoden kallas för Tobaksavvänjning på recept (ToR) och baseras på FaR, Socialstyrelsens riktlinjer för sjukdomsförebyggande metoder 2011 och på resultaten från en av delstudierna i denna avhandling. ToR består av personcentrerad rådgivning om tobak i minst 10 minuter, skriftlig individanpassad ordination av behandling för tobaksavvänjning och uppföljning vid minst ett tillfälle.

10.2 SYFTE

Det övergripande syftet med denna avhandling var att undersöka och utvärdera ToR som en primärvårdsintervention med fokus på socioekonomiskt utsatta områden i Stockholm. Detta undersöktes i fyra delstudier som var och en besvarade ett av följande specifika syften med fokus på den denna kontext:

- Studie I: Att undersöka den upplevda genomförbarheten och optimala utformningen av ToR bland patienter, vårdpersonal och experter inom andra livsstilsinsatser på recept

- Studie II: Att utvärdera effektiviteten av ToR jämfört med behandling enligt nuvarande rutiner för tobaksavvänjning, mätt i total avhållsamhet från tobak under de senaste 7 dagarna vid 6 månaders uppföljning
- Studie III: Att undersöka upplevda hinder och möjligheter med att implementera ToR bland vårdpersonal
- Studie IV: Att undersöka patienters erfarenheter av tobaksavvänjning och ToR

10.3 METOD

Alla delstudier i avhandlingen genomfördes i primärvården med fokus på vårdcentraler belägna i socioekonomiskt utsatta områden i Stockholm. Studie I var en explorativ kvalitativ studie där patienter, vårdpersonal och experter inom olika livsstilsinsatser på recept intervjuades om den upplevda genomförbarheten och optimala utformningen av ToR. Totalt genomfördes 32 semistrukturerade intervjuer med 15 patienter, 14 vårdgivare och tre experter. Intervjuerna analyserades med hjälp av konventionell induktiv innehållsanalys.

I Studie II utvärderades effektiviteten av ToR i en klusterrandomiserad kontrollerad studie där 18 vårdcentraler slumpades in i två olika grupper; till interventionsgruppen där alla patienter fick ToR och till kontrollgruppen där alla patienter fick behandling enligt vårdcentralernas ordinarie rutiner för tobaksavvänjning. Data på patienternas tobaksvanor och hälsa samlades in genom självrapporterade patientenkäter innan behandlingen och efter 6 månader. Data analyserades med beskrivande statistik samt regressionsmodeller.

Studie III och IV var explorativa kvalitativa studier där vårdpersonal och patienter med personlig erfarenhet av ToR intervjuades om deras erfarenheter av interventionen. I Studie III genomfördes åtta individuella intervjuer och en fokusgruppsintervju med åtta vårdgivare om deras upplevda hinder och möjligheter med att implementera ToR. Analysen baserades på riktad deduktiv innehållsanalys och utgick från det teoretiska ramverket Consolidated Framework for Implementation Research. I Studie IV genomfördes åtta semistrukturerade intervjuer med patienter för att undersöka deras upplevelser av ToR och av att försöka sluta med tobak. Dessa intervjuer analyserades med hjälp av kvalitativ induktiv innehållsanalys.

10.4 RESULTAT

I Studie I föreslog studiedeltagarna att ToR skulle bestå av en mall med information om patienten, evidensbaserade behandlingsalternativ för tobaksavvänjning, alternativ för uppföljning, andra åtgärder och stöd för egenvård. För patienter hade ToR främst en emotionell betydelse (ökad motivation att sluta, bevis på stöd från hälso- och sjukvården) medan det för vårdpersonal hade en mer praktisk betydelse (underlättande vid planering och

dokumentation). Upplevda utmaningar med ToR var ofta kopplade till en eventuell framtida implementering av metoden.

Studie II visade att fler patienter lyckades sluta med tobak vid 6 månaders uppföljning om de hade fått ToR (38 av 108 patienter) jämfört med standardbehandling för tobaksavvänjning (4 av 31 patienter). Odds för detta var 5,4 gånger högre i interventionsgruppen jämfört med kontrollgruppen efter justering för signifikanta kovariater. Denna skillnad var statistiskt signifikant.

Studie III visade att ToR upplevdes öka vårdpersonalens tilltro till sin egen förmåga att arbeta med tobaksavvänjning och patienters delaktighet i behandlingen vilket i sin tur upplevdes leda till mer intensiv rådgivning och att råd om tobak togs på större allvar av patienter. Brist på organisatoriskt stöd och resurser samt olika attityder hos vårdpersonal avseende arbetet med tobaksavvänjning upplevdes som hinder för att implementera ToR. Kostnader för behandling, långa väntetider och fokus på fysiska besök upplevdes även begränsa tillgången till behandling för socioekonomiskt utsatta patienter.

Studie IV visade att patienter upplevde ett behov av individanpassat stöd för att sluta med tobak som tar hänsyn till deras hälsotillstånd, erfarenhet och inställning till tobak och avvänjning. De upplevde också ett behov av en stöttande omgivning för att lyckas sluta, såsom professionellt stöd från hälso- och sjukvården, den sociala omgivningen och andra samhällsstrukturer. Ordinationsblanketten som ingår i ToR upplevdes mer som ett hjälpmedel för vårdpersonal än för patienter. Den verkade inte ha någon direkt inverkan på patienters tobaksbruk men individanpassad rådgivning från en specialist, ett empatiskt förhållningssätt i rådgivningen och långsiktig uppföljning upplevdes som viktigt.

10.5 SLUTSATS

Vårdpersonal och patienter upplevde ToR som ett hjälpmedel som kan underlätta vårdpersonalens arbete med tobaksavvänjning. ToR kan också vara en effektiv behandlingsmetod för att minska förekomsten av tobaksbruk i primärvården med fokus på socioekonomiskt utsatta områden i Stockholm. Eftersom socioekonomiskt utsatta grupper kan uppleva särskilda utmaningar med att sluta med tobak är det viktigt att vårdpersonal har ett empatiskt förhållningssätt vid rådgivning om tobak som tar hänsyn till patienters individuella livssituation, hälsa och erfarenhet av tobak och avvänjning. Dock behöver primärvårdens förutsättningar för att arbeta med tobaksavvänjning stärkas för att förbättra befintlig behandling för tobaksavvänjning och underlätta implementeringen av ToR. Primärvården behöver sannolikt omorganisera sina tjänster för tobaksavvänjning för att öka tillgängligheten av stöd för socioekonomiskt utsatta grupper och bättre möta deras behov. Andra interventioner utanför hälso- och sjukvården behövs också för att vidare stötta denna målgrupp att sluta med tobak.

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APPENDIX A – STUDY PROTOCOL FOR STUDY II

Protocol

A Cluster-Randomized Controlled Trial Evaluating the Effectiveness and Cost-Effectiveness of Tobacco Cessation on Prescription in Swedish Primary Health Care: A Protocol of the Motivation 2 Quit (M2Q) Study

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Abstract

Background: In Sweden, the prevalence of tobacco use is disproportionately high among socioeconomically disadvantaged groups. Previous research and clinical experience suggest that prescribed lifestyle interventions in the primary health care (PHC) setting such as Physical Activity on Prescription are effective in changing behavior. However, there is a lack of evidence for if and how such a prescription approach could be effectively transferred into the tobacco cessation context.

Objective: The aim of this trial is to evaluate the effectiveness and cost-effectiveness of Tobacco Cessation on Prescription (TCP) compared to current practice for tobacco cessation targeting socioeconomically disadvantaged groups in the PHC setting in Sweden.

Methods: The design is a pragmatic cluster-randomized controlled trial. The sample will consist of 928 daily tobacco users with Swedish social security numbers and permanent resident permits, recruited from 14-20 PHC centers located in socioeconomically disadvantaged areas in Stockholm County. The primary outcome will be measured in self-reported 7-day abstinence at 6 and 12 months after the intervention. The secondary outcomes will be measured in daily tobacco consumption, number of quit attempts, and health-related quality of life at 6 and 12 months after the intervention. Data will be collected through questionnaires and review of electronic medical records. Cost-effectiveness will be estimated through decision analytic modeling and measured by the incremental cost per quality-adjusted life year.

Results: In the first set of PHC centers participating in the study, eight centers have been included. Recruitment of individual study participants is currently ongoing. Inclusion of a second set of PHC centers is ongoing with expected study start in September 2016.

Conclusions: If TCP is found effective and cost-effective compared to standard treatment, the method could be implemented to facilitate tobacco cessation for socioeconomically disadvantaged groups in the PHC setting in Sweden.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 11498135; <http://www.isrctn.com/ISRCTN11498135> (Archived by WebCite at <http://www.webcitation.org/6kTu6giYQ>)

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KEYWORDS

tobacco use cessation; primary health care; vulnerable populations; randomized controlled trial; pragmatic clinical trial; cost-effectiveness analysis; Sweden

Introduction

Smoking is a major risk factor for more than 60 different diseases, out of which cardiovascular diseases, lung diseases and cancers are the most common [1]. In Sweden, tobacco use is estimated to cause approximately 12,000 deaths and 100,000 new cases of tobacco-related diseases each year [2], corresponding to 8% of the total disease burden in the country [3]. In addition to the negative effects that tobacco use has on the health and quality of life of the population [4], it is also associated with increased costs for the health care system and for society at large [5]. Currently, 20% of the general adult population in Sweden are daily tobacco users [6]. However, the prevalence of tobacco use is unequally distributed as it is almost twice as high in lower socioeconomic groups compared to higher socioeconomic groups [7].

Since tobacco cessation has been found to reduce the risk of premature morbidity and mortality caused by tobacco-related diseases [8], it is a prioritized area in Swedish public health policy [9]. Treatment guidelines for tobacco cessation in the health care setting have been issued both on the national level in Sweden [1] and the regional level, eg, in Stockholm County [10]. The guidelines recommend that health care providers should offer cessation support to all daily smokers [1]. Although tobacco cessation interventions are one of the most cost-effective interventions available in health care [11], the treatment intensity for tobacco cessation is relatively low in Sweden [12]. In addition, high-risk groups that have an increased need of support are often not reached by such health promoting activities [1]. This could partly be explained by a lower motivation, self-efficacy and social support for quitting, a limited understanding of the harmful effects of tobacco use, and a stronger addiction to tobacco among tobacco users in lower compared to those in higher socioeconomic groups [13]. Other influencing factors include targeted marketing by the tobacco industry and lower adherence to treatment [13]. Moreover, there is a lack of awareness in this target group regarding available treatment options and misconceptions regarding the use and effectiveness of such services [14]. In addition, costs related to seeking and completing treatment for tobacco cessation present particular barriers for socioeconomically disadvantaged tobacco users [14,15]. The need for a more systematic approach and improved access to cessation support for socioeconomically disadvantaged groups has recently been emphasized [16]. There is also a need for more knowledge and training for PHC staff in how to communicate with and empower disadvantaged groups for efficient health promotion [17,18].

Studies conducted on health care consumption in Stockholm in different social groups show that individuals with foreign background, low educational level and low income visit primary health care (PHC) more often than their counterparts [19]. The

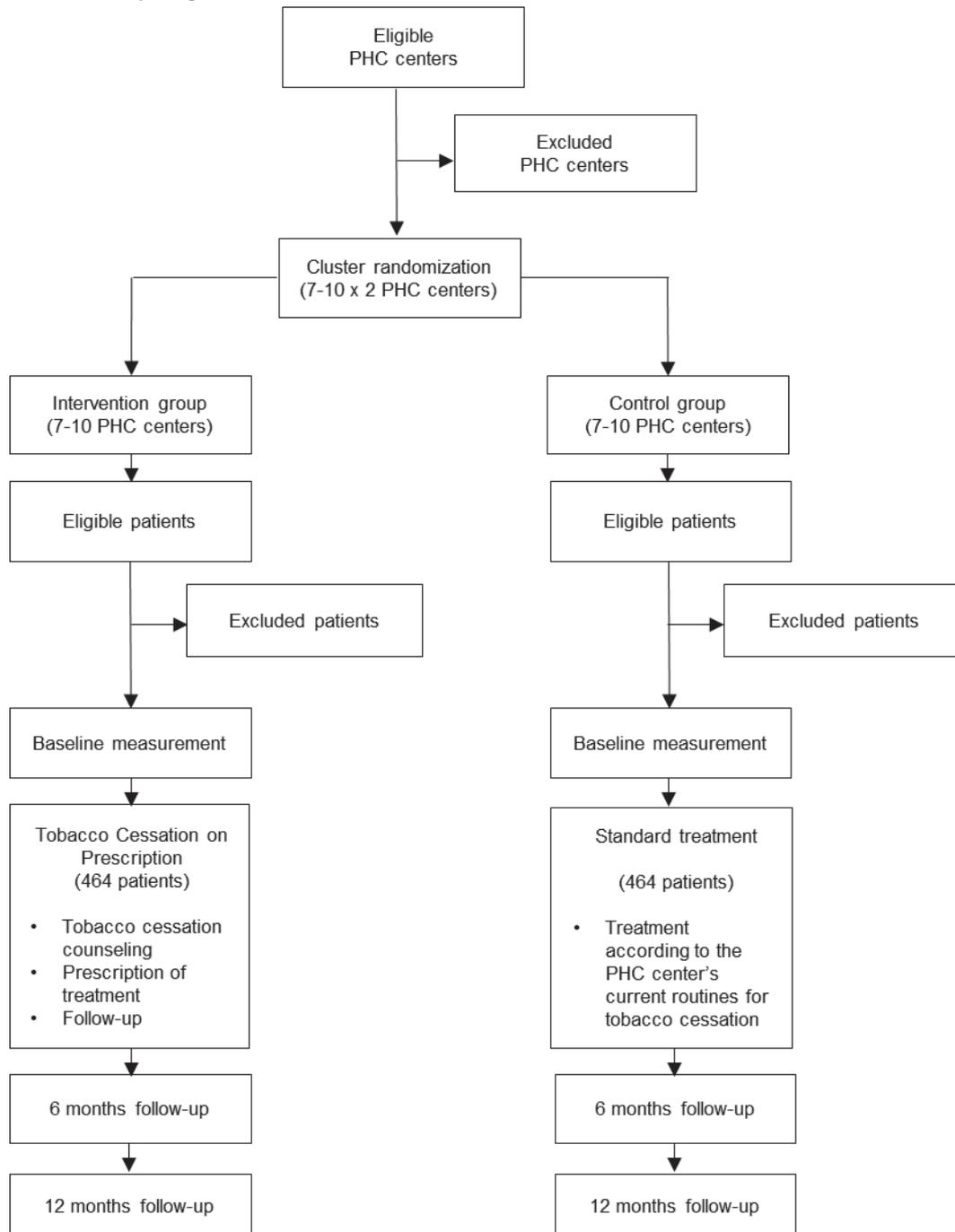
public has confidence in the health care system [20] and most tobacco users seek care for different health problems at PHC centers. In addition, 87% of patients are positive towards receiving advice on lifestyle changes from health care providers [20]. According to the Swedish Healthcare Act, PHC has the main responsibility for health promotion and disease prevention in the Swedish health care system [21]. Therefore, PHC can be seen as a potential platform to improve the reach of health promoting activities, such as tobacco cessation support, to socioeconomically disadvantaged groups.

In a recent study, the perceived feasibility and optimal design of Tobacco Cessation on Prescription (TCP) as a PHC intervention targeting disadvantaged groups in Sweden, was explored [22]. The study found that TCP was perceived as a useful tool for tobacco users and health care providers and that it could facilitate a more structured and effective approach to tobacco cessation in the future compared to current tobacco cessation practices in PHC [22]. Based on these findings, there is now a hypothesis that TCP could be implemented and prescribed in a similar manner as Physical Activity on Prescription (PAP). PAP has been found effective in changing behavior and improving health and quality of life and is already in use in the PHC setting in Sweden to prevent disease and promote health in the general population [23]. A prescription approach to tobacco cessation could potentially increase the treatment intensity of tobacco cessation in the PHC setting and thus lead to decreased tobacco use and improved health in the target population. The aim of this study is to evaluate the effectiveness and cost-effectiveness of TCP as PHC intervention targeting socioeconomically disadvantaged groups in Stockholm, Sweden.

Methods

Study Design

In order to evaluate the effectiveness and cost-effectiveness of the intervention, a two-armed pragmatic cluster-randomized controlled trial [24], with an economic evaluation as a component, has been chosen as the study design. In total, 14-20 PHC centers will be randomized to either intervention or control conditions with a 1:1 ratio. Study participants in the control arm will be offered standard treatment, while study participants in the intervention arm will be offered TCP as a complement to current treatment practices for tobacco cessation at the PHC center. Measurement of patient outcomes will be conducted at baseline and 6 and 12 months after the intervention. The trial has been approved by the Regional Ethical Review Board in Stockholm (ref: 2015/207-31, 2015/1226-32). The study details in this protocol are presented according to the SPIRIT 2013 Statement to ensure high quality in reporting [25]. The study design is presented in [Figure 1](#).

Figure 1. Flow chart of the study design.

Study Setting and Participants

Study participants will be recruited from participating PHC centers located in socioeconomically disadvantaged areas in Stockholm County, Sweden. Eligible PHC centers will be identified based on a socioeconomic index, which takes into account the income, educational level, ethnicity and health status of the population in a PHC center's catchment area [26]. Daily tobacco users over 18 years of age with Swedish social security numbers and permanent residence permits, fluent in one of the two most common languages in the study setting, Swedish or Arabic, will be eligible for inclusion in the study. Daily tobacco use will be defined as daily use of cigarettes, snus (smokeless tobacco) or other tobacco products for at least the last year.

Ongoing treatment for tobacco cessation and cognitive impairment affecting ability to participate in the study on a voluntary basis will be applied as exclusion criteria.

Sampling and Recruitment

PHC centers located in areas with low socioeconomic status in Stockholm County will be identified through the previously mentioned socioeconomic index [26], purposively sampled by the researchers and invited to participate in the study. The managers at the PHC centers will be contacted via telephone by the researchers and offered further information via email and a physical meeting before agreeing to participate in the study.

Study participants will be recruited by one to three appointed providers employed at each of the participating PHC centers.

However, all staff at the participating PHC centers will be able to refer patients to recruiting staff for more information about the study. In order to reduce selection bias, eligible participants will be identified through a short screening questionnaire before being invited to participate. Further information about the study will be administered by the recruiting staff at the participating PHC centers and written informed consent to participate sought before invited participants will be included in the study. Staff responsible for the recruitment of study participants will receive a brief training in the study design and recruitment procedure before the study start. Recruiting staff will also receive posters to help facilitate the recruitment of individual study participants. The recruitment period is expected to last for 18 to 24 months.

Interventions

Tobacco Cessation on Prescription (Intervention)

The TCP method is based on the PAP concept, which consists of person-centered counseling on physical activity, individualized prescription of physical activity, co-operation between prescribers and providers of physical activity, follow-up of the prescription, and a comprehensive manual that describes for which indications and how the method should be used [27]. In the TCP method, the components in PAP have been adjusted to the tobacco cessation context (see conceptual model in Figure 2 and full description of the core components below). The initial TCP prescription form was drafted by the researchers based on the national guidelines for tobacco cessation treatment in Sweden [1] and the results from the qualitative study that explored the perceived feasibility and optimal design of TCP [22]. The prescription form was then further developed based on an iterative process of feedback from waiting room interviews with patients, as well as workshops and written correspondence with health care providers, researchers and experts on tobacco cessation and lifestyle interventions already available by prescriptions in Sweden. The intervention design was also adjusted based on feedback from PHC providers that pilot tested the TCP method during a 6-week period at a PHC center located in a socioeconomically disadvantaged area in Stockholm.

Prior to the administration of the intervention, one to three PHC providers per center, responsible for the treatment of patients in the intervention group, will receive 4 hours of training by representatives from the Swedish National Tobacco Quitline (SNTQ) [28] and the Stockholm County Council (the regional authority and health care provider) in available treatment options for tobacco cessation and the TCP method. A manual which summarizes the training and describes how the prescription form should be filled out and how it can be used in tobacco cessation counseling, has been developed and will be distributed in connection with the education of PHC providers in the intervention group.

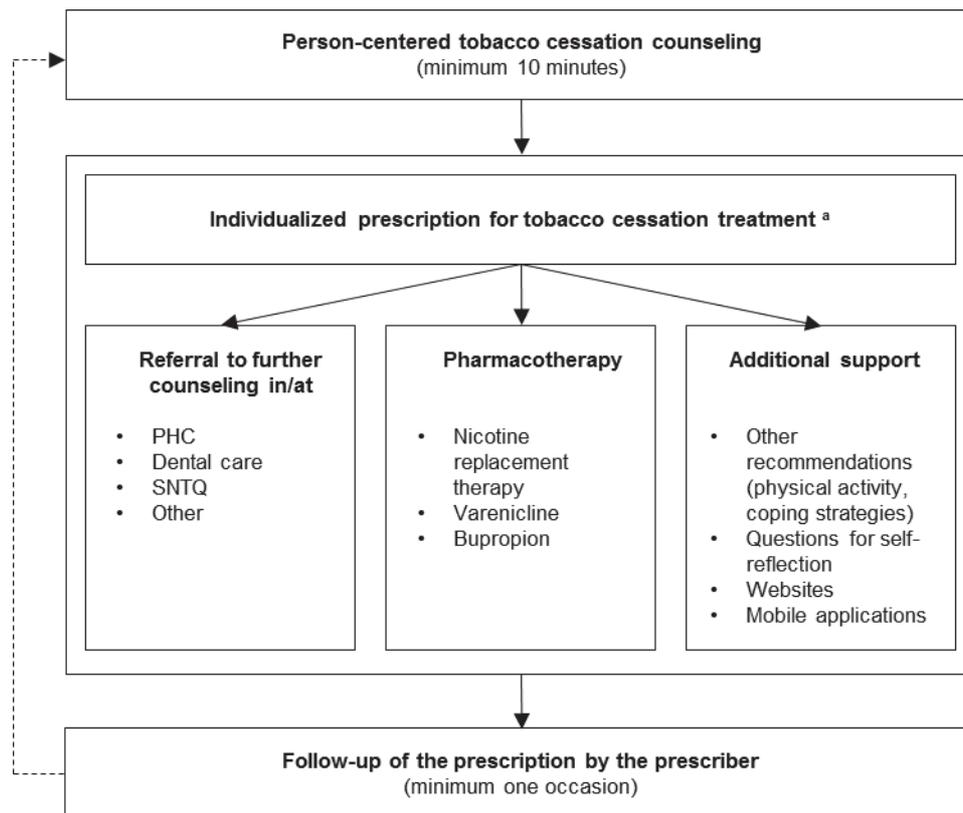
The core components of the intervention consist of tobacco cessation counseling of tobacco users according to the TCP method. This is defined as tobacco cessation counseling (minimum 10 minutes) provided by a qualified health care professional in combination with a prescription for individualized tobacco cessation treatment, including options for (1) further counseling (referral to a health care provider with more competence or SNTQ), (2) pharmacotherapy (nicotine replacement therapy, varenicline, bupropion), (3) other measures for tobacco cessation (physical activity and other strategies to cope with withdrawal symptoms), (4) follow-up (by telephone or revisit) and (5) support for self-management (questions for self-reflection, reference to mobile applications, Web-based counseling and websites for more information and support). The approach will be individualized in the sense that providers will discuss the available treatment options, contraindications, preferences, and other relevant circumstances with the patient and then decide together which treatment alternative(s) suit the individual best. The TCP method also includes follow-up of the prescription by the prescriber on at least one occasion.

Standard Treatment (Control)

Standard treatment is defined as treatment for tobacco cessation according to current practices at the PHC center. Since the choice of tobacco cessation treatment varies depending on individual characteristics and preferences of tobacco users and it is up to each PHC center to decide for themselves how their tobacco cessation services should be organized, the treatment components (eg, type of counseling and pharmacotherapy) are expected to vary both within and between the study arms. Thus, the provided treatments will be documented by one to three PHC providers per center in the control group responsible for the treatment of study participants and further defined retrospectively. Since the same treatment components are likely to be present in both study arms, it is important to state that the major difference between them is how the counseling is administered (with or without a prescription form). The minimum intervention for the control group is a brief advice (<5 minutes).

To ensure that the difference between the trial conditions is dependent on the prescription form and not on the training of PHC staff, the PHC providers responsible for the treatment of patients in the control group will receive 3.5 hours of training by representatives from SNTQ and the County Council in available treatment options for tobacco cessation prior to the study start (the same training as the intervention group, excluding the 30 minute TCP component). A manual identical to the one developed for the intervention group, excluding all information about the TCP method and summarizing the training, has been developed and will be distributed in connection with the education of PHC providers in the control group.

Figure 2. Conceptual model for TCP.



^a individual tobacco users may receive more than one out of the three treatment options

Outcomes

The primary outcome of the intervention will be measured in self-reported point prevalence of 7-day abstinence (total abstinence from tobacco use during the 7 days preceding follow-up) at 6 months after the intervention. The secondary outcomes are self-reported point prevalence of 7-day abstinence at 12 months after the intervention and 3-month continued abstinence, daily tobacco consumption (number of cigarettes), number of quit attempts (periods of total abstinence from tobacco use for more than 24 hours) and health-related quality of life (on a scale from 0-1 where 0 represents death and 1 represents perfect health) at 6 and 12 months after the intervention. All outcomes will be based on patients' self-reports. Cost-effectiveness will be measured as the incremental cost per quality-adjusted life year.

Data Collection

Data on sociodemographic characteristics, tobacco use, and nicotine dependence, previous quit attempts, self-efficacy and motivation to quit, health status and health-related quality of life will be collected through patient questionnaires. The questionnaires are based on questions from the Swedish Public Health Survey 2014 [29], a questionnaire that was used in a previous study that evaluated the effectiveness of brief advice for tobacco cessation in dental practices in Sweden [30] and the Swedish and Arabic (Lebanon) version of the EQ-5D-5L instrument [31]. Questions not included in the EQ-5D-5L questionnaire were translated from Swedish to Arabic and back by two different professional translation agencies and critically

reviewed by a research assistant fluent in both Swedish and Arabic. The questionnaires were pilot tested in Swedish prior to the study start and in Arabic prior to the recruitment of Arabic speaking participants.

The measurements will be conducted at baseline (before the intervention) and 6 and 12 months after the intervention. In the follow-up questionnaires, questions regarding the tobacco cessation-related care the patients have received during the study period have been added. The baseline questionnaires will be administered by staff responsible for the treatment of patients at the participating PHC centers. The PHC providers administering the treatment will also document what treatment the patients have received (duration, content, intensity and number of visits, mode of counseling, referrals, any recommended and prescribed pharmacotherapy, follow-ups, etc) in the electronic medical records and in study specific documentation protocols. Staff will be educated in the documentation procedures before the start of the study. The follow-up questionnaires will be sent to the participants via mail by the researchers to avoid attrition caused by additional costs and administrative burden of revisits for the study participants. A reminder with a new follow-up questionnaire attached will be sent out via mail by the researchers if the follow-up questionnaire is not returned within ten days. If the reminder questionnaire is not returned, additional reminders to return the questionnaire will be sent out via mail, email and SMS text messaging (short message service, SMS) by the researchers. In connection with the second reminder, the participants will be offered the opportunity to answer the questionnaire in a telephone interview. Multiple reminders and forms of contact

have been found essential in promoting high retention rates among disadvantaged research participants who are often highly mobile [32]. The strategy above is expected to be sufficient in reaching study participants who are willing to respond to the follow-up questionnaires. Arabic speaking staff will assist the researchers in contacting and collecting data from the Arabic speaking participants.

Additional data on the characteristics of participating PHC centers and providers delivering the intervention will be collected through questionnaires and interviews. This includes data on organizational aspects such as number of listed patients, number of employees, and type of professions and routines for tobacco cessation at the PHC center level and data on age, sex, profession, qualifications, and personal experiences of tobacco use and tobacco cessation at the PHC provider level. Data on structural changes in the PHC centers during the study period (eg, staff turnover) will also be collected retrospectively. This data will be collected by the researchers.

Sample Size

The required sample size was calculated based on the primary outcome, assuming a 7% rate of 7-day prevalence in abstinence from tobacco use at 6 months follow-up in the control group, significance level of 5% and 80% power to detect a 2.0 relative risk of successful quit attempts in the intervention group compared to the control group. The estimated prevalence of abstinence in the control group corresponds to the success rate of brief advice [33] which is the minimum intervention for the control group in this study. The estimated relative risk corresponds to the relative risk of abstinence from tobacco use for combined pharmacotherapy and counseling, as recommended for the intervention group in this study, compared to minimal intervention or usual care [34]. The unadjusted sample size was found to be 300 per arm. Assuming an intra-cluster coefficient (ICC) of 0.01 according to Adams et al [35] the sample size was adjusted for design effect using the formula: $1 + (m - 1) \rho$, where m represents the mean number of participants in each cluster and ρ is the ICC. Having 7 clusters per arm and 43 participants per cluster, the adjusted sample size will be 426 per arm. Finally adjusted for an attrition/drop-out of 8%, the final sample size will be 464 per arm or 928 in total. The estimated attrition rate of 8% is based on reported attrition rates from two other tobacco cessation trials with similar study designs, both conducted in the Swedish health care setting [30,36]. A higher number of participating PHC centers could decrease the required number of study participants without compromising the power to detect a statistically significant difference in the outcomes between the groups at follow-up, wherefore the aim is to recruit a total of 20 PHC centers. A total sample size of 840 would then be needed.

Randomization

A computer generated random allocation sequence will be applied to randomize the PHC centers to either intervention or control conditions with a 1:1 ratio. Cluster-randomization will be employed at the PHC center level, meaning that all individual study participants recruited from a particular PHC center will receive the same treatment. This will be done due to feasibility reasons and to avoid contamination of the trial conditions. The

PHC centers will be paired based on their socioeconomic index and allocated to the treatment conditions from each pair after they have agreed to participate, approximately one month before the PHC provider training. Each set of participating PHC centers will be randomized separately. The randomizations will be conducted by a statistician.

The PHC providers and study participants will not be blinded. However, the study participants will not be informed about the difference between the trial conditions until after the study. This will be done in order to avoid attrition and preconceptions regarding the treatment effectiveness that could affect the study results (risk that study participants in the control group could perceive standard treatment as less effective compared to TCP).

Statistical Analysis

In order to describe the setting and the effectiveness of the randomization, descriptive statistics of the study population's baseline characteristics at both individual and cluster level will be presented separately for the intervention and control arm, as proportions for categorical variables and as mean values with corresponding standard deviation (SD) for continuous variables.

The association between the treatment and the outcomes post-intervention will be analyzed using multiple regression models. A logistic regression model will be used for binary outcomes, including the primary outcome, 7-day abstinence. The result will be presented as an odds ratio (OR) and corresponding 95% confidence interval (CI). The association between the treatment and continuous/count outcomes, including the secondary outcomes, daily tobacco consumption, number of quit attempts and health-related quality of life, will be analyzed using multiple linear and Poisson regression models. All analyses will be conducted according to the intention to treat principle [37], meaning that the individual study participants will be analyzed according to how the PHC centers where they were recruited and treated were randomized, regardless of which intervention they received. Inference will be targeted at the individual level and hierarchical models will be used to handle potential clustering on the PHC center level. Model covariates will include age, sex, educational level, nicotine dependence, motivation and readiness to quit, previous quit attempts, previous use of pharmacotherapy, and diagnosis of chronic disease. For main analysis no missing data will be imputed. However, classical multiple imputation methods will be used for an additional sensitivity analysis if any of the included variables have more than 5% missing observations. The analyses will be conducted by the research team, including a statistician.

Process Evaluation

A process evaluation will be conducted to measure implementation outcomes such as service delivery of tobacco cessation at the PHC center level and self-reported fidelity to the intervention at the PHC provider level and the participant level [38]. Data will be collected through review of electronic medical records, PHC provider documentation protocols and patient questionnaires. Semi-structured interviews with PHC providers and tobacco users will also be conducted and qualitatively analyzed with content analysis to explore the

acceptability, appropriateness, adoption [38], and general experiences of TCP.

Economic Evaluation

A health economic evaluation will be conducted alongside the trial to evaluate the cost-effectiveness of the intervention compared to standard treatment. This will be done by incorporating the trial results on effectiveness and data from other sources into a decision analytic model specifically developed to estimate the future costs and outcomes of tobacco cessation interventions. Decision analytic models are often used in health economic evaluations since they allow for synthesis of data from different sources and extrapolation of events beyond a clinical trial [39]. The analysis will be conducted from a societal perspective with a lifetime horizon where the incremental cost-effectiveness ratio (difference in cost, divided by the difference in effectiveness between the treatment alternatives), is defined as the additional cost in Swedish Krona (SEK) per quality-adjusted life year. Cost (resource use) and epidemiological data will be collected from the trial as well as from registers, reports, and previously published scientific articles. Cost data will include indirect costs of production loss and direct health care costs of PHC staff, pharmacotherapy, and other resources used in the delivery of tobacco cessation treatments and overhead costs in both study arms throughout the entire study period. Future health care costs will be calculated as average annual costs of health states included in the evaluation. Epidemiological data will include population data on life expectancy and relative risk of tobacco related diseases among tobacco users and former tobacco users. The evaluation, including discounting, sensitivity analysis, and reporting will be conducted based on best practice guidelines for health economic evaluations in Sweden [40].

Results

From April to November 2015, eight PHC centers were recruited and randomly assigned to the trial conditions. The PHC providers responsible for the treatment of study participants were trained in February and April 2016. Recruitment of individual study participants is currently ongoing. Recruitment of a second set of PHC centers is also ongoing. The expected study start of the second set of PHC centers is in September 2016.

Discussion

This study aims to evaluate the effectiveness and cost-effectiveness of a novel intervention that builds on previous research and experiences of prescribed lifestyle interventions in the PHC setting in Sweden that could potentially facilitate a more structured approach to tobacco cessation for socioeconomically disadvantaged groups compared to current practice. The method is based on clinical guidelines for tobacco cessation treatment in the Swedish health care setting [1] and has been developed in close collaboration with a variety of relevant stakeholders including the target population [32]. Stakeholders that have been involved in this process include researchers and experts on tobacco cessation and lifestyle interventions on prescription in Sweden (researchers experienced

in intervention research, tobacco control and PAP, as well as representatives from the Swedish Professional Agency Against Tobacco and SNTQ), PHC providers (mainly nurses and physicians but also dieticians and occupational therapists) and tobacco users of various ages and sexes from PHC centers located in socioeconomically disadvantaged areas in Stockholm. Since community involvement in intervention design has been found to have positive effects on the uptake of an intervention [32], this is expected to have a positive effect on the effectiveness and acceptability of TCP. Results from the previously mentioned study that explored the perceived feasibility and optimal design of TCP suggest that there is support for the method [22].

A key concern when conducting the study is reaching the intended target population. For example, language barriers may limit the access to the most disadvantaged groups. However, the two most common languages in the target population, Swedish and Arabic, are considered in the study. It is important that the participating PHC centers have access to interpretation services, or staff fluent in these languages, and that the materials are available in both languages to enable recruitment of participants and delivery of the intervention as intended [32]. It is also important to consider that not all tobacco users who visit PHC centers located in socioeconomically disadvantaged areas have a low socioeconomic status. However, recruitment of patients to health interventions has been found much more effective in the PHC setting in socioeconomically disadvantaged areas compared to community approaches [41]. For feasibility and ethical reasons, a common research approach is to focus on socioeconomically disadvantaged areas rather than individuals when recruiting such populations. Since the intended target population may be difficult for outsiders of the community to reach [32], PHC staff will be responsible for recruitment of individual study participants. As in other studies conducted on disadvantaged populations, the participants will receive a gift certificate worth 100 SEK to promote their partaking in the research and increase retention rates [32]. In order to describe the study population and assess whether it is representative for the intended target population, data on socioeconomic status will be collected on the individual level at baseline.

A possible limitation of the study is due to self-reported tobacco-related outcomes. The accuracy of self-reported tobacco use tends to be lower compared to biochemical markers such as cotinine measurements and may lead to underestimates of tobacco use due to underreporting as a consequence of social desirability [42]. However, self-reported tobacco use is a common research approach and was chosen in this study due to budget restrictions and feasibility reasons. In addition to higher costs for equipment and training, cotinine measurement would require two more compulsory revisits per study participant which could compromise the retention rate due to an increase in administrative burden and costs for the study participants who have to pay out-of-pocket for their visits. This is expected to have a particularly negative impact on the retention of the participants in this study as they are recruited from socioeconomically disadvantaged areas. Cotinine measurements are also expected to decrease the willingness among PHC to participate due to the increased administrative

burden of additional compulsory revisits. However, a correction factor may be used to adjust for underreporting which is expected to be lower than 10% [42].

Another potential limitation is that the education of PHC providers is relatively brief (4 hours). However, data collected at the PHC center level prior to the study start showed that the majority of the PHC providers responsible for the treatment of patients had previous training in tobacco cessation treatment, motivational interviewing or lifestyle counseling. Given this fact, the length of the education was considered sufficient by the participating PHC centers and the representatives from SNTQ and the County Council that were involved in designing the training of the PHC providers in the study.

A major strength of the study is the robustness of its design. The pragmatic approach will provide high external validity under real world conditions in the context under study [24] and lead to useful results for policy making and health systems

development. Furthermore, the inclusion of data on cost-effectiveness will facilitate policy decisions on wider use of the program [24,39]. Another strength of the study is that it focuses on socioeconomically disadvantaged groups who have a greater need for tobacco cessation support due to the higher prevalence of tobacco use and difficulties in reaching this target group with health promoting interventions compared to groups with higher socioeconomic status. To the authors' knowledge, this is the first study to evaluate the effectiveness and cost-effectiveness of tobacco cessation services targeting socioeconomically disadvantaged groups in the PHC setting in Sweden. The study is expected to offer valuable insights regarding how such services are currently organized. If TCP is proven to be effective and cost-effective, it will be a valuable tool for tobacco prevention that can be readily implemented to promote health among socioeconomically disadvantaged populations in the PHC setting in Sweden.

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Authors' Contributions

TT conceived the study and led procurement of funding assisted by AL. AL drafted study protocol supervised by TT with assistance by PL, CJS and MP. The latter provided statistical expertise. AL wrote first draft of study protocol manuscript, all provided input. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

- PAP:** Physical Activity on Prescription
PHC: primary health care
SNTQ: Swedish National Tobacco Quitline
TCP: Tobacco Cessation on Prescription

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APPENDIX B – BASELINE QUESTIONNAIRE IN STUDY II

Kodnummer: _____

Datum: _____

Vårdcentral: _____

1. Födelseår _____

2. Kön

Man

Kvinna

Annat

3. Vilken är din högsta avslutade utbildning/examen?

Om du studerar, kryssa i den utbildning du går. Sätt bara ett kryss.

Grundskola (sammanlagt mindre än 10 år)

Gymnasieskola (sammanlagt 10 till 12 år)

Universitets- eller högskoleutbildning (sammanlagt mer än 12 år)

Annan utbildning: _____

4. Vilken är idag din huvudsakliga sysselsättning?

Anställd deltid. Befattning: _____

Anställd heltid. Befattning: _____

Egen företagare

Student

Arbetslös

Pensionär (ålderspensionär)

Sjuk-/aktivitetsersättning (förtids-, sjukpensionär)

Annat: _____

5. I vilket land är du född? _____

6. Om du är född utomlands, vilket år kom du till Sverige? _____

Om du är född i Sverige kan du bortse från denna fråga.

7. Under de senaste 30 dagarna, hur mycket tobak har du på ett ungefär använt per dag?

Fyll i varje ruta i den nedanstående tabellen. Skriv "0" om du inte alls använder en viss typ av tobak (t.ex. snus).

	Per dag
Antal cigaretter	
Antal snusprillor	
Antal annan typ av rökt tobak*	

*T.ex. cigarrer, vattenpipa, pipa

8. Hur många år har du använt tobak (cigaretter och/eller snus/annan typ av rökt tobak)?

Räkna bort uppehåll som varade minst ett år.

Antal år: _____

9. Hur snart efter uppvaknandet röker du dagens första cigarett eller använder annan typ av tobak eller snus?

- Mindre än 5 minuter
- 6-30 minuter
- 31-60 minuter
- Mer än 60 minuter

10. Sedan du började använda tobak så gott som dagligen, hur många gånger har du varit tobaksfri i minst 24 timmar (ett dygn)?

Kryssa för svar för både cigaretter, snus och annan typ av rökt tobak.

Cigaretter

- 0
- 1
- 2-3
- 4-5
- 6 eller flera gånger
- Har aldrig använt cigaretter så gott som dagligen

Snus

- 0
- 1
- 2-3
- 4-5
- 6 eller flera gånger
- Har aldrig använt snus så gott som dagligen

Annan typ av rökt tobak

- 0
- 1
- 2-3
- 4-5
- 6 eller flera gånger
- Har aldrig använt annan typ av rökt tobak så gott som dagligen

11. Hur viktigt är det för dig att sluta använda tobak?

0=inte alls viktigt, 10=maximalt viktigt

0 1 2 3 4 5 6 7 8 9 10

12. Hur säker är du på din förmåga att sluta använda tobak om du bestämmer dig?

0=inte alls säker, 10= maximalt säker

0 1 2 3 4 5 6 7 8 9 10

13. Har du någon gång använt nikotinläkemedel eller annat läkemedel som stöd för att sluta använda tobak?

Fyll i ja eller nej för alla läkemedel.

	Nej	Ja
Nikotinplåster	<input type="checkbox"/>	<input type="checkbox"/>
Nikotintuggummi	<input type="checkbox"/>	<input type="checkbox"/>
Nikotintabletter/sugtabletter	<input type="checkbox"/>	<input type="checkbox"/>
Nikotininhalator	<input type="checkbox"/>	<input type="checkbox"/>
Nikotinspray (näs- eller munhålespray)	<input type="checkbox"/>	<input type="checkbox"/>
Nikotinmunhålepulver	<input type="checkbox"/>	<input type="checkbox"/>
Annat nikotinpreparat	<input type="checkbox"/>	<input type="checkbox"/>
Champix®	<input type="checkbox"/>	<input type="checkbox"/>
Zyban®	<input type="checkbox"/>	<input type="checkbox"/>

14. Hur ser du på ditt tobaksbruk i framtiden?

- Jag har inte bestämt om och när jag ska sluta helt
- Jag vill sluta helt men jag har inga planer på att sluta inom de närmaste 6 månaderna
- Jag vill sluta helt och jag är beredd att sluta inom de närmaste 2-6 månaderna
- Jag vill sluta helt och jag är beredd att sluta inom den närmaste månaden

15. Har du av en läkare fått följande diagnoser?

	Nej	Ja
Diabetes	<input type="checkbox"/>	<input type="checkbox"/>
KOL	<input type="checkbox"/>	<input type="checkbox"/>
Hjärtinfarkt	<input type="checkbox"/>	<input type="checkbox"/>
Stroke	<input type="checkbox"/>	<input type="checkbox"/>
Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Depression	<input type="checkbox"/>	<input type="checkbox"/>

16. Har du någon annan långvarig sjukdom eller besvär?

Nej

Ja, skriv vad: _____

APPENDIX C – FOLLOW-UP QUESTIONNAIRE IN STUDY II

Kodnummer: _____ Datum: _____

1. Under hur många av de senaste 7 dagarna har du använt tobak?

Kryssa i nedanstående tabell.

	Inga dagar	1-2 dagar	3-4 dagar	5-7 dagar
Cigaretter				
Snusprillor				
Annan typ av rökt tobak*				

* T.ex. cigarrer, vattenpipa, pipa

2. Hur mycket tobak har du på ett ungefär använt per dag under de senaste 7 dagarna?

Fyll i varje ruta i nedanstående tabell. Om du inte alls har använt en viss typ av tobak de senaste 7 dagarna skriv då "0" i den rutan.

	Per dag
Antal cigaretter	
Antal snusprillor	
Antal annan typ av rökt tobak*	

*T.ex. cigarrer, vattenpipa, pipa

3. När rökte eller snusade du senast?

År: _____ Månad: _____ Dag: _____

4. Hur många gånger har du under de senaste 6 månaderna varit tobaksfri i minst 24 timmar (ett dygn)?

Om du är tobaksfri nu, räkna då endast uppehållen före det nuvarande uppehållet. Kryssa för både cigaretter, snus och annan typ av rökt tobak.

Cigaretter

- 0
 1
 2
 3
 4
 5 eller flera gånger
 Har inte använt cigaretter under perioden

Snus

- 0
 1
 2
 3
 4
 5 eller flera gånger
 Har inte använt snus under perioden

Annan typ av rökt tobak

- 0
 1
 2
 3
 4
 5 eller flera gånger
 Har inte använt annan typ av rökt tobak under perioden

5. Hur viktigt är det för dig att sluta använda tobak?

0=inte alls viktigt, 10=maximalt viktigt. Om du slutat med tobak under de senaste 6 månaderna kan du bortse från denna fråga.

0 1 2 3 4 5 6 7 8 9 10

6. Hur säker är du på din förmåga att sluta använda tobak om du bestämmer dig?

0=inte alls säker, 10= maximalt säker. Om du slutat med tobak under de senaste 6 månaderna kan du bortse från denna fråga.

0 1 2 3 4 5 6 7 8 9 10

7. Hur ser du på ditt tobaksbruk i framtiden?

- Jag har inte bestämt om och när jag ska sluta helt
- Jag vill sluta helt men jag har inga planer på att sluta inom de närmaste 6 månaderna
- Jag vill sluta helt och jag är beredd att sluta inom de närmaste 2-6 månaderna
- Jag vill sluta helt och jag är beredd att sluta inom den närmaste månaden
- Jag har slutat helt men jag är ganska osäker på att jag kommer att hålla mig tobaksfri även i framtiden
- Jag har slutat helt och jag är ganska säker på att jag kommer att hålla mig tobaksfri även i framtiden

8. Har du under de senaste 6 månaderna använt nikotinläkemedel eller annat läkemedel som stöd för att sluta använda tobak?

Fyll i ja eller nej för alla läkemedel.

	Nej	Ja
Nikotinplåster	<input type="checkbox"/>	<input type="checkbox"/>
Nikotintuggummi	<input type="checkbox"/>	<input type="checkbox"/>
Nikotintabletter/sugtabletter	<input type="checkbox"/>	<input type="checkbox"/>
Nikotininhalator	<input type="checkbox"/>	<input type="checkbox"/>
Nikotinspray (munhålespray)	<input type="checkbox"/>	<input type="checkbox"/>
Nikotinmunhålepulver	<input type="checkbox"/>	<input type="checkbox"/>
Annat nikotinpreparat	<input type="checkbox"/>	<input type="checkbox"/>
Champix®	<input type="checkbox"/>	<input type="checkbox"/>
Zyban®	<input type="checkbox"/>	<input type="checkbox"/>

9. Om du inte använt något av läkemedlen i fråga 8 under de senaste 6 månaderna, vilken var orsaken/orsakerna till att du inte gjorde det?

Fler alternativ kan anges! Om du har använt något av läkemedlen i fråga 8 under de senaste 6 månaderna kan du bortse från denna fråga.

- Ville sluta utan läkemedel
- Kände inget behov
- Ekonomiska skäl/hade inte råd
- Hade för långt till apoteket
- Trodde inte att läkemedlet skulle hjälpa
- Annan orsak: _____

10. Har du under de senaste 6 månaderna sökt stöd hos några av följande för att sluta med tobak?

Fyll i ja eller nej för alla alternativ.

	Nej	Ja
Sjuksköterska	<input type="checkbox"/>	<input type="checkbox"/>
Läkare	<input type="checkbox"/>	<input type="checkbox"/>
Personal från tandvården	<input type="checkbox"/>	<input type="checkbox"/>
Personal från apotek	<input type="checkbox"/>	<input type="checkbox"/>
Sluta-Röka-Linjen	<input type="checkbox"/>	<input type="checkbox"/>
Familjemedlem, vän, arbetskamrat	<input type="checkbox"/>	<input type="checkbox"/>
Internet	<input type="checkbox"/>	<input type="checkbox"/>
Mobilapplikation (app)	<input type="checkbox"/>	<input type="checkbox"/>
Annan: _____	<input type="checkbox"/>	<input type="checkbox"/>

11. När du sökte stöd, fick du den hjälp du behövde?

Om du inte har sökt stöd för att sluta med tobak under de senaste 6 månaderna kan du bortse från denna fråga.

- Nej, förklara hur det gick till: _____
- Ja

12. Hur lång tid på ett ungefär har du sammanlagt fått stöd för att sluta med tobak under de senaste 6 månaderna?

Om du inte har sökt stöd för att sluta med tobak under de senaste 6 månaderna kan du bortse från denna fråga.

- Mindre än 1 timme
- 2 timmar
- 3 timmar
- 4 timmar
- 5 timmar
- 6 timmar
- 7 timmar
- 8 timmar
- 9 timmar
- 10 timmar
- Mer än 10 timmar

13. Om du inte sökt stöd för att sluta med tobak under de senaste 6 månaderna, vilken var orsaken/orsakerna till att du inte gjorde det?

Fler alternativ kan anges! Om du har sökt stöd för att sluta med tobak under de senaste 6 månaderna kan du bortse från denna fråga.

- Ville sluta utan stöd
- Kände inget behov
- För långa väntetider
- Ekonomiska skäl/hade inte råd
- Hade inte tid
- Visste inte vart jag skulle vända mig
- Trodde inte att det skulle hjälpa
- Annan orsak: _____