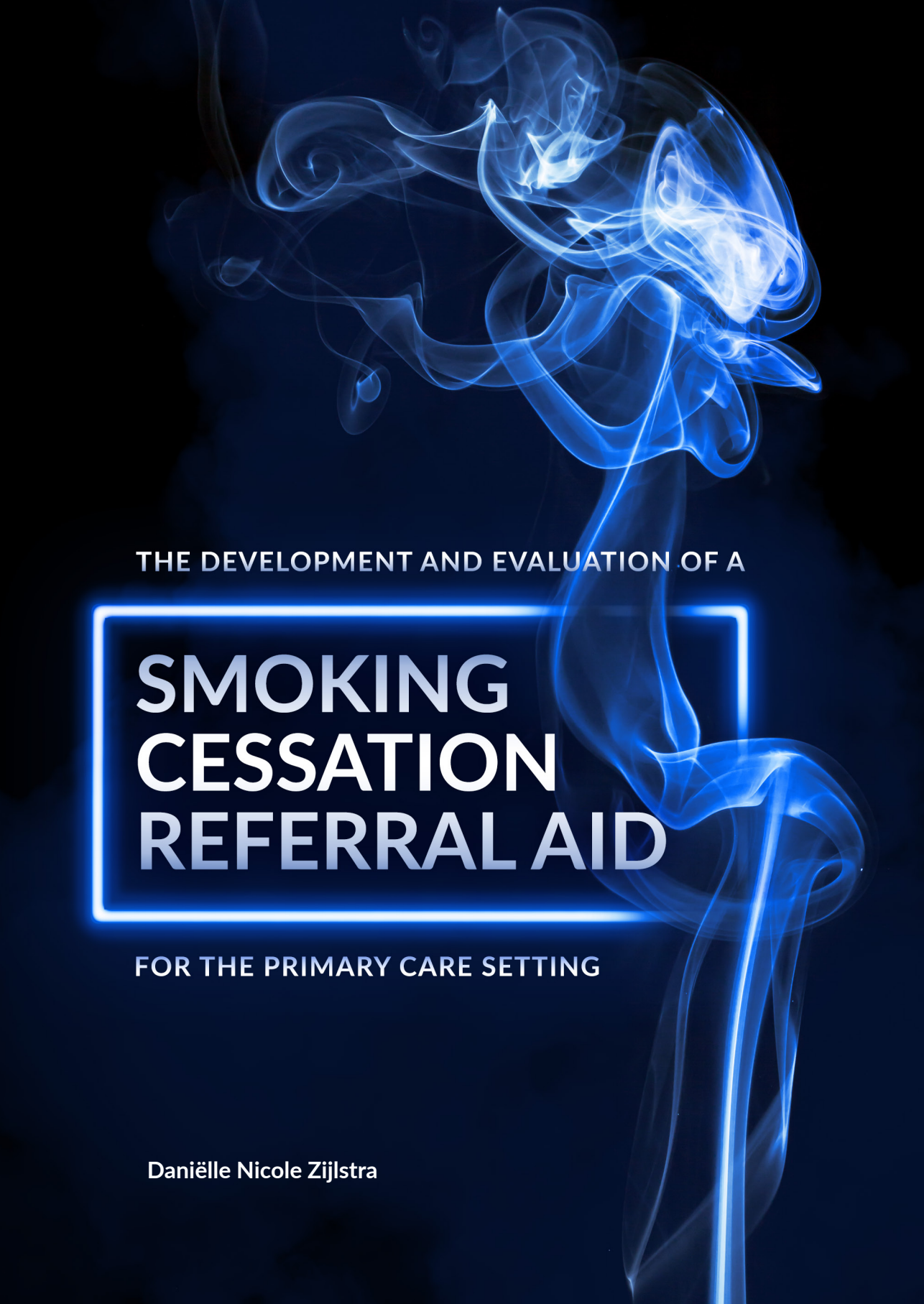
# The development and evaluation of a smoking cessation referral aid for the primary care setting


THE DEVELOPMENT AND EVALUATION OF A
SMOKING CESSATION REFERRAL AID
FOR THE PRIMARY CARE SETTING
Daniëlle Nicole Zijlstra

# The development and evaluation of a smoking cessation referral aid for the primary care setting

**Daniëlle Nicole Zijlstra**

The research presented in this thesis was conducted at CAPHRI Care and Public Health Research Institute, Department of Health Promotion, of Maastricht University. CAPHRI participates in the Netherlands School of Public Health and Care Research CaRe.

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# The development and evaluation of a smoking cessation referral aid for the primary care setting

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# CHAPTER 1

General introduction

## SMOKING (STILL) KILLS

Tobacco has been used as a natural stimulant since it was first discovered around 5000 BCE. The first reports of the negative effects of tobacco use were published in 1602 (1) and 1761 (2); however, this message was not widely disseminated and globally accepted (though half-heartedly) until 1964 (3), and the negative effects of tobacco use were not widely accepted in the Netherlands until 1969 (4).

Today, the negative consequences of tobacco use are universally recognized, particularly the consequences of inhaling tobacco smoke through the respiratory tract (5). Yet, 1.4 billion individuals worldwide still use tobacco (6). The share of individuals who smoke tobacco differs significantly by country. Developing countries such as Nigeria have a relatively low (reported) percentage (3%), whereas a higher share of people report smoking in countries in which inhabitants have resources to acquire tobacco products and few best-practice smoking cessation measures have been adopted, such as Greece (31%; (6). Tobacco use in Europe decreased starting in 2006, but the decreasing trend came to a halt between 2014 and 2017, and the average smoking percentage in 2017 was about 26% (7). In the Netherlands, the percentage of smokers declined from 60% in 1958 to 25.7% in 2014 (6, 8); however, the share of Dutch individuals who smoke has remained stable in recent years, indicating that a core group of smokers persists (9).

Smoking tobacco has dire consequences for society. In 2018, there were eight million deaths worldwide from cancer, cardiovascular diseases, and respiratory diseases (6); smoking is the most important and preventable risk factor for these outcomes (6, 10). In the Netherlands, cancer, cardiovascular disease, and respiratory disease account for approximately 20,000 deaths per year (11). In addition to mortality, smoking is associated with other societal issues, including increased health care cost, potential loss of labor caused by illness or absence, and increased inequality between high socioeconomic status (SES; 20% smoking rate) and low SES households (30% smoking rate; (12, 13). Individuals in low SES groups disproportionately suffer from smoking-related diseases (14, 15) and are less likely than those in high SES groups to attempt to quit smoking, to seek professional help, and to successfully quit smoking (15, 16). Decreasing tobacco use, especially among low SES groups, is therefore an important public health focus in the Netherlands and in many other countries.

## THE FOCUS ON SMOKING CESSATION IN DUTCH PUBLIC HEALTH

Several national policy measures have been implemented at the policy, organizational, and individual levels to reduce the negative public health consequences of tobacco usage in the Netherlands.

**The policy level**

Policy measures aimed to reduce tobacco consumption include financial implications, constraints, and governmental campaigns. Financial implications are regular tax increases that result in an increase in the price of tobacco products (17, 18). Constraints that have been or will be implemented in the Netherlands include: a ban on smoking in public places such as government buildings, introduced in 2004 (19, 20) and in the hospitality sector in 2008 (21); a ban on the sale of cigarettes to people younger than 18 years, implemented in 2018 (13); a ban on the sale of cigarettes with non-tobacco flavors and non-standard colors and a ban on packaging with brand-related colors, images and logos (i.e., packaging can only contain a health warning and brand in a neutral font), implemented in 2020 (22); and a ban on stocking tobacco products in full view of shoppers (i.e., products must be stocked out of sight behind closed doors), implemented in 2021 (22). Examples of recent governmental campaigns in the Netherlands include the smoke-free generation (*rookvrije generatie*) campaign, which aimed to shield children from the harmful effects of (co-) smoking (23) and enable parents to raise their children in a smoke-free environment, and the Stoptober campaign, based on a UK initiative, which aimed to motivate people to quit smoking for at least 28 days in October (24). These and other policy measures have been collectively described in the Dutch National Prevention Agreement (*Nationale Preventie Akkoord*), which was drafted by the government and more than 70 civil society organizations in 2018. The aim of the agreement was to implement measures such as banning smoking from public spaces (e.g., playgrounds, sports clubs, and health care institutions(22).

**The organizational level**

Interventions at the organizational level include smoking cessation interventions specifically targeted at organizations and workspaces from different industries (18, 25, 26). Workplace interventions are usually group-based and conveniently provided during working hours, which lowers the threshold for participation (26, 27). These interventions are implemented to supplement national measures and policies.

**The individual level**

Interventions at the individual level may be targeted directly at individuals (28-30) or delivered through health care institutions, such as primary care providers (PCPs; (31, 32), midwives (33), nurses working in coronary wards (34, 35), and other health care professionals outside of primary care (36). Of all health care providers, dentists are least likely to discuss smoking cessation with their patients (37). Obstetricians discuss smoking cessation with their patients most often, followed by medical specialists and general practitioners (37). Two-thirds of all smokers in the Netherlands access primary care services (PCS) yearly (37-39), a similar share to that of smokers in the United States (40). PCS are widely used and are often the first point of entry to professional help for people who want to quit smoking.

**The role of the primary care setting in smoking cessation**

In the 1990s, there was an increase in the general medical practice workload (41). At that time, the general practitioner (GP) was the main point of contact for smoking cessation support within the Dutch PCS. Due to concerns about ensuring the quality of primary care, reducing GP workloads, and addressing lifestyle-related issues, there was a need for additional high-quality resources for smoking cessation support referral. The function of Practice Nurses (PN; *Praktijkondersteuner* or POH in Dutch) was created in 1999 to provide chronic care support for cardiovascular risk management and lung diseases (practice nurse somatic care) and to support the treatment of mental disorders (practice nurse mental health care, POH-GGZ since 2007; (41). Smoking cessation is directly linked to chronic diseases; thus, smoking cessation support has become part of PN job responsibilities (42). Today, GPs generally provide limited smoking cessation advice grounded in the evidence-based Minimal Intervention Smoking Cessation Strategy (MIS; (43, 44). This smoking cessation method has been adapted for certain risk groups (45) and translated for other medical professionals, such as midwives (46, 47) and cardiology nurses (48, 49). The MIS strategy has also been applied as part of a blended care variant that combines face-to-face counseling and Web-based intervention (28, 50). In 2005, about 50% of Dutch GPs used the MIS strategy at least once for smoking cessation counseling (51).

In 2009, The Dutch Guideline for Smoking Cessation Care (DGSCC) was established to assist PNs and other PCPs in the PCS to guide motivated patients to quit smoking (52, 53). The DGSCC, like the STIMEDIC (54) and MIS (43), shares similarities with the internationally known "5 As" (Ask, Advise, Assess, Assist, and Arrange) method of smoking cessation (55). The DGSCC uses a stepwise approach that is comprised of the following steps: 1) provide brief quitting advice, 2) assess smoking profile, 3a) assess motivation, 3b) increase motivation, 4a) explore barriers, 4b) discuss/remove barriers, 5) discuss cessation aids, 6) help set a quit date and develop a quit plan, and 7) offer support after the quit date (52). Figure 1 presents a comparison of the 5 As method and the DGSCC method.

Adherence to all steps of the DGSCC has proven to increase patients' quit rates more successfully than providing brief quitting advice or less intensive counseling (56, 57). However, researchers have found that not all PNs adhere to the steps of the DGSCC (54, 58-60). Step 5—discussing evidence-based smoking cessation interventions (EBSCIs)—is the step that is most often skipped by international PCPs (58, 59) and Dutch PNs (31).

A possible reason for failing to discuss EBSCIs could be practitioners' lack of familiarity with EBSCIs outside the PCS. Lack of knowledge about the effectiveness of EBSCIs could also be a barrier to discussing these interventions with patients (54). Other factors that have been identified as barriers to the provision of smoking cessation advice include PCPs' lack of time, not having a reason to discuss smoking behavior or having discussed the topic before, and the belief that medication is unnecessary because motivation and willpower should be enough for patients to quit (61).

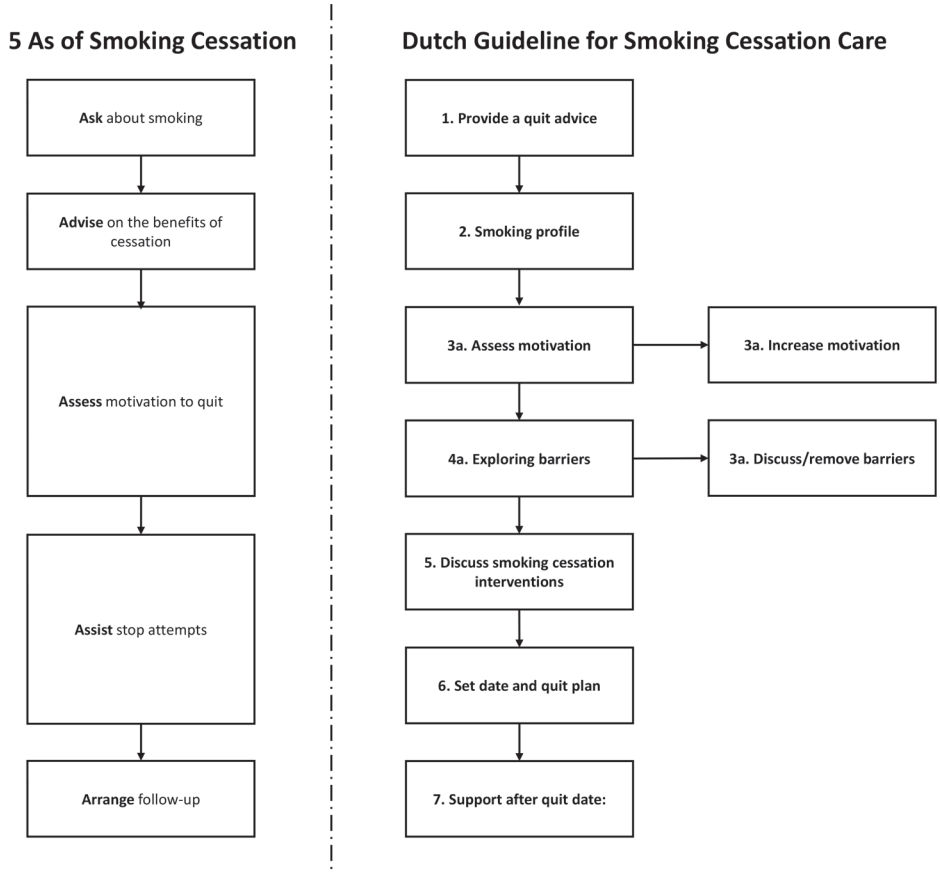



**Figure 1.** Schematic representation of the 5 As of smoking cessation and the DGSCC.

## THE OFFER AND UPTAKE OF EVIDENCE-BASED SMOKING CESSATION AIDS

A distinction is drawn between three types of smoking cessation aids: 1) behavioral counseling, 2) (pharmacological) supplementations and 3) non-evidence-based cessation assistance.

### Behavioral counseling

Behavioral counseling uses techniques from cognitive behavioral therapy to change the thoughts, addictive responses, and habits an individual has acquired to maintain their smoking behavior (55). Behavioral counseling can consist of face-to-face counseling, eHealth, telephone counseling, and group counseling.

Face-to-face counseling ranges from brief quitting advice provided by a GP (which is 1–3% more effective than an unassisted quit attempt; (57) to more extensive counseling that includes at least one follow-up contact by a PN or trained stop-coach outside the PCS. The effectiveness of more extensive counseling methods varies based on the setting and the individual PCP (44, 57, 62-66).

eHealth counseling primarily consists of tailored online counseling interventions. The effectiveness of eHealth interventions varies based on the level of tailoring to the individual's needs and the number of interactive elements. Some interventions have proven effective in comparison to a control group, including Smoke Alert (2.0; (67), Stay Quit For You (SQ4U; (68), Personal Advice in Stopping Smoking (PAS; (28), and Support to Quit (STQ; (69), all of which are based on the I-Change model described later in this chapter (70). Additional Dutch eHealth interventions are available; however, limited effectiveness data exist for these interventions due to a lack of effectiveness studies (70, 71).

Telephone counseling methods are similar to face-to-face counseling; however, these interventions are provided over the telephone without face-to-face contact. The effectiveness of telephone counseling ranges from 7–10% for helplines to 11–14% for counseling conducted by PCPs (72).

Group counseling is also based on behavioral techniques, but these interventions offer the added value of mutual support among participants. The effectiveness of group counseling is comparable to individual counseling of similar intensity (73, 74).

**Pharmacotherapy for smoking cessation**

Pharmacotherapy focuses on counteracting the biological aspects of nicotine addiction. Specific methods may include nicotine replacement therapy (NRT) or drugs like bupropion or varenicline (75-77). NRT consists of using nicotine gum or patches, which are available over the counter at pharmacies, drugstores, and major supermarkets (78). The use of NRT in combination with behavioral care can increase the chances of successfully quitting smoking by 50–60% in comparison to a placebo or no treatment. Higher success rates have been observed when two forms of NRT are combined (79). The success rates for pharmacotherapy range from 52–77% (80, 81), and varenicline is the most effective and most often prescribed medication (81, 82). In the Netherlands, pharmacotherapy can only be prescribed by a GP to patients who indicate that they want to use it (52). A combination method that includes a behavioral intervention is recommended to patients who use smoking cessation medications (52), because such methods have proven significantly more effective than the use of medication alone (81, 83, 84).

**Non-evidence-based cessation assistance**

Non-evidence-based smoking cessation aids are forms of therapy for which a solid evidence base has not yet been established. The most common forms of non-evidence-based cessation assistance are acupuncture or acupressure, laser therapy, and electrostimulation (85).

**Reported use of EBSCIs**

The use of an EBSCI has proven to double the likelihood of successful smoking cessation after 12 months (86, 87). However, only 25–30% of smokers who attempt to quit report using a behavioral counseling method (88-90). The range of smokers who use non-evidence-based cessation assistance is slightly lower than 25–30% (91), and this share decreased slightly from 2012–2017 (88). Smokers may choose to use less effective cessation methods because they are not aware of the full range of available EBSCIs or are uncertain or uninformed about the effectiveness of these methods (92). Since January 2011, Dutch smokers have been allowed to claim one fully reimbursed EBSCI annually through their PCS (93); however, that claim was counted against their deductible until January 2020 (22, 94, 95). Smokers may be unaware of the recent change in the rules regarding compensation for the use of EBSCIs (92).

As previously mentioned, nearly 70% of smokers in the Netherlands visit their GP annually, but smoking cessation is only discussed with one-quarter to one-third of these smokers (37). In 2016, only 37.4% of smokers who received smoking cessation advice from a PCP were advised to use an EBSCI (96). Smokers may be reluctant to use EBSCIs because they have low expectations of the effectiveness of these methods (97, 98), they consider EBSCIs unnecessary because they believe that smoking is not a problem or that they should be able to quit without support (99), or they lack knowledge of the available options (100). Data regarding the current use of EBSCIs are scarce because the use of these methods is not always reported. However, 18% percent of former smokers reported using professional counseling, nicotine replacements, or medications for smoking cessation in 2018 (101, 102). Fewer than 14% of smokers reported using a method that had not been proven effective, and more than 68% reported that they did not use any cessation support (101, 102).

By advising smokers to use EBSCIs and actively engaging smokers in choosing a cessation method that is aligned with their own expectations and preferences, PCPs can increase their patients' commitment to smoking cessation (103, 104). A referral aid (RA) was developed in 2019 for the purpose of this study. The RA aimed to help PNs and smokers identify an individual patient's preferred method for quitting smoking, and the aim of developing this resource was to increase the use of EBSCIs for smoking cessation.

## INTRODUCTION OF THE STOPWIJZER INTERVENTION

The newly developed referral aid is named "StopWijzer," which translates as "stop-guide" or "stop-smarter." The content of StopWijzer is based on a needs assessment that consisted of a literature review regarding smoking cessation in the primary care setting (e.g., (31, 52, 69, 105). Several semi-structured interviews were conducted with GPs (n = 5) and PNs (n = 20) to inform the development of the StopWijzer (see Chapter 3), as was a Delphi study

of referrals to EBSCIs (see Chapter 2). In addition, an advisory committee was formed, comprised of a wide range of stakeholders from different fields of health care (with a particular focus on primary care) to provide input on smoking cessation and health behavior change during the conceptualization of the StopWijzer. Finally, pilot tests were conducted among PCPs and smokers to identify their needs and incorporate them into the intervention to facilitate adoption and later use.

After conceptualizing the StopWijzer, an evaluation phase was implemented to test the effectiveness of the aid when used by PCPs in the PCS. This evaluation, conducted from 2019–2020 in the Netherlands, consisted of a randomized controlled trial as described in Chapter 4. The trial explored the effects of the StopWijzer on the use of EBSCIs and smoking cessation, and it also examined PCPs' willingness to adopt the StopWijzer in their daily routine.

**Facilitating adoption of the referral aid**

The first step of successfully disseminating a new intervention is to achieve successful adoption among end users (106, 107). Adoption of the StopWijzer in daily routine requires behavioral changes and routine adjustments on the part of end users to achieve the intended effect (108). Several models have been proposed to explain and predict behavior and behavioral changes, including the social cognitive theory (109), the transtheoretical model (110), the health belief model (111), and the theories of reasoned action and planned behavior (112, 113). These models are all integrated in the overarching I-change model (de Vries, 2017), which is used to map beliefs about health behavior. In this case, the model is used to examine PNs' intention to adopt a new behavior related to the StopWijzer intervention.

**Using the I-change model to explore factors related to willingness to adopt**

The I-change model has been used in the development of a wide range of health-related behavioral interventions, including smoking cessation interventions. The I-change model has also been used to explore factors that may influence individuals' intention to adopt an intervention (32, 54, 114-118). The model assumes three phases of motivational states that are moderated by information factors and preceding factors (see Figure 2). The three phases of motivational states include pre-motivational (awareness phase), motivational (motivation phase) and post-motivational (action phase). Researchers have identified post-motivational factors that influence adoption of an intervention, including users' perception of few barriers to adoption of a new smoking cessation method (117) and users' comfort in executing the steps of an intervention (32).

Users' motivation to adopt an intervention (daily practice of the StopWijzer, in this case) is driven by three factors: 1) attitude, 2) social influences, and 3) self-efficacy. An individual's attitude is defined as one's consideration of the perceived advantages and disadvantages of the desired behavior. For example, PNs may consider the RA a useful tool to inform

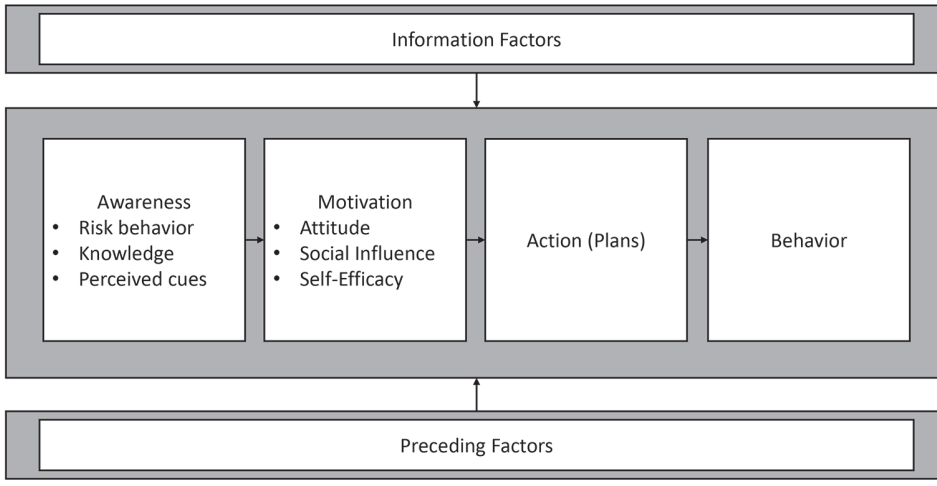



**Figure 2**. Simplified version of the I-Change Model, adapted from de Vries (2017) (105).

patients about smoking cessation and EBSCIs (advantage), but they may also consider the RA difficult to apply during a counseling session (disadvantage). The weighing of advantages and disadvantages results in a positive, neutral, or negative attitude toward a certain behavior. Previous research studies of the motivational factors related to the intention to adopt a smoking cessation intervention have found that attitude is a strong predictor of the intention to adopt an intervention (32, 115-117).

Social influence refers to users' perceptions of relevant other parties' opinions regarding the norms of a certain behavior (social norms), perceptions of pressure from other parties to perform a certain behavior (social pressure), or support from other parties to adopt a healthy behavior and perceptions of other parties' behavior (social modeling). In the case of the adoption of the StopWijzer RA, social influence refers to perceptions of colleague PCPs' opinions about and use of the RA in the PCS. Social support is less strongly associated with the intention to adopt an intervention than attitude, likely because PNs are often the only smoking cessation counseling point of contact within their individual practice (54).

Self-efficacy describes an individual's perceptions, expectations, and experiences of confidence and difficulty in performing a desired behavior, including under difficult circumstances (e.g., if the PCP is busy or the patient is not motivated). Some studies have found an association between high self-efficacy and a high intervention adoption rate (54, 114-118); however, other studies have found no such relationship (32). The combined influences of attitude, social support, and self-efficacy determine an individual's intention to change a certain behavior.

A study of the willingness of PCPs to actively refer patients to other evidence-based cessation strategies rather than provide face-to-face counseling themselves has not yet

been conducted. However, such a study could be valuable because PNs may be more willing or able than PCPs to apply the RA. To investigate the feasibility of the RA for adoption in daily practice, promoting and hindering factors for adoption of the intervention among PCPs in the Dutch PCS were analyzed (see Chapter 5). Prior research has indicated that PCPs sometimes lack the skill and time to assist patients with smoking cessation, and they are not often reimbursed for such activities (119, 120); therefore, potential applications of the RA outside of the PCS were also investigated.

## ALTERNATIVE APPLICATIONS

It is challenging to reach smokers, motivate them to quit, and educate them about EBSCIs. Additionally, smokers may find it difficult to make decisions regarding the different EBSCI options (121, 122) due to a lack of understanding of the available options and their effectiveness. Therefore, smokers may profit from a PCP's knowledge, skills, and support in smoking cessation. To facilitate the decision process among smokers who are ready to quit, shared decision-making could be applied. In a shared decision-making process, at least two parties (e.g., the smoker and the PCP) jointly take active steps to reach a decision that they both support and agree on (123). The process of shared decision-making often requires multiple steps, including providing clear information, answering patient questions, sharing and discussing the decision (which requires a strong and open patient-caregiver bond) and, ultimately, reaching agreement between both parties (124). Adequately applying shared decision-making principles requires a significant amount of time and communication skills, neither of which are often readily available to PCPs (125).

Another way to inform smokers about their EBSCI options without requiring intensive PCP guidance is to engage patients in an informed decision-making process in which the decision-making responsibility rests entirely with the patient (126). In an informed decision-making process, individuals must obtain information about all relevant details of the EBSCIs, including cost and effectiveness, and they must weigh the advantages and disadvantages based on their own personal priorities (127). The information can be provided in different ways (e.g., verbal, textual, or visual), provided that the information is clear, easy to understand, and unbiased (e.g., all aspects of the situation are explained). However, making a decision can still be a difficult or stressful process even with sufficient information and skills, because the smoker must assess which options best fit their values and preferences (128).

A decision aid can be deployed to support smokers in their individual decision-making processes. Decision aids are intended to aid the informed decision-making process by providing the user with all relevant information. Such aids often include value clarification exercises or methods that are aimed to help the user evaluate a wide range of options in their own specific context to determine which option best fits their needs (127, 129, 130).

Decision aids are often deployed to support patients in making clinical decisions in which the options radically differ (e.g., in terms of cost, effectiveness, or side effects; (127). However, decision aids have most often been used for treatment or screening decisions, and little is known about the potential effectiveness of such aids to support decision-making regarding treatment or interventions to change individual health-related behaviors (see Chapter 6).

Previous studies have found that online interventions may be particularly successful at reaching target groups of smokers who visit their PCPs less often (e.g., individuals who are young and comparatively healthy), and such interventions are also cheaper to implement and distribute than others (131, 132). The PCS is considered an entry point to reach smokers; however, the recruitment rate in the PCS of both PN and smoker participants for scientific research has been lower than expected (31, 132-134). An additional usability study was conducted among a sample of smokers recruited through the Internet to examine applicability of the RA in an (online) stand-alone form (see Chapter 7).

## AIM AND OUTLINE OF THE DISSERTATION

The aim of this dissertation is to increase the use of EBSCIs among smokers who are willing to undertake a quit attempt. The first part of the dissertation examines the potential of a referral aid intended to increase the use of smoking cessation interventions for smoking patients within the PCS. The second part of the thesis explores potential future applications of this referral aid outside of the PCS in the form of a decision aid.

**Part I: The potential of a referral aid in the primary care setting**

*Chapter 2* presents the findings of a Delphi study that provides an overview of PCP and researchers' knowledge and viewpoints about the effectiveness and use of EBSCIs in the field of smoking cessation. The objectives of this study were to obtain an overview of: 1) the most important criteria for SCI recommendations, 2) PCP and researchers' perceptions of the effectiveness of SCIs, 3) important factors to consider when counseling different (high-risk) groups of smokers, and 4) PCP and researchers' perceptions of the use of e-cigarettes as an SCI. This study examined the possibility of using a referral aid to promote the use of EBSCIs.

*Chapter 3* describes the study protocol of the RA (de StopWijzer), including the trial design and the testing of the effectiveness and cost-effectiveness of the study.

*Chapter 4* reports the evaluation results regarding the process and effectiveness of the RA among smoking patients who were recruited by PNs in the Dutch PCS. The aim of the process evaluation was to investigate: 1) the recruitment rate and reach of the participants, 2) the usage of the RA materials, and 3) the appreciation of the RA. The aim of the effectiveness evaluation was to examine the effects of the RA on 1) the promotion and

usage of EBSCIs and 2) the abstinence and smoking behavior of participants.

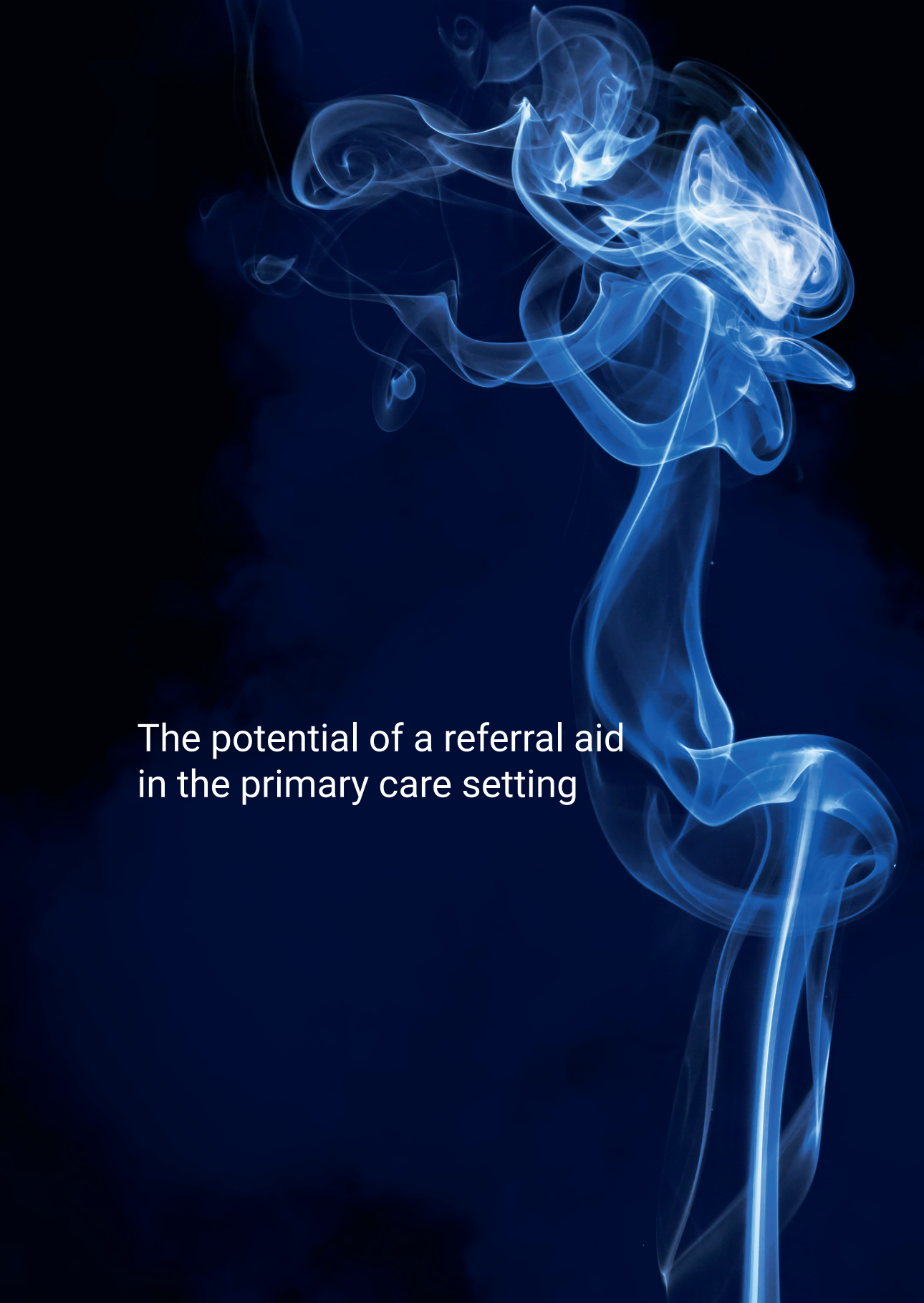
*Chapter 5* provides an evaluation of factors associated with the intention to adopt an RA for EBSCIs. This chapter includes an assessment of the differences between PCPs who did and did not intend to adopt the referral aid as part of their provision of smoking cessation counseling in the PCS.

**Part II: Future applications and possibilities**

*Chapter 6* presents a scoping review of scientific and grey literature on decision aids to support behavioral decision-making (e.g., diet, physical activity, sleep, substance use, and smoking cessation). The literature review identifies existing decision-making processes and aids used in health promotion, positive behavioral effects, and areas for improvement (e.g., effective elements of intervention development).

*Chapter 7* describes a free-standing usability study of the RA among smokers who were recruited through an online survey panel. This study examines the usability of the RA among a large sample of smokers to test whether an adapted version of the RA would be suitable as a stand-alone self-help decision tool. The thesis ends with a reflection on all studies conducted (see General Discussion) and a description of the implications for practice and further research (see Impact Paragraph).

# PART ONE



# The potential of a referral aid in the primary care setting

# CHAPTER 2

## Do professional perspectives on evidence-based smoking cessation methods align? A Delphi study among researchers and healthcare professionals

**This chapter has been published as:**
Zijlstra, D. N., Hoving, C., Bolman, C. A. W., Muris, J. W. M. & De Vries, H. (2021). Do professional perspectives on evidence-based smoking cessation methods align? A Delphi study among researchers and healthcare professionals. *Health Education Research.*

## ABSTRACT

The use of evidence-based smoking cessation interventions (SCIs) can significantly increase the number of successful smoking cessation attempts. To obtain an overview of the knowledge and viewpoints on the effectiveness and use of SCIs, a three-round online Delphi study was conducted among researchers and primary care professionals (PCPs). The four objectives of this study are to gain an overview of 1) the criteria important for recommending SCIs, 2) the perceptions of both groups on the effectiveness of SCIs, 3) the factors to consider when counseling different (high-risk) groups of smokers and 4) the perceptions of both groups on the use of e-cigarettes as an SCI. We found a high level of agreement within groups on which smoker characteristics should be considered when recommending an SCI to smokers. We also found that PCPs display a lower degree of consensus on the effectiveness of SCIs. Both groups see value in the use of special protocols for different (high-risk) groups of patients, but the two groups did not reach consensus on the use of e-cigarettes as a means to quit. Making an inventory of PCPs' needs regarding SCIs and their usage may provide insight into how to facilitate a better uptake in the primary care setting.

## 1. BACKGROUND

Globally, smoking continues to be a leading cause of preventable morbidity and premature death (135). Although in the Netherlands the prevalence of smoking has decreased, 21.7% of adults (3.0 million people) still smoked in 2019. (136). Each year, around one-third of Dutch smokers report making at least one serious (at least 24 hours of no smoking) quit attempt (136). However, only a small percentage of smokers manages to quit long-term (137, 138).

Each year, around two-thirds of Dutch smokers visit their primary care practice (37). As such, Dutch primary care providers (PCPs) are well-positioned to initiate smoking cessation. In practice, the provision of smoking cessation support in Dutch primary care practices has to a large extent shifted from general practitioners (GPs) to trained practice nurses (PNs) (42, 114), who counsel and treat patients on an independent basis but operate under the responsibility of a GP (139) and rely to a large extent on the use of evidence-based guidelines and protocols (139).

In the Netherlands, the Dutch College of General Practitioners (Nederlands Huisartsen Genootschap), is responsible for developing national smoking cessation guidelines for the primary care setting (53), similar to for example the '5 As'(Ask, Advise, Assess, Assist and Arrange) (55).

Although a majority of PNs reports using evidence-based guidelines to structure their smoking cessation counseling (SCC) (114), important counseling elements such as increasing patients' motivation and removing cessation barriers are not always implemented (37, 61, 114, 140) PNs list several psychological (e.g., low self-efficacy to increase patient motivation) and practical barriers (e.g., difficulties in providing patients with relevant and up-to-date information) which prevent them from (fully) adhering to the guidelines (114). Another study found several barriers, such as SCC being too time-consuming and insufficient reimbursements for treating smoking patients without smoking-related illnesses (61). Similar and other barriers have been found in the primary care settings in other countries (120, 141).

These guidelines can be used by PCPs to structure consultations with smoking patients and discuss a range of smoking cessation interventions (SCIs), focusing not only on behavioral counseling by PCPs (e.g., face-to-face counseling), but also discussing behavioral counseling outside of the primary care setting (e.g., eHealth or counseling in groups) and pharmacological interventions (e.g., nicotine replacement therapy; NTR) (86) Although a wide range of SCIs with a strong evidence base is available (142), these interventions often remain underused (12). The use of evidence-based interventions to support smoking cessation can significantly increase the success rate of quit attempts (86).

This study was conducted as part of a needs assessment in the development of a referral aid which aims to support PCPs in their referral of smoking patients to SCIs. To this end, we were interested in exploring the knowledge and viewpoints on the effectiveness and use of SCIs among PCPs. , To our knowledge, no prior research has been conducted

on these topics. Therefore, the first objective of this study is to gain an overview of criteria (both patient and intervention related) that are perceived to be important to consider when recommending an SCI to individual smoking patients. The second objective is to gain an overview of perceptions on the effectiveness of existing SCIs. As smokers who visit PCPs often display smoking-related complaints such as asthma or COPD, the third objective is to gain an overview of criteria that are important to consider when counseling different (high-risk) groups of smoking patients. Other high-risk groups of smokers, as also indicated in the Dutch guidelines for smoking cessation, are pregnant smokers, smokers with a low social economic status (low-SES) and smokers with a low motivation to quit. The fourth and last objective pertains to the use of e-cigarettes. As e-cigarettes have not been proven to be an effective and safe smoking cessation aid, their use as an SCI is discouraged by the Dutch smoking cessation guidelines. However, to our knowledge, no research has been done on PCPs adherence to this recommendation and therefore our last objective is to gain an overview of perceptions on the use of e-cigarettes as a means to quit.

As smoking cessation is a complex health issue which is not only tackled by the primary care setting, we decided to include not only PCPs but also researchers from the field of tobacco control. Other similar structured studies have suggested that researchers are sometimes more able to identify overarching themes and bring a unique perspective (143, 144). Studying the perceptions of researchers and PCPs simultaneously may give a unique insight into the challenges of the current daily practice, and provide solutions to eliminate certain barriers, while also allowing us to pinpoint potential evidence-practice gaps (145). For this purpose, we used a three-round Delphi study to identify topics that are related to SCIs and on which of those consensus does or does not exist among two different sets of experts.

## 2. METHODS

### 2.1 Study Design

The Delphi method is a technique for structuring communication in order to derive consensus on certain subjects for which scientific evidence is limited or conflicting by involving a panel of knowledgeable experts or individuals (146, 147). The three rounds of this Delphi study were conducted in the period from October 2017 to April 2018. Participants who completed both the second and third round were awarded a €20 gift voucher.

#### *2.1.1 First round*

Through a database search in PsycINFO, PubMed and Google Scholar, 63 researchers (national and international) were identified who had (co-)authored at least five papers on a topic related to smoking cessation in the field of health promotion, behavior change and/or addiction in the previous five years (convenience sampling).

The Dutch Healthcare Chart (www.zorgkaartnederland.nl), a review site of Dutch care providers and care facilities, was used to identify 21 PCPs (both GPs and PNs) who were employed in a primary care practice at the time of the study and who regularly (i.e., at least once a week) offered smoking cessation advice and counseling (i.e., actively assisting patients in a quit attempt keeping with the Dutch guidelines for smoking cessation). Only providing a brief cessation advice was used as an exclusion criterion. The questionnaires for the researchers were formulated in English and the questionnaires for the PCPs were formulated in Dutch (in all three rounds). The questionnaires were otherwise identical.

The first-round questionnaire consisted of 15 open-ended questions covering five main topics (in accordance with the study's objectives). Participants were each asked to 1) list patient characteristics that should be taken into account when recommending an SCI to an individual patient (patient characteristics), 2) list criteria that should be met by an SCI when recommending an SCI to an individual patient in order for it to be most effective (intervention characteristics), 3) list existing SCIs they perceive to be effective, 4) list factors that should be taken into account when counseling different (high-risk) groups of smoking patients and 5) to voice their opinion on the use of e-cigarettes as a means to quit.

The responses to the open-ended questions were qualitatively analyzed by two researchers, using the Framework method (148) to merge individual responses into closed-ended statements and questions that were used as input for the second-round questionnaire. Duplicate items were deleted, and semantically similar items were merged. Inter-rater correlation was then calculated using Cohen's Kappa (K). This resulted in an intercoder reliability of 99% (percentage of agreement) and a K=0.71, indicating a substantial level of agreement between both researchers (149).

#### *2.1.2 Second round*

All participants who had completed the first round were invited to participate in the second round. An additional 215 researchers were identified using the same strategy as used in the first round. An additional 174 PCPs were identified through the "Dutch Register for Qualified Smoking Cessation Professionals" (Kwaliteitsregister Stoppen met Roken) (DRQSCP) (150). All 409 potential participants were then invited via email to participate in the second and third round.

The second-round questionnaire consisted of 63 closed-ended statements (see appendix - Table 2), which were based on the responses to the open-ended questions from the first round. For all questions and statements, answers were given on a 7-point Likert Scale (depending on the type of item 1 = strongly disagree to 7 = strongly agree, 1 = not important at all to 7 = very important, or 1 = not effective at all to 7 = very effective).

For each of the 63 items, each group's level (depending on the type of item) of agreement was analyzed by calculating the median score (Mdn) and each group's level of consensus was analyzed by calculating the interquartile range (IQR). A cut-off point of a

median score of ≥ 6 was used. The IQR represents the level of consensus by calculating the difference between the 25th and 75th percentiles, with a smaller value indicating a smaller data spread and a higher level of consensus. An IQR ≤ 1 is considered to be indicative of good consensus on a 7-point scale (151).

#### *2.1.3 Third round*

All 78 participants who had completed the second round were invited to participate in the third round, using the same procedure as used in the second round.

The third-round questionnaire consisted of the items from the second round on which consensus had not yet been reached (IQR ≥ 1) in the second round. For each item, the group median and IQR from the second round was presented to the participants.

For each item, the median score and IQR was calculated. The between-group consensus was analyzed using Wilcoxon signed-rank sum tests, as the data was not normally distributed.

## 3. RESULTS

Of the 84 potential participants who were approached, 20 completed the first round (24% response rate); 10 in each group (see Figure 1 for an overview of the recruitment process and the response rates). In the first round, the PCPs group consisted solely of PNs, who provided on average 8.2 hours of smoking cessation advice and counseling each month. The researchers group varied in experience level, ranging from junior researchers to full professors (See Table 1).

In the first round, the participants identified 12 patient characteristics (e.g., the patient's preference for an SCI) and 13 intervention characteristics (e.g., the intervention continues over a longer period of time) which they deemed important when recommending an SCI to individual patients. They also listed 13 different smoking cessation interventions and 22 factors that should be taken into account when counseling four different (high-risk) groups of patients. Lastly, three different statements could be derived from participants' opinions on the use of e-cigarettes as a means to quit (e.g., e-cigarettes can be recommended as a smoking cessation intervention but not as the most preferred option).

These 63 items identified in the first round were converted into closed-ended statements and statements and included in the second-round questionnaire. In the second round, 27 researchers and 51 PCPs (both GPs and PNs) participated. The researchers group then reached consensus (IQR ≤ 1) on 37 (59%) items and the PCPs group reached consensus on 45 (71%) items (all items are listed in appendix - Table 2).

In the third round, 20 researchers and 35 PCPs (GPs and PNs) participated. Consensus was then reached by the researchers' group on 55 (87%) items and by the PCPs group on

53 (84%) items. Finally, between-group consensus (sig ≥ 0.05) was reached on 39 (62%) items. The results of the Wilcoxon signed-rank sum tests can be found in appendix - Table 3. Detailed results per topic are discussed below.

**Table 1.** Characteristics of the participants

| | Round 1 | Round 2 | Round 3 |
|---|---|---|---|
| Current occupation of health professionals | | | |
| General practitioner (%) | 0 (0.0) | 23 (45.1) | 14 (40.0) |
| Practice nurse (%) | 10 (100.0) | 28 (54.9) | 21 (60.0) |
| Mean monthly hours of providing smoking cessation advice (SD) | 8.2 (3.1) | 5.6 (8.2) | 4.7 (4.5) |
| Current occupation of researchers | | | |
| Junior researchers (%) | 6 (60.0) | 13 (48.1) | 6 (30.0) |
| Assistant professor (%) | 3 (30.0) | 4 (14.8) | 5 (25.0) |
| Associate professor (%) | 0 (0.0) | 6 (22.2) | 4 (20.0) |
| Full professor (%) | 1 (10.0) | 4 (14.8) | 5 (25.0) |
| Field of expertise of researchers* | | | |
| Smoking behavior and tobacco use | 3 | 21 (77.8) | 16 (79.2) |
| (Development of) Tobacco interventions | 7 | 14 (51.9) | 13 (61.9) |
| (Development of) Health promotion interventions | 3 | 11 (40.7) | 11 (52.4) |
| Other, but relevant for this study** | 1 | 5 (18.5) | 0 (0.0) |

* Researchers were able to mark more than one field of expertise
** E.g., reaching low socioeconomic status groups, lung cancer screening trials, development of tobacco control policy and guideline development

### 3.1 Patient characteristics that should be taken into account when choosing recommending an SCI (patient characteristics

The researchers group reached consensus (IQR ≤ 1) on the level of importance of all twelve listed characteristics in the second round. Of the twelve characteristics, six were rated as important or very important (Mdn ≥ 6) (see appendix – Table 2). Over the course of rounds two and three, the PCPs group also reached consensus on the level of importance of all twelve items. With the exception of the patient's level of nicotine addiction, the PCPs group rated the same items as important or very important as the researchers group. Between-group consensus was reached on eight items (67% consensus), with three characteristics regarding the smoker's preference, experience with previous attempts and motivation rated as very important (Mdn ≥ 6) (see appendix – Table 3).

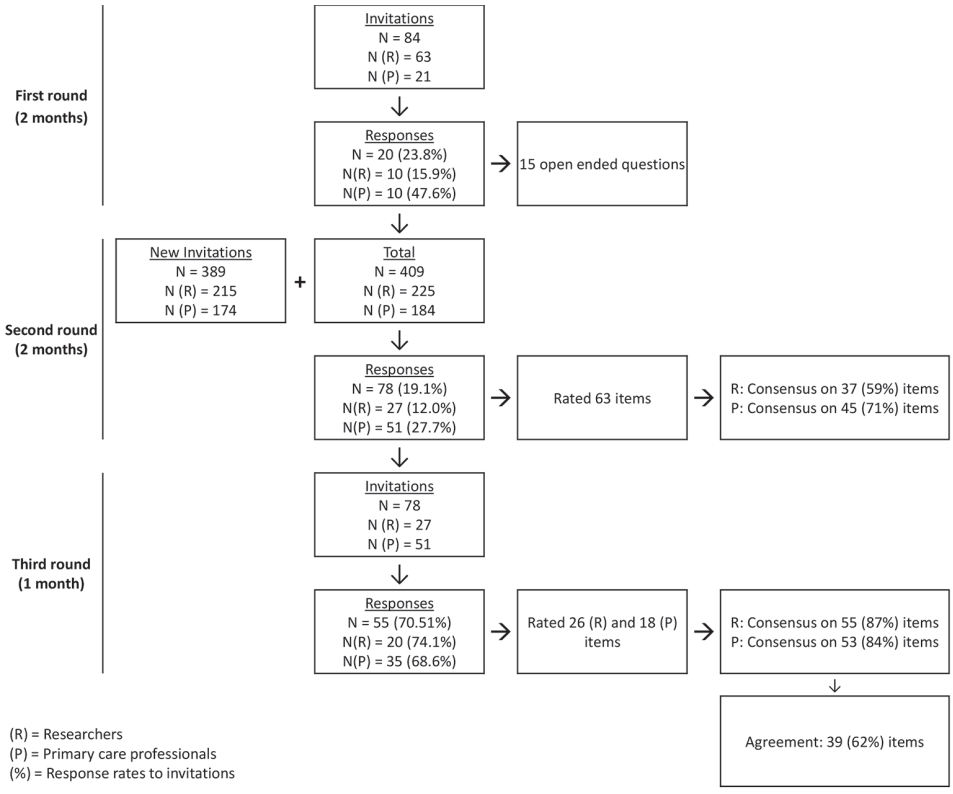



**Figure 1.** Overview of the recruitment process.

### 3.2 Criteria that should be met by an SCI when choosing recommending an SCI for to an individual patient (intervention characteristics

The researchers group reached consensus on the level of importance of twelve of the thirteen listed criteria over the course of rounds two and three; no consensus was reached on the inclusion of highly detailed information on smoking cessation in the intervention. Seven criteria were rated as important or very important (Mdn $\geq$ 6). The PCPs group also reached consensus on the level of importance of twelve of the thirteen items over the course of rounds two and three (all except the item regarding the length of the intervention). Four items were rated as important or very important. Between-group consensus was reached on nine items (69%) in which high motivation scored as the most important item (Mdn = 6.5) and the intervention including fewer session as the least important (Mdn = 4.5).

**3.3 How is the effectiveness of existing SCIs perceived?**

The researchers group reached consensus on the level of effectiveness of ten of the thirteen listed SCIs over the course of rounds two and three. Four of these were rated as effective or very effective (pharmacotherapy, NRT, brief cessation advice by a healthcare professional without additional interventions, and counseling in groups) (Mdn ≥ 6).

The PCPs group reached consensus on the level of effectiveness of eight of the thirteen items over the course of rounds two and three. Only two items were rated as effective or very effective: (1) pharmacotherapy, and (2) brief cessation advice by a health-care professional without additional interventions. Combining the results on importance and consensus, we can conclude that consensus was only reached on the latter. Between-group consensus was reached on seven out of thirteen interventions, with pharmacotherapy scoring the highest on effectiveness (Mdn = 6) and e-cigarettes the lowest (Mdn ≤ 3).

**3.4 Factors that should be taken into account when counseling different (high-risk) groups of smoking patients.**

Participants were asked to rate the level of importance of 22 factors divided over 4 (high-risk) groups of smoking patients.

***3.4.1 Patients with smoking-related complaints:***

The researchers group reached consensus on the level of importance of five of the six listed factors over the course of rounds two and three and rated these factors as important or very important (Mdn ≥ 6). The PCPs group reached consensus on the level of importance of all six items in round 2 and rated the same five items as important or very important as the researchers. Between-group consensus was reached on four items with the most important factors being that the smoker should be informed about his or her health risk (both Mdn = 6.5) (67% consensus).

***3.4.2 Pregnant patients:***

Both groups reached consensus on the importance of five of the six listed factors (consensus was reached in round two); neither group reached consensus on providing pregnant patients with the same cessation support as non-pregnant patients. Except for this factor, both groups rated the other five factors as important or very important (Mdn ≥ 6). Between-group consensus was reached on two items with the most important factor being that the smoker should be informed of the risks of smoking during pregnancy (Mdn ≥ 6.5) (33% consensus).

***3.4.3 Patients with a low SES:***

The researchers group reached consensus on the level of importance of three of the five listed factors over the course of rounds two and three. These factors were also rated as

important or very important (Mdn ≥ 6). The PCPs group reached consensus on the level of importance of four of the five items over the course of rounds two and three and also rated these as important. Between-group consensus was reached on all items, with 'the smoker should be informed about his or her health risk' scoring the highest (Mdn ≥ 6.5) (100% consensus).

***3.4.4 Patients with a low motivation to quit:***

Both groups reached consensus on the level of importance of four of the five listed factors (consensus was reached in round two) and rated those factors as important or very important (Mdn ≥ 6). Between-group consensus was reached on four items, with the item on focusing the counseling on increasing motivation scoring the highest (Mdn ≥ 6.0) (80% consensus).

**3.5 The use of e-cigarettes as a means to quit**

The researchers group reached consensus on their level of agreement on only one of the three statements on the use of e-cigarettes as a means to quit (consensus was reached in round two): informing patients fully about the risks of e-cigarettes before talking about them as an SCI. This statement was also the only one on which agreement with the statement was reached. The group of PCPs did not reach consensus on the statements. Between-group consensus was reached on one statement, namely, recommending e-cigarettes as a means to quit but not as the most preferred option.

## 4. DISCUSSION

**4.1 Main findings**

The four objectives of this study were to gain an overview of 1) the criteria important for recommending SCIs, 2) the perceptions on the effectiveness of SCIs, 3) the criteria important for counseling different (high-risk) groups of smokers and 4) the perceptions on the use of e-cigarettes. These topics will be discussed below.

First, consensus within both groups was exceptionally high on the level of importance of the different criteria for recommending an SCI to individual patients. Other studies have also found that the socio-economic status and smokers' experience with previous cessation attempts play a significant role in successful smoking cessation (152, 153). It is also known that raising the smokers motivation to quit, for example through the use of motivational interviewing techniques, during SCC can facilitate successful smoking cessation (154, 155). The Dutch guidelines (53) also advise PCPs to discuss previous quit attempts and to inquire after the reasons why these failed in order to adapt treatment accordingly.

Secondly, the PCPs group only reached consensus on the level of effectiveness of one SCI: a brief cessation advice by a healthcare professional without additional interventions. A brief quit advice by a health-care professional has been shown to significantly increase smoking abstinence, regardless of the patient's level of motivation (57). This corresponds with the first step of the Dutch smoking cessation guidelines. However, the combination of two or more evidence-based SCIs increases the chance of a successful quit attempt (156, 157). The use of multiple SCIs can help to increase smoking abstinence while also providing a wider range of options for smokers who are not able to visit their primary care practice or who have other preferences for SCC. The use of multiple SCIs can also take the form of in-practice counseling combined with an out-practice intervention such as eHealth or supplemental NRT.

Neither group rated the five non-evidence-based interventions (e-cigarettes, acupuncture, laser therapy, relaxation exercises and quitting without any form of cessation support) to be effective. Noted should be, however, that the level of effectiveness of three of these SCIs (i.e., acupuncture, laser therapy, and quitting without any form of cessation support) was rated higher in the PCPs group than in the researcher's group. A possible explanation is that PCPs' vision on the effectiveness is based on positive (personal) experiences. Further studies should investigate whether this is the case, how this vision can be adjusted and how to best discuss non-evidence-based interventions with patients.

Thirdly, we can conclude that both groups see some value in providing additional cessation support to the four (high-risk) groups of patients. As smoking prevalence is higher among disadvantaged groups, and disadvantaged smokers may face higher exposure to tobacco's harms, they might have different needs related to cessation support (16, 117, 158) and the necessity of providing additional support to pregnant patients is widely recognized as smoking is associated with risks for both the patient and the unborn child (159). Both groups indicated that smokers not motivated to quit should also be targeted, with the PCPs group stating that they find it important to increase motivation and use motivational interview techniques (154, 155).

Lastly, concerning the use of e-cigarettes, almost no consensus within or between the groups was reached. Possible explanations may be that research is still inconclusive on the use of e-cigarettes as a means to quit (160), that the quality and composition of e-cigarettes is highly variable (161), and that no concrete long-term effects in terms of effectiveness, safety and addiction are known (162-164).

### 4.2 Practice implications

First, with regards to high-risk groups of smokers, our results indicated that both groups found it important to provide additional support to high-risk groups of patients. Referring high-risk groups, such as older smokers (165) or patients with multimorbidity diseases (166), to extended cognitive behavioral therapy increases the chances of a successful quit attempt,

so this additional support is very valuable. Yet, in practice, PCPs do not always manage to pay extra attention to these group because of a lack of self-efficacy or time (33, 54) or a lower motivation among these type of patients (167-169). As stated earlier, motivational interview techniques (154, 155) can help PCPs to increase motivation as well as convince smokers of their increased health risk (especially during pregnancy). Although the Dutch guidelines for smoking cessation mention low motivation, smoking related diseases and low-SES, specific support directions are only provided for pregnant smokers. By adding support directions for the other high-risk groups, including information on the use of SCIs among high-risk groups (e.g., information on interventions designed for smokers with low language skills or interventions specifically targeted to pregnant woman), PCPs will be better able to support these groups, which may lead to higher quit percentages within these groups.

Secondly, while researchers reached consensus on the effectiveness on ten out of thirteen listed SCIs, PCPs only reached consensus on eight. In addition, as mentioned before, PCPs tend to rate the effectiveness of several non-evidence-based SCIs higher than the researchers' group, which may indicate an evidence-practice gap. An evidence-practice gap sometimes is associated with a lack of knowledge or formal training in CSS (170). Despite the fact that most Dutch PCPs are registered in the DRQSCP (150), this does not necessarily prevents misconceptions about the effectiveness of SCIs and this may imply the need for training programs or supplemental materials in order to fully acquaint PCPs with SCIs. To our knowledge, no prior research has been conducted on the perceptions of the effectiveness of SCIs among GPs and other PCPs.

Lastly, communication with PCPs on recent scientific findings may also reduce the uncertainty surrounding cigarettes, breaching the evidence-practice gap (145, 171). While the Dutch national smoking cessation guidelines advise against the use of e-cigarettes (172), they do not elaborate on how to approach patients who express a desire to use them as an SCI. Until a clear outcome on the use of e-cigarettes as an SCI is reached, a consensus on how to respond to these patients may aid PCPs in their counseling.

### 4.3 Limitations

A possible limitation is the response rate, especially among the researchers. Although these percentages are low, they are in line with those reported in similar Delphi studies or unsolicited questionnaires (173). We included international researchers to realize a large and varied sample of expertise in order to obtain a large spectrum of responses. One may argue that this could lower the generalizability to the Dutch context; yet, as the effectiveness of the SCIs is very similar across countries, and international data are often used in the Netherlands in communication on the effectiveness of SCIs, we believe that the level of distortion caused by this choice is probably very low.

We tried to include both GPs and PNs in the PCP group, but the first round only PNs were included. All GPs from our first round declined participation by stating that they themselves did not provide much SCC and referred us to their practice's PNs (42, 174). By

recruiting PCPs via the DRQSCP (150), we successfully managed to include a more diverse range of PCPs in our second and third round. Including a wide variety of participants is a strength of the study.

It may be possible that selectivity has occurred within the group of PNs, as participants who might have a particular interest in, or a strong opinion on this topic are more likely to participate. However, when inviting PCPs we tried to include a balanced mix of occupations of PCPs who provided active SCC, to ensure a heterogenic group. This may strengthen generalizability, mainly for the national setting, but perhaps also for a part for other countries, as primary care guidelines often are similar (for example the '5 As'(55)) even if the setting or the execution may slightly differ (e.g., SCC not being provided by specially trained PNs but by more general educated GPs)

## 5. CONCLUSIONS

This systematic exploration and consensus study focused on obtaining an overview of the knowledge and viewpoints on the effectiveness and use of SCIs different smoking cessation experts. The four objectives of this study were to gain an overview of 1) the criteria important for recommending an SCI, 2) the perceptions on the effectiveness of SCIs, 3) the criteria important for counseling different (high-risk) groups of smokers and 4) the perceptions on the use of e-cigarettes as a means to quit. Based on a three-round Delphi-study, we found a high agreement among researchers and PCPs on which patient characteristic should be taken into account when choosing a fitting SCI for individual patients (e.g., taking into account the patient's needs and previous cessation attempts). We also found that PCPs display a lower degree of consensus on the effectiveness of SCIs. Both researchers and PCPs see value in the use of special protocols for high-risk groups of patients, but the two groups did not reach consensus on the use of e-cigarettes as a means to quit. Making an inventory of PCPs' needs regarding SCIs and their usage may provide insight into how to facilitate a better uptake in the primary care setting.

## APPENDIX

**Table 2.** Results per item of the second- and third-round of 'research' and 'health professionals'

| |
|---|
| **Topic 1. Patient characteristics that should be taken into account when recommending an SCI (patient characteristics)** |
| The smoker's preference for a specific (type of) intervention |
| The extent to which the characteristics of an intervention meet the smoker's needs |
| The smoker's background (such as educational level or health literacy skills) |
| The smoker's personal characteristics (such as age, gender, or overall lifestyle) |
| The (type of) intervention(s) the smoker has previously used |
| The number of quit attempts that the smoker has previously undertaken |
| The level of success of the smoker's previous cessation attempts |
| The time elapsed since the smoker's last smoking cessation attempt |
| The difficulties the smoker experienced in previous cessation attempts |
| The smoker's motivation to quit smoking |
| The smoker's level of nicotine addiction |
| The financial costs of using the intervention |
| **Topic 2. Criteria that should be met by an SCI when recommending an SCI for an individual patient (intervention characteristics)** |
| When the smoker is highly motivated to quit |
| When the intervention meets the smoker's needs as perceived by the healthcare professional |
| When the intervention matches the smoker's preferences |
| When the intervention is tailored to that what the smoker already knows about smoking cessation |
| When the intervention supports the smoker in developing self-control regarding smoking and smoking cessation |
| When the intervention includes more rather than fewer sessions. |
| When the intervention continues over a longer period of time |
| When the intervention includes highly detailed information on smoking cessation |
| When the intervention is used by the smoker as it is meant to be (intervention fidelity) |
| When an independent RCT study shows that the intervention significantly increases the likelihood of smoking cessation over 6 months or longer when compared to usual care |
| When an independent RCT study shows that the intervention significantly increases the number of quit attempts when compared to usual care |
| When the intervention is certified as being effective (for example by national smoking cessation associations) |
| When the intervention is recommended by national guidelines for tobacco cessation |
| **Topic 3. How is the effectiveness of existing SCIs perceived?** |
| Pharmacotherapy |
| E-cigarettes |

| Research experts | | | | | | PCPs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Second round | | | Third round | | | Second round | | | Third round | | |
| N | Mdn | IQR | N | Mdn | IQR | N | Mdn | IQR | N | Mdn | IQR |
| 27 | 6.5 | **1** | | | | 51 | 6.0 | **1** | | | |
| 27 | 6.0 | **1** | | | | 51 | 6.0 | **1** | | | |
| 27 | 5.5 | **1** | | | | 51 | 5.0 | **1** | | | |
| 27 | 5.5 | **1** | | | | 51 | 5.5 | **1** | | | |
| 27 | 6.0 | **1** | | | | 51 | 6.0 | **1** | | | |
| 27 | 5.5 | **1** | | | | 51 | 5.5 | **1** | | | |
| 27 | 5.5 | **1** | | | | 51 | 5.5 | **1** | | | |
| 27 | 5.0 | **1** | | | | 51 | 5.0 | 2 | 32 | 5.5 | **1** |
| 27 | 6.0 | **1** | | | | 51 | 6.5 | **1** | | | |
| 27 | 6.0 | **1** | | | | 51 | 6.5 | **1** | | | |
| 27 | 6.0 | **1** | | | | 51 | 5.5 | **1** | | | |
| 27 | 5.5 | **1** | | | | 51 | 5.0 | 2 | 32 | 5.0 | **1** |
| 27 | 6.5 | **1** | | | | 50 | 6.5 | **1** | | | |
| 27 | 5.0 | **1** | | | | 50 | 6.0 | **1** | | | |
| 27 | 6.0 | **1** | | | | 50 | 6.0 | **0** | | | |
| 27 | 5.0 | 2 | 19 | 5.5 | **0** | 50 | 5.5 | **1** | | | |
| 27 | 6.0 | **1** | | | | 50 | 6.0 | **0** | | | |
| 27 | 4.0 | 3 | 19 | 4.5 | **1** | 50 | 4.0 | **1** | | | |
| 27 | 5.0 | 2 | 19 | 5.0 | **1** | 50 | 5.0 | 2 | 32 | 4.5 | 2 |
| 27 | 4.0 | 2 | 19 | 4.5 | 2 | 50 | 4.5 | **1** | | | |
| 27 | 5.5 | 2 | 19 | 6.0 | **1** | 50 | 5.5 | **1** | | | |
| 27 | 6.0 | 2 | 19 | 6.0 | **0** | 49 | 5.5 | **1** | | | |
| 27 | 5.0 | 2 | 19 | 5.5 | **1** | 49 | 5.0 | **1** | | | |
| 27 | 6.0 | **1** | | | | 49 | 5.0 | 2 | 32 | 5.5 | **1** |
| 27 | 6.0 | **1** | | | | 49 | 5.5 | **1** | | | |
| 26 | 6.0 | 2 | 19 | 6.0 | **1** | 49 | 6.0 | 2 | 32 | 6.0 | 2 |
| 26 | 3.0 | 2 | 19 | 3.0 | 2 | 49 | 3.0 | 3 | | | |

**Table 2.** continued

| |
|---|
| Freely available nicotine replacement therapy (for example patches or chewing gum) |
| Acupuncture |
| Laser therapy |
| Brief cessation advice by a healthcare professional without additional interventions |
| Brief cessation advice by a healthcare professional in combination with pharmacotherapy |
| Behavioral counseling – face-to-face |
| Behavioral counseling – via telephone |
| Behavioral counseling – in groups |
| Behavioral counseling – eHealth |
| Relaxation exercises (for example mindfulness or yoga) |
| Quitting without any form of counseling or other resources |
| **Topic 4. Factors that should be taken into account when counseling different (high-risk) groups of smoking patients** |
| Smokers with smoking related complaints or conditions |
| The smoker should be informed about his or her health risk |
| The smoker should be informed about the health risks for others in their surroundings |
| When a smoker is motivated to quit, treatment should start as soon as possible |
| Counseling should be based on motivational interviewing techniques |
| Counseling should be tailored to the smoker's individual health problems |
| This group of smokers should receive the same cessation support as smokers without complaints or conditions |
| Smoking pregnant women |
| The smoker should be informed about her health risk as well as the risks for the unborn child |
| When a smoker is motivated to quit, treatment should start as soon as possible |
| The smoker's partner should be encouraged to provide cessation support |
| The smoker's partner should also be encouraged to quit smoking |
| The smoker should be informed of the risks of smoking during pregnancy |
| This group of smokers should receive the same cessation support as non-pregnant smokers |
| Smokers with a low SES |
| The smoker should be informed about his or her health risk |
| The smoker should be informed of the money they could save by quitting |
| Support should be focused on planning and performing alternative behaviors (coping planning) |
| Counseling should be based on motivational interviewing techniques |
| This group of smokers should receive the same cessation support as smokers with an average SES |
| Smokers with a low motivation to quit |
| Counseling should focus first on increasing motivation (quitting should be attempted after motivation has increased) |

| Research experts | | | | | | PCPs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Second round | | | Third round | | | Second round | | | Third round | | |
| N | Mdn | IQR | N | Mdn | IQR | N | Mdn | IQR | N | Mdn | IQR |
| 26 | 6.0 | 2 | 19 | 6.0 | **1** | 49 | 5.5 | **1** | | | |
| 26 | 2.5 | 2 | 19 | 2.0 | **1** | 49 | 4.0 | 2 | 32 | 5.5 | 2 |
| 26 | 2.5 | 2 | 19 | 1.5 | **1** | 49 | 3.5 | **1** | | | |
| 26 | 6.0 | 2 | 19 | 6.5 | **1** | 49 | 6.0 | 2 | 32 | 6.0 | **1** |
| 26 | 5.0 | 2 | 19 | 5.0 | **0** | 49 | 5.0 | 2 | 32 | 5.5 | 2 |
| 26 | 6.0 | 2 | 19 | 6.0 | 2 | 49 | 5.0 | 2 | 32 | 5.5 | 2 |
| 26 | 5.5 | **1** | | | | 49 | 5.5 | **1** | | | |
| 26 | 6.0 | **1** | | | | 49 | 5.5 | **1** | | | |
| 26 | 5.5 | **1** | | | | 49 | 5.0 | **1** | | | |
| 26 | 4.5 | **1** | | | | 49 | 4.5 | **1** | | | |
| 26 | 3.0 | 3 | 19 | 3.0 | 2 | 49 | 4.0 | 2 | 32 | 4.5 | 3 |
| 25 | 6.5 | 2 | 19 | 6.5 | **1** | 48 | 6.5 | **1** | | | |
| 25 | 6.0 | **1** | | | | 48 | 6.0 | **0** | | | |
| 25 | 7.0 | 0 | | | | 48 | 6.0 | **1** | | | |
| 25 | 5.5 | 2 | 19 | 6.5 | **1** | 48 | 6.5 | **1** | | | |
| 25 | 6.0 | **1** | | | | 48 | 6.5 | **1** | | | |
| 25 | 4.0 | 3 | 19 | 5.0 | 2 | 48 | 4.5 | **1** | | | |
| 25 | 7.0 | **0** | | | | 48 | 6.5 | **1** | | | |
| 25 | 7.0 | **0** | | | | 48 | 6.5 | **1** | | | |
| 25 | 6.5 | **0** | | | | 48 | 6.5 | **1** | | | |
| 25 | 7.0 | **0** | | | | 48 | 6.5 | **1** | | | |
| 25 | 7.0 | **0** | | | | 48 | 6.5 | **1** | | | |
| 25 | 4.0 | 3 | 19 | 3.5 | 3 | 48 | 4.0 | 2 | 32 | 3.5 | 3 |
| 25 | 6.5 | **1** | | | | 48 | 6.5 | **1** | | | |
| 25 | 6.0 | **1** | | | | 48 | 6.0 | 2 | 32 | 6.0 | **1** |
| 25 | 6.0 | 2 | 19 | 6.0 | 1 | 48 | 6.0 | 2 | 32 | 6.0 | **0** |
| 25 | 6.0 | 2 | 19 | 6.0 | 2 | 48 | 6.0 | **1** | | | |
| 25 | 4.0 | 3 | 19 | 4.5 | 3 | 48 | 4.5 | 2 | 32 | 4.5 | 3 |
| 25 | 6.0 | **1** | | | | 47 | 6.5 | **1** | | | |

**Table 2.** continued

| |
|---|
| Healthcare professionals should use motivational interview techniques |
| The smoker should be informed about his or her health risk |
| The smoker should be informed about the health risk for others in their environment |
| This group of smokers should receive the same cessation support as smokers who are highly motivated |
| **Topic 5. The use of e-cigarettes as a means to quit** |
| The healthcare provider should discourage using e-cigarettes as an aid for smoking cessation |
| The healthcare provider should inform the smoker fully about the use and risks of e-cigarettes before talking about them as a form of smoking cessation intervention |
| The caregiver can recommend e-cigarettes as an aid for smoking cessation, but not as the most preferred option |

| Research experts | | | | | | PCPs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Second round | | | Third round | | | Second round | | | Third round | | |
| N | Mdn | IQR | N | Mdn | IQR | N | Mdn | IQR | N | Mdn | IQR |
| 25 | 6.0 | **1** | | | | 47 | 6.5 | **1** | | | |
| 25 | 6.5 | **1** | | | | 47 | 6.0 | **1** | | | |
| 25 | 6.0 | **1** | | | | 47 | 6.0 | **1** | | | |
| 25 | 4.5 | 4 | 19 | 5.0 | 2 | 47 | 4.5 | 2 | 32 | 5.0 | 2 |
| 25 | 4.0 | 4 | 19 | 4.0 | 2 | 49 | 5.0 | 2 | 32 | 5.0 | 2 |
| 25 | 6.0 | **1** | | | | 49 | 5.0 | 2 | 32 | 5.5 | 2 |
| 25 | 5.5 | 2 | 19 | 5.0 | 2 | 49 | 4.0 | 3 | 32 | 4.0 | 2 |

**Table 3.** Consensus between the groups of research experts and healthcare professionals

| |
|---|
| **Topic 1. Patient characteristics that should be taken into account when recommending an SCI (patient characteristics)** |
| The smoker's preference for a specific (type of) intervention |
| The extent to which the characteristics of an intervention meet the smoker's needs |
| The smoker's background (such as educational level or health literacy skills) |
| The smoker's personal characteristics (such as age, gender, or overall lifestyle) |
| The (type of) intervention(s) the smoker has previously used |
| The number of quit attempts that the smoker has previously undertaken |
| The level of success of the smoker's previous cessation attempts |
| The time elapsed since the smoker's last smoking cessation attempt |
| The difficulties the smoker experienced in previous cessation attempts |
| The smoker's motivation to quit smoking |
| The smoker's level of nicotine addiction |
| The financial costs of using the intervention |
| **Topic 2. Criteria that should be met by an SCI when recommending an SCI for an individual patient (intervention characteristics)** |
| When the smoker is highly motivated to quit |
| When the intervention meets the smoker's needs as perceived by the healthcare professional |
| When the intervention matches the smoker's preferences |
| When the intervention is tailored to that what the smoker already knows about smoking cessation |
| When the intervention supports the smoker in developing self-control regarding smoking and smoking cessation |
| When the intervention includes more rather than fewer sessions. |
| When the intervention continues over a longer period of time |
| When the intervention includes highly detailed information on smoking cessation |
| When the intervention is used by the smoker as it is meant to be (intervention fidelity) |
| When an independent RCT study shows that the intervention significantly increases the likelihood of smoking cessation over 6 months or longer when compared to usual care |
| When an independent RCT study shows that the intervention significantly increases the number of quit attempts when compared to usual care |
| When the intervention is certified as being effective (for example by national smoking cessation associations) |
| When the intervention is recommended by national guidelines for tobacco cessation |
| **Topic 3. How is the effectiveness of existing SCIs perceived?** |
| Pharmacotherapy |
| E-cigarettes |
| Freely available nicotine replacement therapy (for example patches or chewing gum) |
| Acupuncture |
| Laser therapy |
| Brief cessation advice by a healthcare professional without additional interventions |
| Brief cessation advice by a healthcare professional in combination with pharmacotherapy |
| Behavioral counseling – face-to-face |
| Behavioral counseling – via telephone |

| N | Mdn research | Mdn PCP | Wilcoxon W | Sig. |
|---|---|---|---|---|
| 78 | 6.5 | 6.0 | 1918.0 | .251 |
| **78** | **6.0** | **6.0** | **1841.0** | **.041** |
| 78 | 5.5 | 5.0 | 1992.0 | .802 |
| 78 | 5.5 | 5.5 | 1972.0 | .633 |
| **78** | **6.0** | **6.0** | **868.5** | **.018** |
| 78 | 5.5 | 5.5 | 896.0 | .054 |
| 78 | 5.5 | 5.5 | 939.5 | .162 |
| 61 | 5.0 | 5.5 | 940.0 | .165 |
| 78 | 6.0 | 6.5 | 1995.5 | .824 |
| 78 | 6.0 | 6.5 | 2009.0 | .948 |
| **78** | **6.0** | **5.5** | **1791.0** | **.010** |
| **61** | **5.5** | **5.0** | **1802.0** | **.020** |
| 77 | 6.5 | 6.5 | 988.0 | .411 |
| **77** | **5.0** | **6.0** | **657.5** | **.000** |
| 77 | 6.0 | 6.0 | 1911.0 | .646 |
| 70 | 5.0 | 5.5 | 925.0 | .127 |
| 77 | 6.0 | 6.0 | 1886.5 | .461 |
| 54 | 4.5 | 4.5 | 1044.5 | .925 |
| 70 | 5.0 | 4.5 | 986.5 | .459 |
| 70 | 4.5 | 5.5 | 1945.5 | .958 |
| 70 | 6.0 | 5.5 | 951.5 | .262 |
| **69** | **5.0** | **4.5** | **1728.0** | **.071** |
| 69 | 6.0 | 5.5 | 900.0 | .112 |
| **61** | **6.0** | **5.5** | **1676.0** | **.017** |
| **76** | **6.5** | **5.5** | **1644.0** | **.005** |
| 54 | 6.0 | 6.0 | 1839.0 | .786 |
| 69 | 3.0 | 3.0 | 912.0 | .385 |
| 69 | 6.0 | 5.5 | 1717.5 | .092 |
| **54** | **2.0** | **5.5** | **589.0** | **.000** |
| **54** | **1.5** | **3.5** | **580.0** | **.000** |
| 54 | 6.5 | 6.0 | 1705.0 | .066 |
| 54 | 5.0 | 5.5 | 1795.0 | .446 |
| **69** | **6.0** | **5.5** | **1525.0** | **.000** |
| 75 | 5.5 | 5.5 | 1744.5 | .172 |

**Table 3.** continued

| |
|---|
| Behavioral counseling – in groups |
| Behavioral counseling – eHealth |
| Relaxation exercises (for example mindfulness or yoga) |
| Quitting without any form of counseling or other resources |
| **Topic 4. Factors that should be taken into account when counseling different (high-risk) groups of smoking patients** |
| Smokers with smoking related complaints or conditions |
| The smoker should be informed about his or her health risk |
| The smoker should be informed about the health risks for others in their surroundings |
| When a smoker is motivated to quit, treatment should start as soon as possible |
| Counseling should be based on motivational interviewing techniques |
| Counseling should be tailored to the smoker's individual health problems |
| This group of smokers should receive the same cessation support as smokers without complaints or conditions |
| Smoking pregnant women |
| The smoker should be informed about her health risk as well as the risks for the unborn child |
| When a smoker is motivated to quit, treatment should start as soon as possible |
| The smoker's partner should be encouraged to provide cessation support |
| The smoker's partner should also be encouraged to quit smoking |
| The smoker should be informed of the risks of smoking during pregnancy |
| This group of smokers should receive the same cessation support as non-pregnant smokers |
| Smokers with a low SES |
| The smoker should be informed about his or her health risk |
| The smoker should be informed of the money they could save by quitting |
| Support should be focused on planning and performing alternative behaviors (coping planning) |
| Counseling should be based on motivational interviewing techniques |
| This group of smokers should receive the same cessation support as smokers with an average SES |
| Smokers with a low motivation to quit |
| Counseling should focus first on increasing motivation (quitting should be attempted after motivation has increased) |
| Healthcare professionals should use motivational interview techniques |
| The smoker should be informed about his or her health risk |
| The smoker should be informed about the health risk for others in their environment |
| This group of smokers should receive the same cessation support as smokers who are highly motivated |
| **Topic 5. The use of e-cigarettes as a means to quit** |
| The healthcare provider should discourage using e-cigarettes as an aid for smoking cessation |
| The healthcare provider should inform the smoker fully about the use and risks of e-cigarettes before talking about them as a form of smoking cessation intervention |
| The caregiver can recommend e-cigarettes as an aid for smoking cessation, but not as the most preferred option |

| N | Mdn research | Mdn PCP | Wilcoxon W | Sig. |
|---|---|---|---|---|
| **75** | **6.0** | **5.5** | **1626.5** | **.006** |
| **60** | **5.5** | **5.0** | **1647.5** | **.012** |
| 75 | 4.5 | 4.5 | 1854.5 | .930 |
| **54** | **3.0** | **4.0** | **753.0** | **.007** |
| 68 | 6.5 | 6.5 | 1659.5 | .135 |
| 73 | 6.0 | 6.0 | 1633.5 | .070 |
| **73** | **7.0** | **6.0** | **1414.0** | **.000** |
| **68** | **6.5** | **6.5** | **739.0** | **.020** |
| 73 | 6.0 | 6.5 | 907.0 | .818 |
| 68 | 5.0 | 4.5 | 872.0 | .516 |
| **73** | **7.0** | **6.5** | **1609.0** | **.015** |
| **73** | **7.0** | **6.5** | **1597.0** | **.007** |
| **73** | **6.5** | **6.5** | **1625.0** | **.047** |
| **73** | **7.0** | **6.5** | **1589.5** | **.012** |
| 73 | 7.0 | 6.5 | 1680.0 | .150 |
| 54 | 3.5 | 4.0 | 1737.0 | .643 |
| 73 | 6.5 | 7.0 | 1703.5 | .345 |
| 59 | 6.0 | 6.0 | 1755.0 | .794 |
| 54 | 6.0 | 6.0 | 1775.5 | .995 |
| 68 | 6.0 | 6.0 | 779.5 | .071 |
| 54 | 4.5 | 4.0 | 896.5 | .733 |
| 72 | 6.0 | 6.5 | 890.0 | .768 |
| 72 | 6.0 | 6.0 | 839.5 | .346 |
| **72** | **6.5** | **6.0** | **1558.5** | **.043** |
| 72 | 6.0 | 6.0 | 1578.5 | .087 |
| 54 | 5.0 | 4.5 | 1694.5 | .799 |
| **54** | **4.0** | **5.0** | **760.5** | **.039** |
| **59** | **6.0** | **5.5** | **1573.5** | **.002** |
| 54 | 5.0 | 4.0 | 1704.5 | .121 |

# CHAPTER 3

## A referral aid for smoking cessation interventions in primary care: study protocol for a randomized controlled trial

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## ABSTRACT

**Background:** To expedite the use of evidence-based smoking cessation interventions (EBSCIs) in primary care and to thereby increase the number of successful quit attempts, a referral aid was developed. This aid aims to optimize the referral to and use of EBSCIs in primary care and to increase adherence to Dutch guidelines for smoking cessation.

**Methods:** Practice nurses (PNs) will be randomly allocated to an experimental condition or control condition and will then recruit smoking patients who show a willingness to quit smoking within 6 months. PNs allocated to the experimental condition will provide smoking cessation guidance in accordance with the referral aid. Patients from both conditions will receive questionnaires at baseline and after 6 months. Cessation effectiveness will be tested via multilevel logistic regression analyses. Multiple imputation as well as intention to treat analysis will be performed. Intervention appreciation and level of informed decision making will be compared using analysis of (co)variance. Predictors for appreciation and informed decision making will be assessed using multiple linear regression analysis and/or structural equation modeling. Finally, a cost-effectiveness study will be conducted.

**Discussion:** This paper describes the study design for the development and evaluation of an information and decision tool to support PNs in their guidance of smoking patients and their referral to EBSCIs. The study aims to provide insight into the (cost) effectiveness of an intervention aimed at expediting the use of EBSCIs in primary care.

## 1. INTRODUCTION

Smoking remains the highest contributor to substance-attributable mortality (175). In the Netherlands, around 20.000 people die from firsthand or secondhand smoke inhalation each year (176). Consequently, in 2018, the Dutch government created the National Prevention Act which, among other things, aims to create a smoke-free generation in 2040 (22). In 2018, 36.9% of Dutch smokers attempted to quit (101). However, only 5% of those who quit remains abstinent after 12 months (137, 177).

The use of an evidence-based smoking cessation intervention (EBSCI) can double the chance of successful smoking cessation after 12 months (86). EBSCIs come in two forms: behavioral counseling and supplementations. Behavioral counseling can consist of: face-to-face counseling by a health care professional (HCP), such as a general practitioner (GP) or a practice nurse (PN) or trained stop coach outside the GP-setting (44, 57, 62-65), tailored online counseling (eHealth) (69, 178), telephone counseling (179) and group counseling (74). However, only 25-30% of smokers report using behavioral counseling methods (88, 89). The effectiveness of behavioral counseling can be increased through supplementation with nicotine replacement therapy such as nicotine gum or patches (available over the counter at pharmacies, drugstores and large supermarkets)(78) or pharmacotherapy (75-77) of which the latter can only be prescribed in the Netherlands via the GP-setting to patients indicating they are willing to make use of them (52).

The general practice setting is a gateway to reach and advise smokers; most Dutch smokers visit their GP yearly (180) and smokers have a high level of trust in their GP (181). Theoretically, a good fit between the treatment and the patient's needs and preferences improves the patient's chances successfully quitting smoking. Discussing intervention options, their characteristics and a subsequently referral to cost-effective EBSCIs, such as eHealth interventions (70) can assist smokers in finding the best way to quit in accordance to their needs, while also lowering the time burden of smoking cessation counseling during (chronic care) consultations.

The Dutch smoking cessation guidelines for general practices instruct HCPs to actively offer smokers cessation treatment and to refer smokers to EBSCIs that fit patients' needs and preferences (52). Up till ten years ago, smoking cessation support was predominantly provided by the GP. Nowadays, in most Dutch practices, smoking patients are referred to a PN (182). PNs are specialized in chronic care (42), which mostly consists of lifestyle change guidance. GPs and PNs usually use an evidence-based health counseling protocol similar to the 5-As (Ask, Advise, Assess, Assist, and Arrange) Tobacco Cessation guideline (177) as also prescribed by the Dutch smoking cessation guidelines (52) and previous studies in the GP setting (44, 183).

However, PNs' adherence to smoking cessation guidelines and the referral of patients to fitting EBSCIs is sub-optimal (114, 184). This may result from PNs unfamiliarity with

EBSCIs , which hinders them in confidently discussing options with patients (114). Other barriers may be a high workload, a shortage of resources or an unfavorable perception of the usability of cessation guidelines (114, 185).

In order to expedite the use of EBSCIs in primary care and to thereby increase the number of successful quit attempts, a referral aid was developed. This aid aims to optimize the referral to and use of EBSCIs in primary care and to increase adherence to Dutch guidelines for smoking cessation. This paper aims to describe the development of the referral aid, as well as the design of the associated effectiveness and cost effectiveness studies.

## 2. METHOD

### 2.1 Ethical Approval

The medical ethics committee of the University Hospital Maastricht and Maastricht University evaluated the research proposal and indicated that no medical ethical clearance for this study was needed according to the rules of the Medical Research Involving Human Subjects Act (WMO – 2018-1038). The study was registered at the Netherlands Trial Register (NL7020, https://www.trialregister.nl/trial/7020).

### 2.2 Study Design

The aim is to conduct a multi-site two-group parallel-randomized controlled trial involving an experimental condition and a control condition. Patients in the control condition will receive care as usual, which usually includes at least a mandatory brief smoking cessation advice and can be supplemented with counseling based on an evidence-based health counseling protocol similar to 5-As (Ask, Advise, Assess, Assist, and Arrange) Tobacco Cessation guideline (177) as also described in the Dutch guidelines for smoking cessation (52) and previous studies in the GP setting (44, 183) in the way the individual PN sees fit. In addition to the usual care, Patients in the experimental condition will receive guidance and referral by the PN in accordance with the referral aid in order to select an EBSCI that fits their needs and preferences, which acts as an expansion on the Assist and Arrange steps from the 5-A protocol (177). The chosen EBSCI can either be administered by the PN (i.e., face-to-face counseling) or coordinated by the PN (e.g., eHealth, telephone counseling).

Randomization will occur on practice level, to prevent bias between on the PN-level or the patients-level. General practices will be randomly allocated to either the control condition or the experimental condition in a 1:1 ratio. Randomization will take place via a random number generator which creates a string of numbers (1=control condition, 2=experimental condition) which will be allocated to general practices in order of registration. Patients are allocated based on their GP practice allocation. By allocation on practice level, PNs cannot

accidently bias patients from the control group with information intended for the experimental group. As PNs from the experimental condition are provided with an intervention and PNs from the control condition are only asked to provide care as usual, blinding of the PNs is impossible. Patients will be semi-blinded, as they are unaware of the procedure of any other group than the one they attend.

Patients have to answer two questionnaires - at baseline and follow-up. This can be done on paper or online. Patients receive a link to the questionnaire or a paper version after they have been registered by the PN. The follow-up measurement will take place 6 months after the baseline questionnaire has been answered. The study design is illustrated in Figure 1.

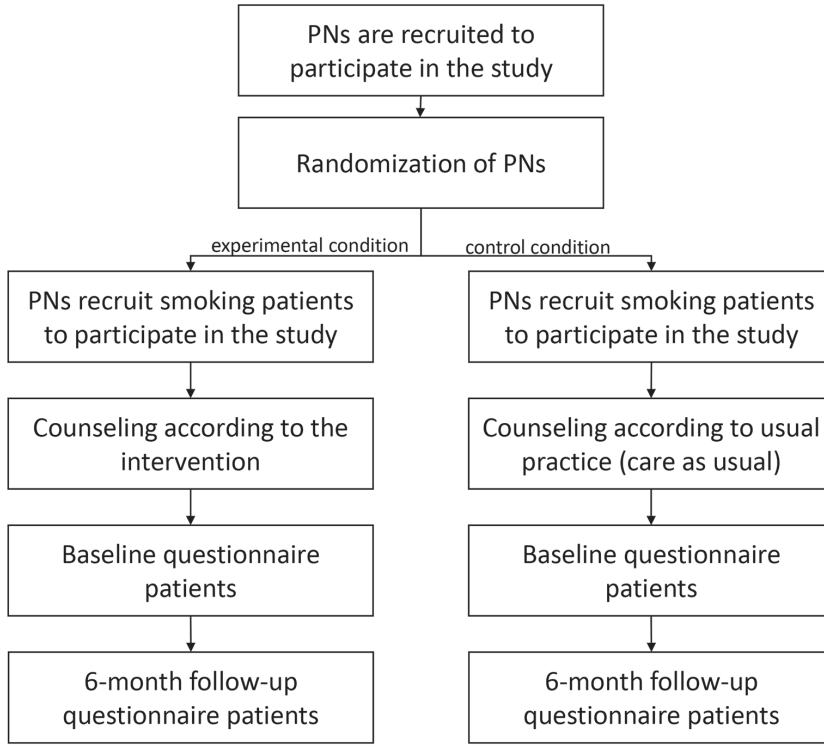



**Figure 1.** Flowchart of the study design.

### 2.3 Recruitment of Practice Nurses

From January 2019 until May 2020, PNs in the Netherlands will be approached to participate in the study. The task of the PNs will be twofold - recruiting smokers and referral to EBSCIs in accordance with the intervention's method.

An information package including a study invitation letter and an intervention summary will be sent to general practices spread over the Netherlands. Dutch primary care associations who support the study will also distribute the information letters to their associate general practices through their own communication channels. To gauge the interest in participating in the study, approached practices will be contacted via telephone after two weeks. Health care professionals expressing an interest in participating will be sent a more detailed guideline for the study and will be asked to sign a study participation form. PNs are requested to recruit 10 to 20 patients each. To prevent attrition and stimulate active recruitment by the PNs, participating PNs who recruit at least five patients will receive a remuneration of €100. Inclusion criteria will be that PNs are employed by one or more general practices in the Netherlands and that they indicate that they provide smoking cessation counseling as such.

**2.4 Recruitment of Smokers**

From May 2019 until May 2020, participating PNs are requested to inquire about the smoking status of all their patients with smoking related complaints. Patients who report to be a smoker (no set minimum requirements), will be asked to participate in the study. If they agree to participate, they will receive brief guidance and referral advice dependent on the condition in which the PN has been assigned. Written informed consent will be obtained from all participants. Smokers will be rewarded a gift voucher of €10 for participating if they answer both questionnaires.

Inclusion criteria will be that patients smoke tobacco products, are at least 18 years old, and able to read and understand Dutch. Patients who only use e-cigarettes / e-cigars are not eligible to participate.

**2.5 Intervention: The referral aid**

The referral aid is named 'StopWijzer', which can be translated as either stop-guide or stop-wiser. The content of the referral aid is based on a needs assessment consisting of a literature review (e.g. (31, 69, 105)), individual semi-structured interviews among General Practitioners (GPs) (n=5), practice nurses (PNs) (n=20) and smokers (n=9), a Delphi study on the referral to EBSCIs (not published yet) and the input of an advisory board consisting of experts representing various Dutch smoking cessation related organizations of whom six were actively involved

The PNs in the experimental condition will receive an intervention's manual to aid them in discussing smoking cessation with their patients and to help them select an EBSCI that fits the patient's needs and preferences. Smoking cessation interventions which are included in the referral aid are 1) face-to-face counseling (44), 2) counseling via internet (eHealth) (69, 178), 3) telephone counseling (179), 4) group counseling (74), 5) pharmacotherapy and 6) nicotine replacement therapy. It is strongly recommended to only offer pharmacotherapy and nicotine replacement therapy in combination with a form of behavioral counseling, as

is also counseled by the Dutch smoking cessation guidelines (52).

The use of non-evidence-based methods such as acupuncture and the use of e-cigarettes is also discussed in the referral aid as smokers might inquire about the effectiveness of these methods. Th referral aid actively encourages PNs to not recommend these methods and stimulates them to advance the aforementioned EBSCIs as suitable alternatives.

The PN starts with inquiring about the patients' smoking habits and his or her interest in undertaking a smoking cessation attempt. They also inform the patient about the referral aid and the underlying study (see also Figure 2).

Patients who agree to participate in the study will be counseled in accordance with the referral aid. Firstly, the PN inquires about earlier cessation attempts and smoking cessation methods patients may have used during these attempts. Secondly, the PN informs the patient about the available EBSCIs and their advantages and disadvantages based on the information provided in the intervention's manual. If necessary, the manual also allows PNs to provide information on possible reimbursements by health insurers. Thirdly, the PN and patient discuss which EBSCI best fits the patient's needs and preferences. Fourthly, the smoker selects an EBSCI and chooses a cessation date. Lastly, depending on the EBSCI chosen by the patient, PNs schedule at least one follow-up appointment in 2-5 weeks, in order to evaluate and, if necessary, to select another EBSCI.

If the smoker is not (yet) interested in participating, PNs are advised to give the smoker a flyer to take home. This flyer contains information about participating in the study and a summary of the different EBSCIs. This way, smokers may be stimulated to consider smoking cessation at a later point of time. If the smoker is uncertain about participating, PNs are advised to, in addition to handing out the aforementioned flyer, schedule a follow-up meeting or telephone call with the smoker for further discussion on participation in the study.

**2.6 Intervention materials**

Materials will consist of a small (letterbox sized) package which will be sent via post and a website (www.stopwijzer.nu). Taking into account the potential of low health literacy of patients, the materials have been written in clear and comprehensible language in accordance with the applicable Dutch guidelines (Language level B1) (186). The main component is an instruction manual for using the referral aid. This manual consists of the following elements (see also Figure 3):

1. an introduction, which explains the goals and relevance of the intervention and gives a brief overview of the different EBSCIs and the other elements of the referral aid;
2. instructions in using the referral aid, which include a roadmap of the most important steps and a summary in the form of a flowchart;
3. an overview of possible reimbursements of EBSCI's by health insurers with a calculation tool to help patients provide insight into how much money they can save by quitting smoking;

4. an overview of the different EBSCIs, in the following order: face-to-face counseling, eHealth, counseling via telephone, group counseling, nicotine replacement therapy, pharmacotherapy and non-evidence based 'cessation' methods (acupuncture (187), laser therapy (188), auriculotherapy (189), hypnoses (190) and e-cigarettes (191));
5. guidelines for following up the initial consultation;
6. some concluding remarks and room for taking notes.

### *2.6.1 Flowchart handout*

Two of the elements of the instruction manual, a summary of the referral aid and a summary of health insurer's reimbursements policies, are printed on A5 carton handouts in order to be used by PNs as a quick reminder (see also Figure 4).

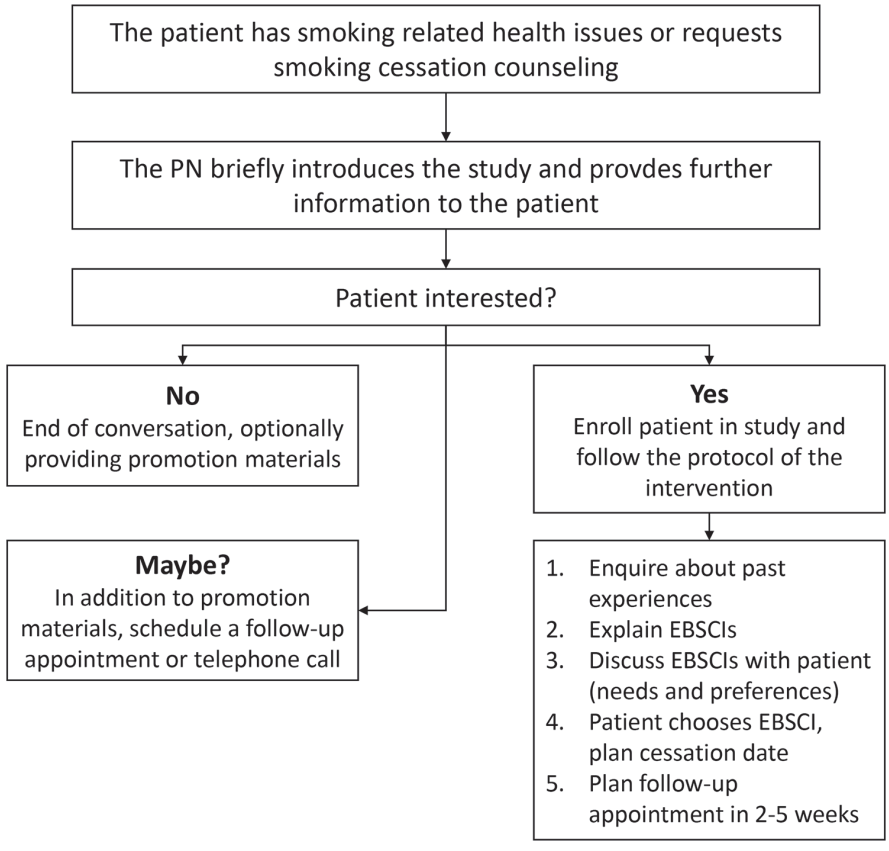



**Figure 2**. Flowchart referral aid

# INLEIDING

*Veel rokers die willen stoppen met roken maken geen gebruik van (effectieve) stopmethodes zoals begeleiding door een huisarts of praktijkondersteuner (POH), online begeleiding, telefonische begeleiding of groepsbegeleiding. Dit is jammer, omdat het gebruik van (effectieve) stopmethodes de kans op succesvol stoppen met wel 10% verhoogt! Via de StopWijzer willen we het gebruik van deze stopmethodes verhogen. Daarom hebben we op basis van evaluaties onder rokers, huisartsen en POHs de StopWijzer ontwikkeld.*

De StopWijzer is bedoeld voor huisartsen, POHs en anderen (hierna zorgverlener genoemd) uit de huisartspraktijk die zich bezighouden met het begeleiden van patiënten die graag willen stoppen met roken. Andere medewerkers binnen de huisartspraktijk kunnen aan de hand van de poster, folder of visitekaartjes verwijzen naar de StopWijzer of patiënten

met de zorgverlener.

WAT IS **DE STOPWIJZER**

De StopWijzer geeft een kort overzicht
vier soorten effectieve gedragsmatig
Gedragsmatige stopmethodes zijn meth
op het rookgedrag van de patiënt en niet
verslaving aan de stof nicotine. Met deze
zorgverleners hun patiënten volgens
inzichten effectief ondersteunen bij het st

De StopWijzer is gemaakt op basis van een
evaluatie. De zorgverlener helpt de roke
kiezen die het beste past bij hem/haar, ook
de huisartspraktijk. Doordat de patiënt ze
een bepaalde methode (of een combinatie
deze meer gemotiveerd het stoptraject in g
kans op een succesvolle stoppoging.

De volgende gedragsmatige stopmetho
StopWijzer toegelicht:

1. Stoppen door begeleiding door een
   persoonlijke stopcoach;
2. Stoppen door effectieve begeleiding v
3. Stoppen door effectieve telefonische
4. Stoppen via effectieve groepsbegeleid

# BEGELEIDING VIA HET INTERNET *(EHEALTH)*

*eHealth betekent informatie over gezondheid via het internet. Ook voor stoppen met roken is er informatie op het internet beschikbaar en zijn er apps te downloaden. Wij verwijzen hieronder naar interventies waarvan het effect is aangetoond en welke bij het 'Loket Gezond Leven' staan geregistreerd als effectief. Deze methodes maken ook vaak gebruik van de stappen die bij de bespreking van persoonlijke begeleiding reeds aan de orde gekomen zijn. Een rokende patiënt moet via een website of app vragen beantwoorden. Daarna krijgt de patiënt een persoonlijk advies en hulp die gebaseerd is op zijn of haar antwoorden. De patiënt kan op ieder moment met een eHealth interventie aan de slag; de lengte varieert van één tot meerdere sessies. Er zijn ook andere eHealth stoppen-met-roken programma's en apps die niet op effectiviteit zijn getest. Van deze interventies kunnen we dus niet met zekerheid zeggen of ze de kans op een*

**UW ROL**

Als de patiënt middels begeleiding via het i
bespreekt u samen de voor- en nadelen van
Ook bespreekt u waar de patiënt terecht ki
via het internet en hoe dit in zijn werk gaa
vragen zelf thuis te kijken en contact op
samen een aanbieder uitzoeken. U kunt o
vervolgafspraken plannen om met de patië
de stoppoging gaat, hoe de begeleiding ga
verdere ondersteuning wil.

**VOORDELEN**

- De patiënt kiest zelf wanneer hij o
- Vanaf elke plek beschikbaar.
- De patiënt bepaalt zijn of haar eig

**AANBIEDERS EFFECTIEVE TRAININGEN GE
EHEALTH IN NEDERLAND**

Stoppen met roken 2.0, 1 sessie (gratis)
► http://www.health-alert.nl/

Steun bij stoppen, minimaal 3 sessies (gra
► http://www.health-alert.nl/

Jellinek (gratis)
► http://www.zelfhulptabak.nl/Portal

# NA HET GESPREK

U heeft de rokende patiënt nu geholpen om een stopmethode (of een combinatie van methodes) te kiezen die het beste bij hem of haar past. Dit kan natuurlijk de begeleiding zijn die u altijd geeft of één van de andere stopmethodes. Mocht de patiënt de voorkeur geven aan één van de andere methodes, zoals begeleiding via het internet of telefonische begeleiding, groepsbegeleiding, dan is het verstandig dat u tussentijds (bijvoorbeeld na 2 of 3 weken) informeert hoe het gaat met de patiënt en nagaat of deze nog aanvullende ondersteuning nodig heeft (bijvoorbeeld toch counseling door u). Een vervolggesprek vindt meestal plaats 2-5 weken na het stoppen met roken consult. Tijdens dit gesprek bespreekt u met de patiënt hoe de stoppoging verloopt. Er zijn dan twee mogelijkheden:

**DE PATIËNT IS ACTIEF AAN DE SLAG GEGAAN**

- Vraag aan de patiënt hoe het stoppen is verlopen; is hij of zij nog tegen moeilijkheden aangelopen?
- Vraag de patiënt expliciet naar zijn of haar ervaringen met de gekozen hulpmiddel(en). Bespreek samen of de patiënt hierbij nog hulp van u wenst of dat hij of zij alleen verder kan.

**DE PATIËNT HEEFT NOG GEEN ACTIE ONDERNOMEN**

- Als de patiënt niet op het consult is verschenen kunt u proberen de patiënt via andere wegen te bereiken (bijvoorbeeld telefonisch of via de email). Herinner de patiënt eraan dat jullie een afspraak hadden en vraag of jullie de afspraak opnieuw kunnen inplannen.
- Vraag de patiënt naar de barrières die hij of zij heeft ervaren tijdens de mislukte stoppoging. Vraag of jullie daar samen een oplossing voor kunnen verzinnen.
- Probeer de patiënt nogmaals te motiveren om samen met u naar de stopmethodes te kijken. Hierdoor kan de patiënt een nieuwe poging starten.

Als het stoppen met de gekozen hulpmiddelen niet volgens plan verloopt, kunt u voorstellen nog eens naar andere hulpmiddelen te kijken. Ook kunt u met de patiënt afspraken maken over eventuele vervolggesprekken. Deze kunnen zowel in de praktijk plaatsvinden maar bijvoorbeeld ook telefonisch als u dat beiden fijn vindt. Op deze manier weet de patiënt dat er altijd iemand is om bij terecht te kunnen wanneer hij of zij vragen heeft. Bij COPD wordt aangeraden patiënten een jaar na de stoppoging nogmaals te vragen of ze nog steeds gestopt zijn.



PAGINA 20

**Figure 3.** Brief overview content interventions' manual

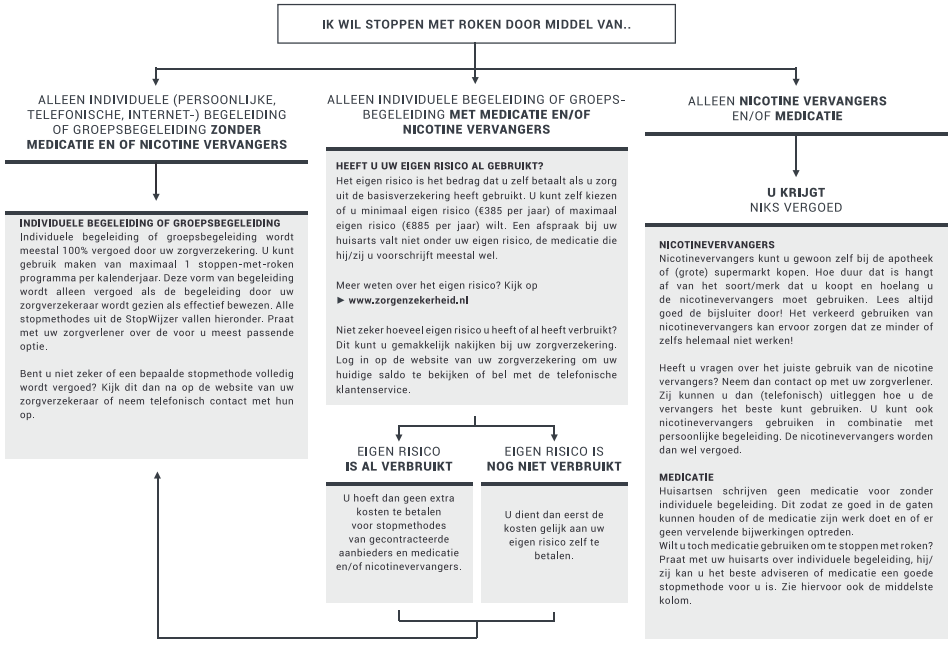



**Figure 4.** Flowchart handout

### *2.6.2 Placemat*

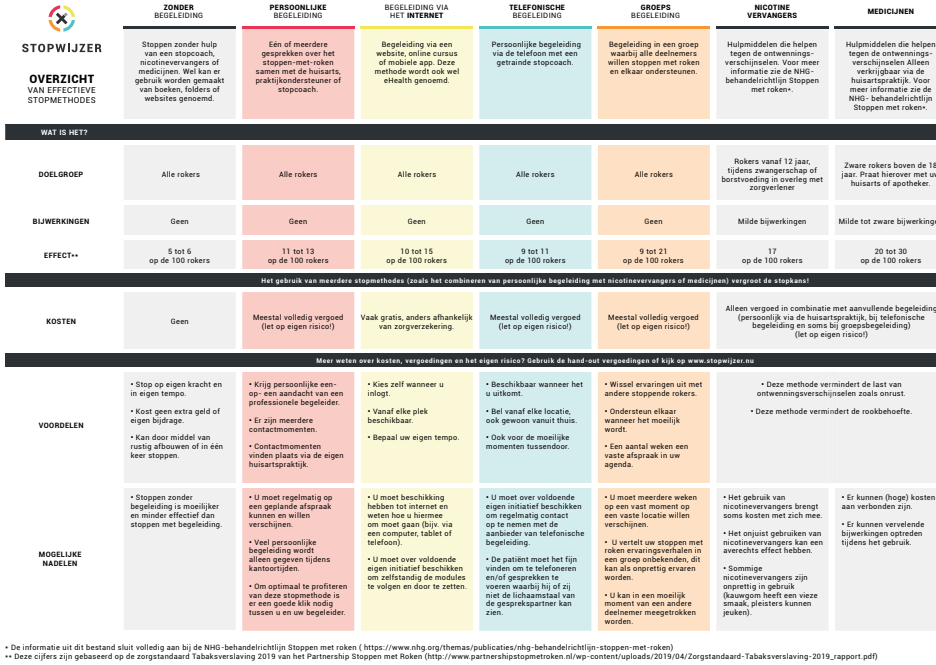
PNs also receive a decision matrix printed on a plastic desk pad. The desk pad can be used as a reminder for the PN or as a conversation tool during a consultation with a smoking patient (see also Figure 5). The matrix lists the EBSCIs mentioned above and gives an outline of their target groups, strengths and weaknesses, effectiveness, and costs. The matrix can also be accessed via the project's website.

### *2.6.3 Flyers*

PNs will receive flyers on which the information on EBSCIs is summarized and which list the contact information of the research team and a link to the project's website.

### *2.6.4 Promotion materials*

In addition, the package also will contain a stack of business cards with the contact information of the research team and a link to the project's website. Also enclosed will be a poster which is to be used to promote the project in the practice's waiting room. A digital version of the poster which van be displayed on waiting room screens will be sent via email. Lastly, a pen and a notebook featuring the project's logo will be included as a small reminder.



| STOPWIJZER<br>**OVERZICHT** VAN EFFECTIEVE STOPMETHODES | ZONDER BEGELEIDING | PERSOONLIJKE BEGELEIDING | BEGELEIDING VIA HET **INTERNET** | TELEFONISCHE BEGELEIDING | GROEPS BEGELEIDING | NICOTINE VERVANGERS | MEDICIJNEN |
|---|---|---|---|---|---|---|---|
| | Stoppen zonder hulp van een stopcoach, nicotinevervangers of medicijnen. Wel kan er gebruik worden gemaakt van boeken, folders of websites genoemd. | Eén of meerdere gesprekken over het stoppen-met-roken samen met de huisarts, praktijkondersteuner of stopcoach. | Begeleiding via een website, online cursus of mobiele app. Deze methode wordt ook wel eHealth genoemd. | Persoonlijke begeleiding via de telefoon met een getrainde stopcoach. | Begeleiding in een groep waarbij alle deelnemers willen stoppen met roken en elkaar ondersteunen. | Hulpmiddelen die helpen tegen de ontwennings-verschijnselen. Voor meer informatie zie de NHG-behandelrichtlijn Stoppen met roken*. | Hulpmiddelen die helpen tegen de ontwennings-verschijnselen Alleen verkrijgbaar via de huisartspraktijk. Voor meer informatie zie de NHG- behandelrichtlijn Stoppen met roken*. |
| **WAT IS HET?** | | | | | | | |
| **DOELGROEP** | Alle rokers | Alle rokers | Alle rokers | Alle rokers | Alle rokers | Rokers vanaf 12 jaar, tijdens zwangerschap of borstvoeding in overleg met zorgverlener | Zware rokers boven de 18 jaar. Praat hierover met uw huisarts of apotheker. |
| **BIJWERKINGEN** | Geen | Geen | Geen | Geen | Geen | Milde bijwerkingen | Milde tot zware bijwerkingen |
| **EFFECT**** | 5 tot 6 op de 100 rokers | 11 tot 13 op de 100 rokers | 10 tot 15 op de 100 rokers | 9 tot 11 op de 100 rokers | 9 tot 21 op de 100 rokers | 17 op de 100 rokers | 20 tot 30 op de 100 rokers |
| **Het gebruik van meerdere stopmethodes (zoals het combineren van persoonlijke begeleiding met nicotinevervangers of medicijnen) vergroot de stopkans!** | | | | | | | |
| **KOSTEN** | Geen | Meestal volledig vergoed (let op eigen risico!) | Vaak gratis, anders afhankelijk van zorgverzekering. | Meestal volledig vergoed (let op eigen risico!) | Meestal volledig vergoed (let op eigen risico!) | Alleen vergoed in combinatie met aanvullende begeleiding (persoonlijk via de huisartspraktijk, bij telefonische begeleiding en soms bij groepsbegeleiding) (let op eigen risico!) | |
| **Meer weten over kosten, vergoedingen en het eigen risico? Gebruik de hand-out vergoedingen of kijk op www.stopwijzer.nu** | | | | | | | |
| **VOORDELEN** | • Stop op eigen kracht en in eigen tempo.<br>• Kost geen extra geld of eigen bijdrage.<br>• Kan door middel van rustig afbouwen of in één keer stoppen. | • Krijg persoonlijke een-op- een aandacht van een professionele begeleider.<br>• Er zijn meerdere contactmomenten.<br>• Contactmomenten vinden plaats via de eigen huisartspraktijk. | • Kies zelf wanneer u inlogt.<br>• Vanaf elke plek beschikbaar.<br>• Bepaal uw eigen tempo. | • Beschikbaar wanneer het u uitkomt.<br>• Bel vanaf elke locatie, ook gewoon vanuit thuis.<br>• Ook voor de moeilijke momenten tussendoor. | • Wissel ervaringen uit met andere stoppende rokers.<br>• Ondersteun elkaar wanneer het moeilijk wordt.<br>• Een aantal weken een vaste afspraak in uw agenda. | • Deze methode vermindert de last van ontwenningsverschijnselen zoals onrust.<br>• Deze methode vermindert de rookbehoefte. | |
| **MOGELIJKE NADELEN** | • Stoppen zonder begeleiding is moeilijker en minder effectief dan stoppen met begeleiding. | • U moet regelmatig op een geplande afspraak kunnen en willen verschijnen.<br>• Veel persoonlijke begeleiding wordt alleen gegeven tijdens kantoortijden.<br>• Om optimaal te profiteren van deze stopmethode is er een goede klik nodig tussen u en uw begeleider. | • U moet beschikking hebben tot internet en weten hoe u hiermee om moet gaan (bijv. via een computer, tablet of telefoon).<br>• U moet over voldoende eigen initiatief beschikken om zelfstandig de modules te volgen en door te zetten. | • U moet over voldoende eigen initiatief beschikken om regelmatig contact op te nemen met de aanbieder van telefonische begeleiding.<br>• De patiënt moet het fijn vinden om te telefoneren en/of gesprekken te voeren waarbij hij of zij niet de lichaamstaal van de gesprekspartner kan zien. | • U moet meerdere weken op een vast moment op een vaste locatie willen verschijnen.<br>• U vertelt uw stoppen met roken ervaringsverhalen in een groep onbekenden, dit kan als onprettig ervaren worden.<br>• U kan in een moeilijk moment van een andere deelnemer meegetrokken worden. | • Het gebruik van nicotinevervangers brengt soms kosten met zich mee.<br>• Het onjuist gebruiken van nicotinevervangers kan een averechts effect hebben.<br>• Sommige nicotinevervangers zijn onprettig in gebruik (kauwgom heeft een vieze smaak, pleisters kunnen jeuken). | • Er kunnen (hoge) kosten aan verbonden zijn.<br>• Er kunnen vervelende bijwerkingen optreden tijdens het gebruik. |

* De informatie uit dit bestand sluit volledig aan bij de NHG-behandelrichtlijn Stoppen met roken ( https://www.nhg.org/themas/publicaties/nhg-behandelrichtlijn-stoppen-met-roken)
** Deze cijfers zijn gebaseerd op de zorgstandaard Tabaksverslaving 2019 van het Partnership Stoppen met Roken (http://www.partnershipstopmetroken.nl/wp-content/uploads/2019/04/Zorgstandaard-Tabaksverslaving-2019_rapport.pdf)

**Figure 5.** Decision matrix, provided in the form of a desk pad and available online.

### *2.6.5 Website*

The project's website will consist of a general part and a password-protected part. PNs from both the experimental and the control condition will be able to register new patients in the password-protected part. PNs from the experimental condition can furthermore access digital copies of the manual and other materials (e.g., the placemat, handouts, and flyer). Patients from the experimental condition can access materials delivering the same information as they receive from their PN. PNs and patients form the experimental condition can access a frequently asked questions (FAQ) page tailored to their needs. Smokers from the control condition can only access the general part of the website, which will contain general information about the project and the study

## 2.7 Prompts to promote intervention use and to prevent questionnaire attrition

PNs will be sent a newsletter once a month in order to keep them informed of the progress of the study and to remind them of their participation. PNs who lag in recruitment will be approached personally via telephone call or practice visit. Further, PNs will be sent personal postcards during the holiday season or when they have recruited their fifth participant. Participants will be able to contact the research team via the project's website or via email or telephone.

Additionally, to the questionnaires we sent directly to the patients, we also sent out paper questionnaires to the general practices, to be delivered to patients by the PN, that intend to reduce attrition in the period between the initial meeting and receiving the questionnaire via post or email. Smokers can complete these paper questionnaires directly after their meeting with a PN, for example in the practice's waiting room. Pre-addressed envelopes including postage are provided with all paper questionnaires.

### 2.7 Usability testing

A prototype version of the intervention was tested by five HCPs in order to identify any ambiguities within the intervention. Open interviews were held in which the HCPs reviewed the materials together with the primary researcher and the HCPs' comments and opinions were used as input for the final intervention. Most changes were minor and related to terminology, for example using the term HCP instead of PN in materials to not exclude other possible participants. Other comments focused more on design elements such as making a more distinct distinction between EBSCIs and non-evidence-based interventions using visual techniques.

### 2.8 Data collection

#### *2.8.1 Measures*

##### *2.8.1.1 Tobacco abstinence*

The primary outcome of the study will be 7-day point prevalence abstinence measured at six month follow-up from baseline (192, 193). Secondary outcomes are 24-hour point prevalence abstinence and 3-month prolonged abstinence (193). Assessing 6-month prolonged abstinence is not possible due to the study design, since follow-up measurement will take place 6 months after answering the baseline questionnaire irrespective of the date the participant quit smoking. Prolonged abstinence will be assessed by asking patients whether they have refrained from smoking tobacco since their last quit attempt allowing for a 2-week grace period during which the participant could smoke 1 to 5 cigarettes. Furthermore, patients will be asked whether and how often they have tried to quit smoking (i.e., no cigarette for 24 hours) during the intervention period. If patients indicate to smoke at follow-up, they will also be asked how many cigarettes on average they smoke per day. Because of minimal personal contact with the research staff and reduced possible contact with HCPs because of Covid-19, biochemical validation will not be possible. Therefore, all tobacco abstinence measures will be assessed at 6-month follow-up using self-report with an added 'bogus pipeline' question ('Do you object if we come to do a saliva test to check your smoking status?) to reduce socially desirable responses by including the threat of biochemical testing (194, 195). Previous studies suggest that the difference between self-reported abstinence rates and those verified with biochemical validation is negligible (196-198). The number of cigarettes smoked on average per day will be measured at baseline as well.

*2.8.1.2 Smoking cessation method chosen*

Patients will be asked which EBSCIs they have used in any previous smoking cessation attempts and to grade the methods they have used on a scale ranging from 1 = very bad to 10 = very good. The following EBSCIs constitute the response options: face-to-face counseling, eHealth, telephone counseling, group counseling, pharmacotherapy, and nicotine replacement therapy. If a participant uses a smoking cessation method that is not included in the response options, it will be possible to indicate this entering free text. The smoking cessation method selected will be assessed at 6-month follow-up.

*2.8.1.3 Quality of life and health care costs*

Quality of life measures EuroQol (199) and ICECAP (200) will be used to measure the incremental costs per quality adjusted life year (QALY). Health care costs (e.g., productivity losses, medical consumption and consumption of informal care) will be measured via the iMTA medical Consumption Questionnaire (iMCQ (201). The valuation of costs will be based on the latest Dutch standards, which include for example hourly wage of HCPs and standardized costs for consults in the GP setting (202, 203). Quality of life and health care costs will be assessed both at baseline and at 6-month follow-up.

*2.8.1.4 Informed decision making*

Decisional conflict (e.g. "I feel I have made an informed choice") will be assessed via 16 items on a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree) (204, 205). Decisional conflict will be assessed at 6-month follow-up.

*2.8.1.5 Contact between PN and smoker*

The contact between the PN and the smoker will be evaluated because a constructive and empathic relationship between PN and smoker is an important factor for intervention success (206). Firstly, patients have to indicate which topics have been discussed during the guidance and referral advice (e.g., "He/she (the PN) has asked you how motivated you are to stop smoking" (0 = yes; 1 = no). Secondly, the relationship between smoker and PN will be assessed via six items (e.g. "During a conversation about quitting smoking, I have the feeling that my caregiver is offering me choices") on a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree). The contact between the PN and the smoker will be assessed both at baseline and at 6-month follow-up.

*2.8.1.6 Appreciation of the intervention*

After assessing which intervention materials have been noticed by the patients (e.g. "Have you seen the intervention's poster in the waiting room of your general practice?; 0 = yes; 1 = no), appreciation of the materials (e.g. "I think the StopWijzer materials are understandable") will be assessed via four 5-point Likert items (1 = strongly disagree; 5 = strongly agree).

Moreover, patients will be asked to grade the intervention materials (1 = very bad; 10 = very good) and patients and for comments and suggestions entering free text. The appreciation of the intervention will be assessed at 6-month follow-up.

#### *2.8.1.7 Demographics, smoking characteristics, health status, and health literacy*

Demographics will be assessed via age, gender (0 = male; 1 = female), nationality (0 = other nationality; 1 = Dutch nationality) education level (1 = low: no education, primary, or basic vocational school; 2 = medium: secondary vocational school or high school; 3 = high: higher vocational school or university) and occupation of the principal wage earner of the household.

Motivation to quit smoking (e.g. 193, 207) will be assessed via four items. Three items (e.g., "I am planning to quit smoking") use 7-point Likert scales (1 = certainly not;7 = certainly yes). One item assesses whether smokers want to quit smoking including the time frame (1 = yes, within one month; 2 = yes, within three months; 3 = yes, within six months; 4 = yes, within one year; 5 = yes, but not within one year; and 6 = no, I do not plan to quit smoking).

The intention to use a specific smoking cessation method will be assessed via 20 items (e.g., "In order to stop smoking, I can best make use of nicotine replacement therapy"). All items use be 7-point Likert items (1 = certainly not to 7 = certainly yes). The questions were developed for this study based on the I-Change model, which aims at explaining motivational and behavioral change via integrating various social-cognitive theories (105).

The current use of e-cigarettes will be assessed via one item ("Do you use e-cigarettes?"; 1 = no; 2 = yes, without nicotine; 3 = yes, with nicotine).

Cigarette dependence will be assessed via the Fagerström Test for Cigarette Dependence (208, 209). The six items of the scale will be converted into an overall score ranging from 0 to 10. The dependence level is classified as 0-2 = low; 3-4 = moderate; 5-6 = strong; and 7-10 = very strong.

The health status of the smoker (e.g. "Do you have type 2 diabetes?") will be assessed for six diseases (0="yes"; 1="no"): COPD, cancer, type 2 diabetes, cardiovascular diseases, asthma, and depression (210).

Health literacy (e.g. "How often do you get help with reading letters or folders of your GP, the hospital or other health care services?") will be assessed via three items (1 = never; 5 = always (211). All variables described in this paragraph will be assessed at baseline.

### *2.8.2 Sample size*

A power analysis for logistic regression was conducted using G*Power version 3.1 (212). Considering an effect size (odds ratio) of 0.30, a power of .80, and an alpha of .05, a total sample size of 292 patients will be required. The effect size was calculated for a 10% difference between control condition and experimental condition. Seven-day point prevalence abstinence was estimated to be 5% in the control condition and 15% in the experimental condition.

Assuming that patients are nested within general practices with an average cluster size of five patients, a total sample size of 300 patients will be required. Based on earlier smoking cessation studies in general practices, intra cluster correlation (ICC) was set at .01. We will aim to recruit 60 PNs that need to recruit an average of 10 patients each. Considering a dropout rate of 50%, there will be five patients per GP-practice that filled out the baseline questionnaire, totaling in 300 patients. In order to account for drop out at 6 months follow-up, multiple imputation will be conducted applying Multivariate Imputation via Chained Equations (MICE) in R (213, 214).

#### *2.8.3 Data analysis*

All analyses will be performed following the intention-to-treat principle. To account for missing observations in the 6-month follow-up questionnaire, multiple imputations will be conducted applying Multivariate Imputation via Chained Equations (MICE) in R (213, 214).

Firstly, descriptive analyses will be conducted to describe the sample characteristics. Secondly, logistic regression will be used to analyze attrition, including baseline factors and condition as predictors. Thirdly, if sample size allows, multilevel logistic regression analyses will be performed to assess differences between conditions in 7-day point prevalence abstinence, 24-hour point prevalence abstinence, and 3-month prolonged abstinence. Fourthly, analyses of variance will be performed to test for differences in decisional conflict and appreciation of the intervention materials between conditions.

The economic evaluation will involve the performance of a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA) of data collected during the baseline and 6-month follow-up measurement (see: quality of life and health care costs). In a CEA, effects are presented in clinical outcomes (here: additional quitters). In the CEA, the incremental cost-effectiveness ratio (ICER) will be expressed as the incremental costs per additional quitter (measured as 6 months Point Prevalence Abstinence (PPA)). The primary outcomes measure for the CUA will be QALYs, measured via EuroQol (199) and ICECAP (200). The economic evaluation will be performed from a health care and societal perspective implying that all relevant costs and outcomes will be considered. Intervention costs, healthcare costs, patient, and family costs (in a subsample), and costs outside the health care sector will be assessed.

## 3. DISCUSSION

### 3.1 Potential strengths of the study

The first potential strength of the study is the use of a random allocation of PNs via a computer algorithm to mitigate possible biases within general practice settings as PNs working within the same general practice setting but allocated to different conditions may

have an impact on the implementation of the study. Secondly, the intervention was pilot tested among a group of potential users, both PNs and smokers, and experts from the field to test the usability and to remove ambiguities. Thirdly, the GP setting was used as a gateway to reach the target group as most smokers visit their general practice yearly (180) and have a high level of trust in their GP (181) which makes it more accessible than specialty centers at the hospital level. Fourthly, the intervention consists of a summary of various already proven effective smoking cessation methods, which are often underused at the moment. This study may help to increase their uptake. Fifthly, a cost-effectiveness study will be performed, which will provide an estimation of the additional costs and benefits of the intervention as compared to care as usual. Sixthly, in order to take into account, the potential of low health literacy of patients, the materials have been written in clear and comprehensible language in accordance with the applicable Dutch guidelines. Lastly, using the intervention takes hardly any additional time, making it a perfect fit in the timeslots their usual consultation sessions. This makes it easier for PNs to participate in the study.

**3.2 Potential limitations**

Firstly, practice nurses provided less smokers than expected, leading to a longer inclusion period and omission of also a 12 month follow up as stated in our trial register, (NL7020/NTR7218). Yet, a 6 months study follow up is still an acceptable period for assessing treatment effectiveness (215).

Secondly, although we aim to include all eligible smoking patients who visit the participating general practices, there is a risk of selection bias by PNs. PNs may tend to invite more smokers who have already shown a willingness to stop smoking or who are deemed to be more easily motivated to participate, as also seen in other studies (54, 114, 216). The conversational guidelines found in the intervention's manual and flowchart handout are aimed to induce PNs to include all types of smokers.

Thirdly, because smokers often just have one face-to-face meeting with a PN and we use mostly online questionnaires at the six months mark, we may face a high attrition rate. This is usual for studies that use online questionnaires (217-219). We tried to overcome this by sending additional questionnaire packages so that patients could answer the questionnaire on site if desired.

In order to try to prevent attrition at the follow-up assessment, we will also provide a shortened questionnaire including three of the aforementioned questions on abstinence (7-day point prevalence abstinence, 24-hour point prevalence abstinence, and 3-month prolonged abstinence) and one question asking the patients about EBSCIs used during their cessation attempt. This shortened questionnaire can be administered via email or telephone.

Lastly, the efficacy of counseling treatment is also dependent on contextual factors, such as the patient-counselor relationship (220). However, due to the nature of this study, targeting the use of evidence-based smoking cessation methods, assessing these contextual factors was beyond the scope of this study.

## 4. CONCLUSION

This paper describes the study design for the development and evaluation of an information and decision tool to support PNs in the guidance of smoking patients and the referral to evidence-based smoking cessation interventions. The results of this study aim to provide insight into the (cost) effectiveness of an intervention aimed at promoting the use of more evidence-based smoking strategies, arriving at a more personalized referral decision and the best way to communicate them to smoking patients. The behavioral effectiveness, as well as the cost-effectiveness, will be reported on in later papers.

# CHAPTER 4

## What went wrong? A randomized controlled trial of a process and effect evaluation of a referral aid for smoking cessation counseling in primary care

**This chapter has been submitted for publication as:**
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## ABSTRACT

The use of evidence-based smoking cessation interventions (EBSCIs) can double the likelihood of a successful smoking cessation attempt. To aid Dutch practice nurses (PNs) in primary care to decide with the smokers the best suitable EBSCI, a referral aid was developed. The aim of this study was to explore the use and effects of the referral aid from the perspective of two user groups: 1) PNs and 2) smokers. To optimally explore the experiences of both groups, two different studies were conducted, namely 1) a randomized controlled trial (process and effect evaluation) among smoking patients recruited by PNs and 2) a process evaluation among a subgroup of PNs. Response in both groups was low. Overall, PNs found the materials clear and understandable. Smokers had similar but (slightly) less positive opinions. However, the referral aid was not intensively used, and the experimental group of smokers did not differ on the amount of discussion and usage of EBSCIs, nor on smoking abstinence. As the main finding concerned a low level of participation and use of the referral aid by PNs, further research should aim at assessing how to better involve PNs and at how to foster effective counseling and referral to EBSCIs.

## 1. INTRODUCTION

Smoking is responsible for 13% of Dutch morbidity, resulting in about 20,000 deaths per year (6, 221) and causing an economic burden of around €33 million for health care costs, decreased work productivity, and premature death (11). To restrict the negative impact that smoking cessation has on public health, national policies and measures have been implemented on different levels of society, such as the policy level (e.g., public smoking restrictions and regular tax increases) (17, 18), the organizational level (e.g., national smoking restrictions in workplaces and smoking cessation interventions specially targeted at organizations) (18, 25) and interventions on an individual level. Interventions on an individual level are directed at the individual (28-30) or can be implemented via healthcare institutions such as the primary care setting (PCS) (31, 32, 63, 156, 222, 223), midwives (33), nurses working on coronary wards (34, 35) or other health care professionals (HCPs) (36). As most smokers visit their PCS at least yearly, the PCS can serve as the primary access point for reaching smokers who want to make a cessation attempt, to stimulate them to use evidence based interventions and to make an informed choice between those different stop smoking options (224).

Within the PCS, most smoking cessation counseling in the Netherlands is provided by a practice nurse (PN) who is predominantly trained in providing care related to chronic conditions, such as diabetes, cardiovascular diseases, and COPD (139, 182). In collaboration with the general practitioner, PNs provide smoking cessation counseling according to a structured, evidence-based counseling guideline (44, 52). This guideline is similar to the more internationally known 5As (Ask, Advise, Assess, Assist and Arrange) strategy (177) and describes an approach comprising seven steps which include, 1) providing a quit advice, 2) assessing a smoking profile, 3) assessing and increasing motivation, 4) exploring, discussing and when possible removing existing barriers, 5) discussing cessation aids, 6) helping to set a quit date and developing a quit plan, and 7) offering support after the quit date.

However, previous research has showed that not all relevant cessation counseling steps are structurally adhered to, specifically informing the smoking patient on evidence-based smoking cessation interventions (EBSCIs) (step 5) (54, 58, 59). The reason for this may be that PNs have insufficient knowledge about EBSCIs to properly inform their patients, despite this being within their responsibilities according to the Dutch Guideline (44, 52, 225). Using readily available EBSCIs such as face-to-face counseling, eHealth (226), telephonic counseling (35), group counseling (74), nicotine replacement therapy (NRT) or pharmacotherapy (227), can double the chance of a successful smoking cessation attempt (86). Referring to EBSCIs may stimulate smokers to choose effective methods and may enable a PN to save time by focusing on steps where a smoker really needs help (as EBSCIs might be of aid in assessing and increasing motivation (step 3), removing existing barriers

(step 4) and developing a quit plan (step 6)), which also allows the PN to provide more aftercare and having at least one follow-up consultation to assess progress and barriers (step 7). Smokers may profit from an approach in which choices for smoking cessation methods are more in line with their own expectations and preferences, resulting in more involvement and commitment of smokers in their own chosen cessation method and their cessation attempt (103, 104).

To aid Dutch PNs and other healthcare providers in primary care in referring smokers to EBSCIs, a referral aid was developed. The content of the referral aid was based on a needs assessment comprising a literature review (e.g. (31, 52, 69, 105)), individual semi-structured interviews among GPs (n=5), PNs (n=20) and smokers (n=9), a Delphi study on the referral to EBSCIs (225) and the input of an advisory board consisting of experts representing various Dutch smoking cessation related organizations. The intervention will be further explained in the method section and the accompanying protocol article (228).
The aim of this study was to explore the use and effect of the referral aid from the perspective of two user groups: 1) PNs (responsible for implementing the referral aid and recruiting smokers) and 2) smokers (end users). To optimally explore the experiences of both groups, two different studies were conducted namely 1) a randomized controlled trial (RCT) among smoking patients recruited by PNs and 2) a process evaluation among a subgroup of PNs. To structurally report this data, the paper is divided into 5 substudies (see table 1) describing 1) the recruitment of PNs, 2) the recruitment and retention of smokers, 3) a process evaluation by practice nurses of the experimental condition, 4) a process evaluation by smokers from the experimental condition and 5) an effect evaluation among smokers.

**Table 1.** Overview of the substudies presented in this article.

| Substudy | Sample | Sample size | Substudy objective |
|---|---|---|---|
| 1. Recruitment of PNs | PNs | N = 73 | Tracking the recruitment and adherence rate of PNs at the outset of the RCT |
| 2. Recruitment and retention of smokers | Smokers | N = 285 | Tracking the recruitment and adherence rate of smokers at recruitment, baseline and 6-month follow-up |
| 3. Process evaluation by practice nurses | PNs (subsample) | N = 40 | Evaluating the usage and appreciation of the referral aids materials by the PNs |
| 4. Process evaluation by smokers | Smokers | N = 82 | Evaluating the usage and appreciation of the referral aids materials by the PNs |
| 5. Effect evaluation among smokers | smokers | N = 82 | Measuring the effect on 1) usage of EBSCIs, 2) decisional conflict, 3) quality of life and 4) abstinence and smoking behavior of smokers |

## 2. METHOD

### 2.1 Design and intervention

The referral aid was named the 'StopWijzer', which can be translated as both stop-indicator or stop-smarter. A multi-site two-group parallel-randomized controlled trial involving an experimental condition and a control condition was conducted. The PNs in the control condition provided care as usual, in accordance with the seven steps from the Dutch treatment guideline of tobacco addiction and smoking cessation support (52). The PNs in the experimental condition received an intervention's manual to aid them in discussing smoking cessation with smokers and to help them select an EBSCI that fits the patient's needs and preferences (extension on step 5 of the Dutch Cessation Guidelines). A full description of the referral aid and the design of the RCT can be found elsewhere (228).

The research proposal for this study has been evaluated and approved by the medical ethics committee of the University Hospital Maastricht and Maastricht University. They declared that no medical ethical clearance for this study was needed under the rules of the Medical Research Involving Human Subjects Act (WMO–2018-1038). The study was registered at the Netherlands Trial Register (NL7020, https://www.trialregister.nl/trial/7020).

#### 2.1.1 Materials

Materials were delivered to the PN in the form of a small (letterbox sized) package sent via post. The packages included the following items:

1. A manual (A4 size, approximately 20 pages), providing a) an introduction and explanation of the aim of the referral aid, b) instructions on the use of the referral aid protocol, including a roadmap detailing the steps of the protocol and a flow-chart, c) an overview of reimbursement, d) an overview of the different readily available EBSCIs (face-to-face counseling, eHealth, telephonic counseling, group counseling, NRT and pharmacotherapy) including discouraging remarks on the use of non-EBSCIs (acupuncture, hypnotherapy, laser therapy and the use of e-cigarettes as a means to quit), e) a short guideline for follow-up consultations and f) concluding remarks and room for taking notes (figure 1);
2. A separate handout (A5 size, printed on both sides) containing a visualization of the most important concepts of the manual (the same flow-chart as in the manual) and a summary of the health insurers reimbursement policies;
3. An overview of the different EBSCIs (option grid or decision matrix; A3 size, laminated), explaining the target groups, strengths and weaknesses, effectiveness, and costs of the mentioned EBSCIs (figure 2);
4. Supplemental materials for promotion of the study such as information flyers aimed at informing smokers about the study, business cards, posters (paper and digital) and last, a pen and notebook featuring the referral aids' logo.

All materials were written in clear and comprehensible language in accordance with the applicable Dutch guidelines (language level B1) (229, 230) and were also available on the referral aids' website (only accessible for the experimental condition). This website also included a frequently asked questions (FAQ) page tailored to both conditions.

PNs in the experimental condition were invited to read the manual at the start of the study in order to inform themselves of the information regarding the EBSCIs. Other materials could be implemented during counseling sessions in a way PNs saw fit. There was no formal training provided to use the materials, but PNs were able ask questions to the research team if necessary.

BEGELEIDING VIA HET INTERNET *(EHEALTH)*

*eHealth betekent informatie over gezondheid via het internet. Ook voor stoppen met roken is er informatie op het internet beschikbaar en zijn er apps te downloaden. Wij verwijzen hieronder naar interventies waarvan het effect is aangetoond en welke bij het 'Loket Gezond Leven' staan geregistreerd als effectief. Deze methodes maken ook vaak gebruik van de stappen die bij de bespreking van persoonlijke begeleiding reeds aan de orde gekomen zijn. Een rokende patiënt moet via een website of app vragen beantwoorden. Daarna krijgt de patiënt een persoonlijk advies en hulp die gebaseerd is op zijn of haar antwoorden. De patiënt kan op ieder moment met een eHealth interventie aan de slag; de lengte varieert van één tot meerdere sessies. Er zijn ook andere eHealth stoppen-met-roken programma's en apps die niet op effectiviteit zijn getest. Van deze interventies kunnen we dus niet met zekerheid zeggen of ze de kans op een geslaagde stoppoging vergroten en daarom noemen wij deze niet.*

**UW ROL**

Als de patiënt middels begeleiding via het internet wil stoppen bespreekt u samen de voor- en nadelen van deze stopmethode. Ook bespreekt u waar de patiënt terecht kan voor begeleiding via het internet en hoe dit in zijn werk gaat. U kunt de patiënt vragen zelf thuis te kijken en contact op te nemen of u kunt samen een aanbieder uitzoeken. U kunt ook één of meerdere vervolgafspraken plannen om met de patiënt te bespreken hoe de stoppoging gaat, hoe de begeleiding gaat en of hij of zij nog verdere ondersteuning wil.

*Nicotinevervangers en medicatie worden alleen vergoed als de patiënt tegelijkertijd ook persoonlijke begeleiding ontvangt via de huisartspraktijk of via effectieve telefonische begeleiding. Patiënten die alleen gebruik willen maken van eHealth kunnen wel op eigen kosten nicotinevervangers aanschaffen via een apotheek, drogist of (grote) supermarkt.*

VOORDELEN

- De patiënt kiest zelf wanneer hij of zij inlogt.
- Vanaf elke plek beschikbaar.
- De patiënt bepaalt zijn of haar eigen tempo.

MOGELIJKE NADELEN

- De patiënt moet beschikking hebben tot internet en voldoende kennis en kunde om hier mee om te kunnen gaan (bijv. via een computer, tablet of telefoon).
- De patiënt moet over voldoende eigen initiatief beschikken om zelfstandig de modules te volgen.

**AANBIEDERS EFFECTIEVE TRAININGEN GEBASEERD OP EHEALTH IN NEDERLAND**

Stoppen met roken 2.0, 1 sessie (gratis)
► http://www.health-alert.nl/

Steun bij stoppen, minimaal 3 sessies (gratis)
► http://www.health-alert.nl/

Jellinek (gratis)
► http://www.zelfhulptabak.nl/Portal

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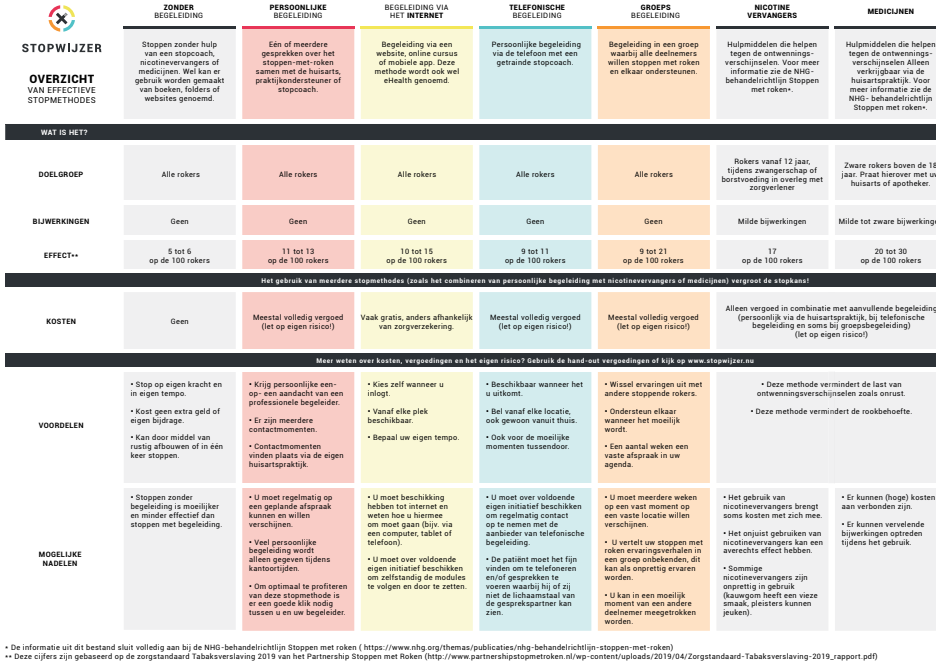
**Figure 1.** eHealth page



| STOPWIJZER<br>**OVERZICHT** VAN EFFECTIEVE STOPMETHODES | ZONDER BEGELEIDING | PERSOONLIJKE BEGELEIDING | BEGELEIDING VIA HET INTERNET | TELEFONISCHE BEGELEIDING | GROEPS BEGELEIDING | NICOTINE VERVANGERS | MEDICIJNEN |
|---|---|---|---|---|---|---|---|
| | Stoppen zonder hulp van een stopcoach, nicotinevervangers of medicijnen. Wel kan er gebruik worden gemaakt van boeken, folders of websites genoemd. | Eén of meerdere gesprekken over het stoppen-met-roken samen met de huisarts, praktijkondersteuner of stopcoach. | Begeleiding via een website, online cursus of mobiele app. Deze methode wordt ook wel eHealth genoemd. | Persoonlijke begeleiding via de telefoon met een getrainde stopcoach. | Begeleiding in een groep waarbij alle deelnemers willen stoppen met roken en elkaar ondersteunen. | Hulpmiddelen die helpen tegen de ontwennings-verschijnselen. Voor meer informatie zie de NHG-behandelrichtlijn Stoppen met roken*. | Hulpmiddelen die helpen tegen de ontwennings-verschijnselen Alleen verkrijgbaar via de huisartspraktijk. Voor meer informatie zie de NHG- behandelrichtlijn Stoppen met roken*. |
| **WAT IS HET?** | | | | | | | |
| **DOELGROEP** | Alle rokers | Alle rokers | Alle rokers | Alle rokers | Alle rokers | Rokers vanaf 12 jaar, tijdens zwangerschap of borstvoeding in overleg met zorgverlener | Zware rokers boven de 18 jaar. Praat hierover met uw huisarts of apotheker. |
| **BIJWERKINGEN** | Geen | Geen | Geen | Geen | Geen | Milde bijwerkingen | Milde tot zware bijwerkingen |
| **EFFECT**** | 5 tot 6 op de 100 rokers | 11 tot 13 op de 100 rokers | 10 tot 15 op de 100 rokers | 9 tot 11 op de 100 rokers | 9 tot 21 op de 100 rokers | 17 op de 100 rokers | 20 tot 30 op de 100 rokers |
| **Het gebruik van meerdere stopmethodes (zoals het combineren van persoonlijke begeleiding met nicotinevervangers of medicijnen) vergroot de stopkans!** | | | | | | | |
| **KOSTEN** | Geen | Meestal volledig vergoed (let op eigen risico!) | Vaak gratis, anders afhankelijk van zorgverzekering. | Meestal volledig vergoed (let op eigen risico!) | Meestal volledig vergoed (let op eigen risico!) | Alleen vergoed in combinatie met aanvullende begeleiding (persoonlijk via de huisartspraktijk, bij telefonische begeleiding en soms bij groepsbegeleiding) (let op eigen risico!) | |
| **Meer weten over kosten, vergoedingen en het eigen risico? Gebruik de hand-out vergoedingen of kijk op www.stopwijzer.nu** | | | | | | | |
| **VOORDELEN** | • Stop op eigen kracht en in eigen tempo.<br>• Kost geen extra geld of eigen bijdrage.<br>• Kan door middel van rustig afbouwen of in één keer stoppen. | • Krijg persoonlijke een-op- een aandacht van een professionele begeleider.<br>• Er zijn meerdere contactmomenten.<br>• Contactmomenten vinden plaats via de eigen huisartspraktijk. | • Kies zelf wanneer u inlogt.<br>• Vanaf elke plek beschikbaar.<br>• Bepaal uw eigen tempo. | • Beschikbaar wanneer het u uitkomt.<br>• Bel vanaf elke locatie, ook gewoon vanuit thuis.<br>• Ook voor de moeilijke momenten tussendoor. | • Wissel ervaringen uit met andere stoppende rokers.<br>• Ondersteun elkaar wanneer het moeilijk wordt.<br>• Een aantal weken een vaste afspraak in uw agenda. | • Deze methode vermindert de last van ontwenningsverschijnselen zoals onrust.<br>• Deze methode vermindert de rookbehoefte. | |
| **MOGELIJKE NADELEN** | • Stoppen zonder begeleiding is moeilijker en minder effectief dan stoppen met begeleiding. | • U moet regelmatig op een geplande afspraak kunnen en willen verschijnen.<br>• Veel persoonlijke begeleiding wordt alleen gegeven tijdens kantoortijden.<br>• Om optimaal te profiteren van deze stopmethode is er een goede klik nodig tussen u en uw begeleider. | • U moet beschikking hebben tot internet en weten hoe u hiermee om moet gaan (bijv. via een computer, tablet of telefoon).<br>• U moet over voldoende eigen initiatief beschikken om zelfstandig de modules te volgen en door te zetten. | • U moet over voldoende eigen initiatief beschikken om regelmatig contact op te nemen met de aanbieder van telefonische begeleiding.<br>• De patiënt moet het fijn vinden om te telefoneren en/of gesprekken te voeren waarbij hij of zij niet de lichaamstaal van de gesprekspartner kan zien. | • U moet meerdere weken op een vast moment op een vaste locatie willen verschijnen.<br>• U vertelt uw stoppen met roken ervaringsverhalen in een groep onbekenden, dit kan als onprettig ervaren worden.<br>• U kan in een moeilijk moment van een andere deelnemer meegetrokken worden. | • Het gebruik van nicotinevervangers brengt soms kosten met zich mee.<br>• Het onjuist gebruiken van nicotinevervangers kan een averechts effect hebben.<br>• Sommige nicotinevervangers zijn onprettig in gebruik (kauwgom heeft een vieze smaak, pleisters kunnen jeuken). | • Er kunnen (hoge) kosten aan verbonden zijn.<br>• Er kunnen vervelende bijwerkingen optreden tijdens het gebruik. |

* De informatie uit dit bestand sluit volledig aan bij de NHG-behandelrichtlijn Stoppen met roken ( https://www.nhg.org/themas/publicaties/nhg-behandelrichtlijn-stoppen-met-roken)
** Deze cijfers zijn gebaseerd op de zorgstandaard Tabaksverslaving 2019 van het Partnership Stoppen met Roken (http://www.partnershipstopmetroken.nl/wp-content/uploads/2019/04/Zorgstandaard-Tabaksverslaving-2019_rapport.pdf)

**Figure 2.** option grid available EBSCIs

## 2.2 Procedure of studies

### *2.2.1 Substudy 1: Recruitment of practice nurses*

PCS were approached in the period of January 2019 until May 2020 to recruit suitable PNs to take part in the RCT (see figure 3 for all time periods). PNs were recruited for two reasons: 1) recruiting smokers and 2) in the case of the experimental condition, referring smokers to EBSCIs in accordance with the method described in the referral aid. To keep the range of tasks as small as possible and to order to include as many as possible PNs, participating in the additional process evaluation substudy (study 3) was not mandatory. PNs eligible to take part needed to be employed by at least one general practice in the Netherlands and had to indicate that they provided smoking cessation counseling at least once a week.

A study invitation letter and a summary of the referral aids aim were sent to PNs throughout the Netherlands. PNs were recruited via three main approaches. First, three Dutch primary care associations (PCAs) in the south of the Netherlands collaborating with Maastricht University were approached to aid in the recruitment of individual PNs. PCAs are groups in the Netherlands that provide integrated care to smokers with chronic diseases, such as asthma and COPD. The PCAs support consisted of sending us contact details of individual GP-setting so that the research team could contact them or promoting the study in their newsletters (two out of three PCAs). One of the PCA's opted to not provide the

research team with individual contact information to prevent high information burden in general of individual PCS. PCS were sent a tailored information letter with recommendations of the PCA and were contacted via telephone. Second, we approached additional individual PCS in the rest of the Netherlands via letter post and, when publicly known, via email. All approached practices were contacted through a minimum of three attempts via telephone two weeks after sending a recruitment letter. Third, alternative channels such as national congresses and advertisements in trade magazines or websites of relevant organizations, e.g., the Dutch 'Quality register for smoking cessation' (*kwaliteitsregister stoppen-met-roken,* www.kabiz.nl ) were used to reach suitable PNs.

PNs expressing interest in participating were sent a more detailed information letter for the substudy and were asked to sign a study participation form. PNs were randomized in a 1:1 ratio on practice level in order of registration. As PNs from the experimental condition were provided with the referral aid and PNs from the control condition were only asked to provide care as usual (no additional intervention), blinding of the PNs was impossible.

Participating PNs were requested to recruit 10 to 20 smokers each (see accompanying protocol paper for the sample size calculation (228)). To stimulate active recruitment and prevent attrition, PNs could receive remuneration in ratio with the number of recruited smokers (up to €100 for recruiting over 15 smokers). In order to track recruitment results, the recruitment context was assessed using one open-ended question ("What were the primary reasons you could not recruit smoking participants?") inquiring about the barriers of patient recruitment.

At the end of substudy 1 (September 2020), all participating PNs were approached via email to partake in an additional process evaluation with the goal to evaluate the course of events during the RCT. In this email, participants received a link to an online questionnaire and a summary of the referral aid and associated materials. The questionnaire took 15 minutes to complete on average, excluding the time PCPs from the control condition needed to look over the materials. PCPs who did not respond within seven days were sent a maximum of two reminders. On completion, PNs received a reimbursement of €20 in the form of gift vouchers.

#### *2.2.2 Substudy 2: Recruitment and retention of smokers*

The recruitment of smokers for the RCT took place in the period from May 2019 until May 2020. PNs from Substudy 1 were requested to inquire on the smoking habits of all smokers they spoke to during their consultations. Besides requiring smokers to use tobacco products, other inclusion criteria entailed being at least 18 years old and to be able to read and understand the Dutch language. Smokers who only used e-cigarettes were not eligible to take part.

Smokers who were eligible and willing to take part in the study were registered by the PN and received an information letter on the participation of the study. Then, they received smoking cessation counseling with or without referral advice, dependent on the condition in which the PN was assigned. Written informed consent was obtained from all participants at the start of the baseline questionnaire. Smokers were semi-blinded, as they were unaware of the procedure of any other group than the one they attended. Smokers were recruited to fill in two questionnaires: one at baseline and one at 6-month follow-up. Smokers who filled in both questionnaires were rewarded with a gift voucher of €10.

To facilitate recruitment of smokers by the PNs, four strategies were employed. First, regular contact by phone was maintained with PNs who did not register smokers. The reason was twofold—as the brief phone call reminded PNs of their participation in the study and could also provide the PNs with tips from other PNs to recruit non-motivated smokers. Second, PNs who registered their first five smokers received a personal postcard congratulating them on their achievement in order to keep them motivated to recruit more. Third, in December all participating PCS received a happy holiday post card together with a "new year's resolutions" poster which they could place in their waiting room. Fourth, all participants received a monthly newsletter which was tailored to them by name and number of recruited smokers. The newsletter included personal success stories and recruitment tips from other participants, as well as recruitment tips based on literature.

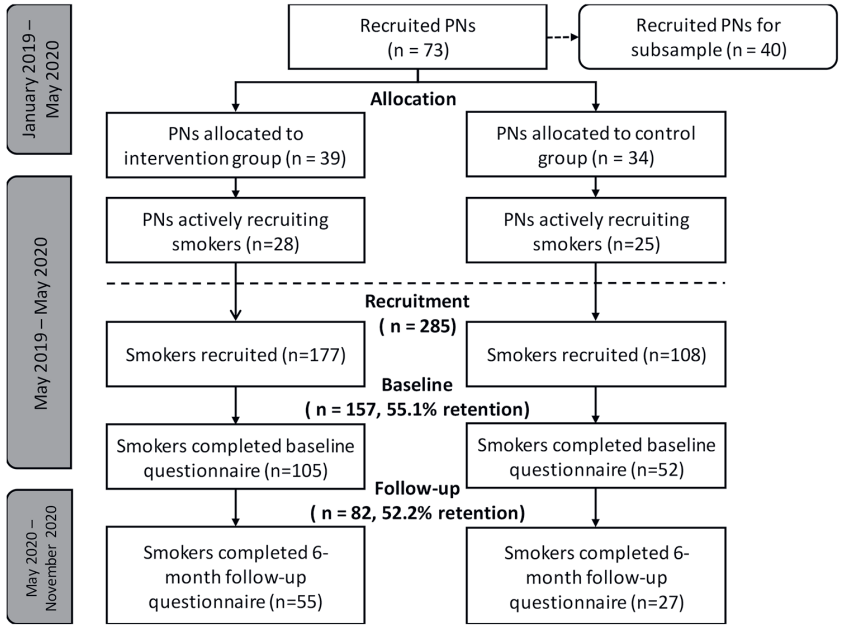



**Figure 3.** Recruitment process during the research

### *2.2.3 Process evaluation among practice nurses (substudy 3) and smokers (substudy 4)*

To measure the usage and appreciation of the materials by both PNs as smokers, as well as the course of discussing the different EBSCIs, a process evaluation was conducted during and alongside the RCT (i.e. only in the smokers and PN of the experimental group in the RCT).

The construct of usage was measured in the form of dichotomous variables (0 = no; 1 = yes) for each of the various materials of the referral aid, namely: 1) the manual, 2) the website, 3) a placemat to stimulate a conversation on smoking cessation, 4) the recruitment poster, 5) the recruitment flyer, 6) the waiting room screen, among PNs from the subsample and smokers who took part in the experimental condition.

The appreciation of the materials (e.g., "I Think the referral aids materials are clear/ understandable/educational") were assessed via three 5-point Likert items (1 = strongly disagree; 5 = strongly agree). Participants were asked to grade the intervention materials on a scale from 1 to 10 (1 = very bad; 10 = very good).

PNs and smokers were asked which EBSCIs were discussed during their consult(s) in order to compare discussion on EBSCIs among both groups. The following EBSCIs made up the response options: Counseling in the GP-setting, counseling by a coach, eHealth, group counseling, telephone counseling, NRT, pharmacotherapy and other non-EBSCIs.

### *2.2.4 Substudy 5: Effect evaluation among smokers*

In order to determine if the referral aid had the desired effect on 1) usage of EBSCIs, 2) decisional conflict, 3) quality of life and 4) smoking abstinence and smoking behavior, an effect evaluation was executed. More details on the effect evaluation plan can be found elsewhere (228).

Demographics of smokers were assessed via age, gender (0 = male; 1 = female), nationality (0 = other nationality; 1 = Dutch nationality) and education level (1 = low: no education, primary, or basic vocational school; 2 = medium: secondary vocational school or high school; 3 = high: higher vocational school or university).

The health status of the smoker (e.g. "Do you currently have type 2 diabetes?") was assessed for six diseases (0= "yes"; 1="no"): COPD, cancer, type 2 diabetes, cardiovascular diseases, asthma, and depression (210).

The number of cigarettes smoker per day was asked via one item (how many cigarettes do you smoke per day?).

The current use of e-cigarettes was assessed via one item ("Do you use e-cigarettes?"; 1 = no; 2 = yes, without nicotine; 3 = yes, with nicotine).

Cigarette dependence was assessed via the Fagerström Test for Cigarette Dependence (208, 209). The six items of the scale were converted into an overall score ranging from 0 to 10.

The number of previous quit attempts was measured via one item ("have you attempted any previous quit attempts?" (0= "yes"; 1="no"):)

One item assessed whether smokers wanted to quit smoking (1 = yes, within one month; 2 = yes, within three months; 3 = yes, within six months; 4 = yes, within one year; 5 = yes, but not within one year; and 6 = no, I do not plan to quit smoking).

At 6-month follow-up, smokers were asked which EBSCIs they ultimately choose to quit smoking using the same response options as in the process evaluation (Counseling in the GP-setting, counseling by a coach, eHealth, group counseling, telephone counseling, NRT, pharmacotherapy and other non-EBSCIs).

Decisional conflict (e.g. "I feel I have made an informed choice") was assessed via the decisional conflict scale (DCS), using 16 items on a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree) (204, 205) at 6-month follow-up to find out whether decisional conflict played a role in choosing a fitting EBSCI.

Last, 24-hour point prevalence abstinence, 7-day point prevalence abstinence and 6-months prolonged abstinence were measured at six-month follow-up from baseline (192, 193, 198). This self-reported measure was supplemented with a 'bogus pipeline' question ('Will you object, if we visit you for a saliva test to check your smoking status?') to reduce socially desirable responses by including the threat of biochemical testing (194, 195).

**2.3 Data analysis**

The recruitment of PNs from the main sample and the subsample (i.e., those who were involved in substudy 3: the process evaluation among PNs), and the recruitment of the smokers, was tracked during the substudies 1 and 2. The context of the subsample of PNs was described by using descriptive statistics, input from the open questions were summarized in text (substudy 2). Differences in the reporting of usage of the materials were analyzed using Person's chi-squared tests between PNs from the experimental and control condition (substudy 3) and smokers who quit smoking after the intervention and those who did not (substudy 4). Appreciation of the materials were analyzed using independent sample t-tests to test for differences between the same groups of PNs and smokers (substudy 3 and 4).

For substudy 5, descriptive analyzes were conducted to describe the sample characteristics. Additional dropout analysis using chi-square tests and t-tests were used to detect differences between smokers retained at the 6-month follow-up and dropouts. Pearson's chi-squared tests were used to compare intervention effects on the discussion of EBSCIs according to PNs and the actual usage of EBSCIs by smokers. Differences between conditions on 24-hour point prevalence abstinence, 7-day point prevalence abstinence and 6-month prolonged abstinence were assessed using Pearson's chi-squared test on complete cases and negative scenario (intention-to-treat principle (214, 231)) (study 5).

## 3. RESULTS

### 3.1 Substudy 1: Recruitment of practice nurses

A total of 1663 PCS were approached to take part in the substudy in accordance with the three approaches as described above: a total of 73 took part (4.4%).

First, the recruitment of practices via the three participating PCAs resulted in 19 PNs out of 420 PNs associated with these PCAs (4,5%).

Second, 1243 PCS that were not part of theses PCAs were individually contacted. This resulted in 54 out of 1243 PNs (4.3%) willing to partake in the substudy. Attempts to contact potential participating PNs were sometimes cut off by the practice operator or assistant. PNs who were reached but did not want to participate explained that they did not have the time, were on special leave within the RCT-period, or had recently moved or would move practices. PNs who wanted to take part sometimes indicated to be new in the PCS and saw the decision aid as a convenient tool for their skills or displayed a general interest in smoking cessation counseling or scientific research.

We promoted the referral aid at two national congresses and placed advertisements in trade magazines issued by the partaking university or smoking cessation associations. This did not yield any unique results. This brought us to a total of 73 out of 1663 approached PNs (4,4%)

### 3.2 Substudy 2: Recruitment and retention of Smokers

In the period between May 2019 and May 2020, the 73 participating PNs recruited 285 smokers to take part in the substudy. Although PNs were asked to recruit at least 10 smokers, recruitment rates varied widely between PNs. A total of 20 PNs did not recruit a single patient (n=11 in the experiment condition and n=9 in the control condition). Of the PNs that did recruit patients, PNs in the experimental condition (N=28) recruited an average of 6.12 smokers (SD = 4.9) in comparison to an average of 5.04 smokers (SD = 4.8) by 25 PNs in the control condition. This difference of the number of patients per PN was not significant.

Of the total 285 participants registered by the PNs, 157 participants filled in the baseline questionnaire, of which 105 were included by PNs in the experimental condition and 52 participants by PNs in the control condition. This amounts to an ultimate participation rate of 55.1% (59.3% in the experimental condition and 48.2% in the control condition). We also experienced a high dropout between the baseline questionnaire and the 6-month follow-up questionnaire (47.8% and respectively 47.6% and 48.1% for both conditions - see Figure 3 for a full overview of the flow of participants). Recruitment rate, as well as retention or dropout rate at six months, did not significantly differ between experimental and control condition.

### 3.3 Substudy 3: Process evaluation by practice nurses

Process evaluation was conducted among a subsample of the PNs. This subsample consisted of 40 PNs (n=22 in the intervention condition and n=18 in the control condition) who filled in the questionnaire with the goal to evaluate the course of events during the RCT (see table 2).

PNs from the experimental condition showed to make the most use of the placemat describing the different available EBSCIs and the details on their advantages, disadvantages, costs, and usage. The digital poster, which they could display on a screen in their waiting room, was used the least. Furthermore, PNs reported a relatively high appreciation of the materials, resulting in a satisfactory mark of 8.8 (SD = 0.9).

All PNs indicated to discuss counseling in the GP-setting, NRT and pharmacotherapy. Counseling via an external smoking cessation coach was discussed the least among both PNs from the experimental and the control condition. Conditions differed on the rate of discussing eHealth (more often discussed in control condition) and group counseling (more often discussed in experimental condition). Other non-EBSCIs that PNs discussed included different variations of quitting or rationing cold-turkey without quit-aids (n=21), acupuncture (n=17), laser therapy (n=9) and hypnosis (n=8). PNs indicated that although these options were discussed, this happened mostly on request of the patient and without endorsement of the PN themselves.

### 3.4 Substudy 4: Process evaluation by smokers

Flyers and posters were seen or received by more than half of the smokers. Around a quarter of all smokers indicated that they saw the digital poster in the waiting room, discussed the placemat during the consult with their PN or visited the website during the consult. Furthermore, smokers reported an appreciation of the materials on a scale of 1-10: 8.0 (SD = 1.8). Usage and appreciation did not differ between smokers who ceased smoking after the intervention and those who continued smoking.

Results among the smokers showed minor differences between experimental condition and control condition, except for NRT and eHealth which were both discussed significantly more often discussed in the experimental condition, whereas eHealth and group counseling were not mentioned to be discussed within the control condition at all.

### 3.5 Substudy 5: Effect evaluation among smokers

Table 4 summarizes all baseline characteristics and 6-month follow-up of smokers from both conditions. Participants were 49% female and had an average age of 49.2 years. More than half (58%) had a low level of education. Respondents smoked around 17.6 cigarettes a day and 61.8% reported no previous quit attempts. Furthermore, 89.2% of the study sample also used e-cigarettes in addition to regular cigarettes. As seen from table 4, smokers from both conditions did not differ on any of the baseline or 6-month follow-up measures,

including their use of EBSCIs to support their smoking cessation attempt. Dropout analysis did not find significant differences between smokers followed up and smokers lost to follow-up after 6 months.

### *3.5.1 Effect on Abstinence and smoking behavior*

As large portions of data at the 6-months measurement (48%) were missing, which also resulted in an disproportionate distribution of smokers among both conditions, multiple imputation or multi-level analyzes could not be performed on the data set (232). We therefore report both complete cases and single imputation based on negative scenario (214) (see Table 5). The group of smokers who indicated to have not smoked a cigarette

**Table 2.** Process evaluation among practice nurses (usage and appreciation of the materials and intervention effects on the discussion of EBSCIs)

| **Usage of materials, % (n)** | **PNs (n = 22 from experimental condition)** | | | | |
|---|---|---|---|---|---|
| Poster | 68.2 (15) | | | | |
| Poster (digital) | 31.8 (7) | | | | |
| Flyers | 59.1 (13) | | | | |
| Placemat | 72.7 (16) | | | | |
| Website during consult | 50.0 (11) | | | | |
| **Appreciation, mean (SD) (I found the materials to be….[1])** | **PNs (n = 22 from experimental condition)** | | | | |
| Clear | 4.14 (0.8) | | | | |
| Understandable | 4.23 (0.7) | | | | |
| Educational | 3.91 (0.6) | | | | |
| Mark [1-10] | 8.68 (0.9) | | | | |
| **Discussion of materials, % (n)** | | | | | |
| | **Total (n=40)** | **Experimental condition (n=22)** | **Control condition (n=18)** | **$\chi^2$** | **P value** |
| Counseling: GP-setting | 100 (40) | 100 (22) | 100 (18) | - | - |
| Counseling: coach | 25 (10) | 36.4 (8) | 11.1 (2) | 3.37 | .067 |
| EHealth | 87.5 (35) | 77.3 (17) | 100.0 (18) | 4.68 | **.031** |
| Group counseling | 82.5 (21) | 72.7 (16) | 27.8 (5) | 8.02 | **.005** |
| Telephone counseling | 70 (28) | 77.3 (17) | 61.1 (11) | 1.23 | .267 |
| NRT | 100 (40) | 100 (22) | 100 (18) | - | - |
| Pharmacotherapy | 100 (40) | 100 (22) | 100 (18) | - | - |
| Other non-EBSCI | 55 (22) | 45.5 (10) | 66.7 (12) | 1.80 | .180 |

[1] 1 = strongly disagree; 5 = strongly agree

in the last 24 hours (24-hour point prevalence abstinence) was identical to the group of smokers who reported to not have smoked a cigarette in the last 7 days (7-day point prevalence abstinence) and this finding is therefore omitted from the table. We found no significant differences between the two conditions in either scenario for 7-day point prevalence abstinence and 6-month prolonged abstinence.

**Table 3.** Process evaluation among (ex-)smokers (usage and appreciation of the materials and intervention effects on the discussion and usage of EBSCIs) measured 6-months after baseline

| **Materials, % (n)** | **Smokers experimental condition (n=54)** | **Ex-smokers N=44** | **Smokers N=36** | **$\chi^2$** | **P value** |
|---|---|---|---|---|---|
| Poster | 67.3 (37) | 75.9 (22) | 60.0 (15) | 1.566 | .211 |
| Poster (digital) | 22.5 (14) | 17.2 (5) | 36.0 (9) | 2.460 | .117 |
| Flyers | 78.2 (43) | 75.9 (22) | 84.0 (21) | 0.548 | .459 |
| Placemat | 27.3 (15) | 17.2 (5) | 40.0 (10) | 3.466 | .063 |
| Website during consult | 27.3 (15) | 17.2 (5) | 32.0 (8) | 1.600 | .206 |
| **Appreciation, mean (SD) (I found the materials to be….[1])** | **Smokers experimental condition** | **Ex-smokers** | **Smokers** | **T-test** | **P value** |
| Clear | 3.55 (0.8) | 3.59 (0.6) | 3.50 (0.9) | 0.414 | .681 |
| Understandable | 3.67 (0.8) | 3.76 (0.7) | 3.58 (0.9) | 0.820 | .416 |
| Educational | 3.65 (0.8) | 3.69 (0.6) | 3.62 (0.9) | 0.363 | .718 |
| Mark [1-10] | 8.00 (1.8) | 8.03 (1.7) | 7.96 (2.0) | 0.147 | .883 |
| **Discussion of materials according to (ex-)smokers** | | | | | |
| | **Total (n=82)** | **Experimental condition (n=55)** | **Control condition (n=27)** | **$\chi^2$** | **P value** |
| Mean number of EBSCIs discussed, mean (SD) | 2.44 (1.5) | 2.64 (1.7) | 2.04 (0.9) | 1.836[2] | .096 |
| Counseling: GP-setting, % (n) | 54.9 (45) | 32 (58.2) | 48.1 (13) | 0.736 | .391 |
| Counseling: coach, % (n) | 23.2 (19) | 20.0 (11) | 29.6 (8) | 0.943 | .331 |
| EHealth, % (n) | 12.2 (10) | 18.2 (10) | 0 (0.0) | 5.591 | **.018** |
| Group counseling, % (n) | 7.3 (6) | 10.9 (6) | 0.0 (0) | 3.178 | **.075** |
| Telephone counseling, % (n) | 39.0 (32) | 40.0 (22) | 37.0 (10) | 0.067 | .796 |
| NRT, % (n) | 42. (35) | 54.5 (30) | 18.5 (5) | 9.608 | **.002** |
| Pharmacotherapy, % (n) | 58.5 (48) | 56.4 (31) | 63.0 (17) | 0.325 | .569 |
| Other non-EBSCI, % (n) | 6.1 (5) | 5.5 (3) | 7.4 (2) | 0.121 | .728 |

[1] 1 = strongly disagree; 5 = strongly agree
[2] T-test

**Table 4.** Baseline and 6-month follow-up characteristics of smokers (N = 157) recruited from May 2019 to May 2020.

| | Overall sample (n = 157) | Experimental condition (n = 105) | Control condition (n = 52) | $X^2$ | T-test | P value |
|---|---|---|---|---|---|---|
| **Baseline** | | | | | | |
| Age (years), mean (SD) | 49.2 (13.6) | 49.0 (13.6) | 49.6 (13.6) | | -0.23 | .819 |
| Gender Female, n (%) | 77 (49) | 51 (48.6) | 26 (50.0) | 0.03 | | .866 |
| Educational level, n (%) | | | | 0.55 | | .760 |
| High | 27 (17.2) | 17 (16.2) | 10 (19.2) | | | |
| Medium | 39 (24.8) | 25 (23.8) | 14 (26.9) | | | |
| Low | 91 (58.0) | 63 (60.0) | 28 (53.8) | | | |
| Dutch, n (%) | 154 (98.1) | 103 (98.1) | 51(98.1) | 3.01 | | .222 |
| Health status, n (%)[1] | | | | | | |
| Pulmonary emphysema and / or chronic bronchitis (COPD) | 37 (23.6) | 23 (21.9) | 14 (26.9) | 0.47 | | .486 |
| Cancer | 10 (6.4) | 6 (5.7) | 4 (7.7) | 0.23 | | .633 |
| Type 2 diabetes | 14 (8.9) | 10 (9.5) | 4 (7.7) | 0.14 | | .705 |
| Heart and / or vascular diseases | 26 (16.6) | 17 (16.2) | 9 (17.3) | 0.03 | | .859 |
| Asthma | 25 (15.9) | 16 (15.2) | 9 (17.3) | 0.11 | | .739 |
| Depression or major depressive disorder | 33 (21.0) | 23 (21.9) | 10 (19.2) | 0.15 | | .699 |
| No health conditions | 70 (44.6) | 49 (46.7) | 21 (40.4) | .56 | | .456 |
| Number of cigarettes smoked/day, mean (SD) | 17.6 (8.2) | 18.1 (8.4) | 16.4 (7.8) | | 1.25 | .212 |
| Use of e-cigarettes, n (%) | | | | 5.421 | | .066 |
| No | 140 (89.2) | 90 (85.7) | 50 (96.2) | | | |
| Yes, without nicotine | 2 (1.3) | 1 (1.0) | 1 (1.9) | | | |
| Yes, with nicotine | 15 (9.6) | 14 (13.3) | 1 (1.9) | | | |
| FTND[2] score (range 1- 10), mean (SD) | 6.0 (1.9) | 6.1 (2.0) | 5.7 (2.0) | | 0.76 | .448 |
| No previous quit attempts (%) | 97 (61.8) | 62 (59.0) | 35 (67.3) | 1.68 | | .641 |
| Readiness to quit, n (%) | | | | 2.82 | | .589 |
| Within 1 month | 105 (66.9) | 71 (67.6) | 34 (65.4) | | | |
| Within 1-3 months | 32 (20.4) | 23 (21.9) | 13 (25.0) | | | |
| Within 4-6 months | 14 (8.9) | 10 (9.5) | 4 (7.7) | | | |
| Within 6-12 months | 1 (0.6) | 0 (0.0) | 1 (1.9) | | | |
| Within >12 months | 1 (0.6) | 1 (1.0) | 0 (0.0) | | | |
| **6-months follow-up** | **Overall sample (n = 82)** | **Experimental condition (n = 55)** | **Control condition (n = 27)** | **$X^2$** | **T-test** | **P value** |
| Usage of materials | | | | | | |
| Mean number of EBSCIs used (SD) | 2.29 (1.6) | 2.09 (1.4) | 2.48 (1.8) | | | .270 |
| Counseling: GP-setting, % (n) | 37.8 (31) | 63.8 (30) | 36.2 (17) | 0.52 | | .469 |
| Counseling: coach, % (n) | 18.3 (15) | 14.5 (8) | 25.9 (7) | 1.57 | | .210 |
| EHealth, % (n) | 8.5 (7) | 12.7 (7) | 0.0 (0) | 3.76 | | .053 |
| Group counseling, % (n) | 11.0 (9) | 7.3 (4) | 18.5 (5) | 4.59 | | .101 |
| Telephone counseling, % (n) | 1.2 (1) | 1.8 (1) | 0.0 (0) | 0.49 | | .481 |
| NRT, % (n) | 35.4 (29) | 34.5 (19) | 37.0 (10) | 0.05 | | .824 |
| Pharmacotherapy, % (n) | 11.0 (49) | 54.5 (30) | 70.4 (19) | 1.87 | | .170 |
| Other non-EBSCI, % (n) | 15.9 (13) | 20.0 (11) | 7.4 (2) | 2.15 | | .142 |
| DCS, mean (SD) | 27.3 (16.1) | 28.7 (13.1) | 26.0 (19.1) | | 0.73 | .465 |

[1]combinations of several conditions possible
[2] Fagerström Test for Nicotine Dependence.

**Table 5.** Effects on abstinence and smoking behavior per condition

| | Total | EXP | CON | $X^2$ | P value |
|---|---|---|---|---|---|
| **Complete Cases, % (n)[1]** | | | | | |
| 7-day point prevalence abstinence | 54.3 (44) | 52.7 (29) | 57.7 (15) | .175 | .675 |
| 6-month prolonged abstinence | 18.5 (15) | 34.8 (8) | 46.7 (7) | .537 | .464 |
| **Negative scenario, % (n)[2]** | | | | | |
| 7-day point prevalence abstinence | 28.0 (44) | 27.6 (29) | 28.8 (15) | .026 | .872 |
| 6-month prolonged abstinence | 9.6 (15) | 7.6 (8) | 13.5 (7) | 1.374 | .241 |

[1] Based on n=82
[2] Based on n=157

## 4. DISCUSSION

### 4.1 Substudy 1: Recruitment of practice nurses

The disappointing recruitment of PNs was remarkable, as only a small percentage (4.4%) of approached PN's were willing to participate in the study. Unfortunately, this is not uncommon for studies within the PCS (31, 134, 233-235). Effective recruitment of both smokers and healthcare professionals is the cornerstone of clinical research, as failure to recruit a sufficiently large sample results in low statistical power (generalizability of the results) (236).

### 4.2 Substudy 2: Recruitment and retention of smokers

PNs involved in the study recruited a small number of smokers. Therefore, it was decided to extend the recruitment time, which negatively affected the study efficiency and made conducting a 12-month measurement unfeasible, although initially planned. As suggested by others (237), we tried to stimulate early recruitment success through postcards with motivational messages, a newsletter (read by 40% of the participating PNs) and telephone calls. We also tried to stimulate recruitment motivation of the PNs by promising financial rewards, but found no immediate effects on recruitment rate.

Besides effective recruitment of smokers, retention rates are also important in clinical trials. We had a retention rate of 44.9% (n=157) at baseline level and 47.8% (n=82) at 6 months, which also meant that a 12-month measurement would not have been meaningful. These dropout rates are comparable with other studies with little direct patient-researcher contact (31, 132-134). Although we used several strategies to prevent dropout (218), e.g., sending several reminders for each follow-up questionnaires and promising respondents a €10 voucher for completing all follow-up questionnaires and using an additional abbreviated follow-up questionnaire consisting of three questions regarding smoking behavior to non-responders, drop-out rates were high. Unfortunately, because of the design of the study resulting in little direct patient-researcher contact, we could not determine the

most important factors for drop-out. This also was not allowed due to research ethics regulations in the Netherlands (https://metc.mumc.nl/). Additional inquiries with PNs also did not provide a constructive answer.

**4.3 Process evaluation among practice nurses (substudy 3) and smokers (substudy 4)**

We assessed reported usage of materials in the experimental condition among the PNs from the subsample and among smokers. Overall, PNs reported a higher percentage of usage of all materials than patients expect for the flyer. The reporting of usage differed between groups on the usage of the placemat and the website, as smokers reported a lesser percentage of use of those during the consults. Furthermore, PNs found the materials percentually more clear and more understandable than smokers. Both groups gave the highest scores to the materials being understandable when rating the appreciation. These percentual differences between PN and smokers might be explained by the characteristics of the PNs in the used subsample, as these consisted largely of PNs who were more motivated to take part in the study. Another explanation can be found in the given that PNs already have more knowledge on EBSCIs, as providing smoking cessation care is part of their responsibilities within their job. PNs reported systematically higher percentages of discussing EBSCIs during consultation than smokers reported discussing them, with the biggest differences found in the discussion of eHealth and group counseling in the control sample (respectively discussed during 100% and 27.8% of their consultations according to PN from the control condition and not discussed at al according to smokers from the control condition). Last, smokers in the experimental condition indicated more often that they discussed the use of NRT instead of pharmacotherapy in comparison to smokers in the control condition, which is the more desirable first option in accordance to the Dutch Guidelines (44, 52).

**4.4 Substudy 5: effect evaluation among smokers**

This substudy did not find different effects between the experimental and control condition on smoking cessation and actual usage of EBSCIs after referral. Only the control condition seemed to report a borderline significant higher use of eHealth.

Although smokers from the experimental condition were introduced to a wide variety of EBSCIs, their scores on the DCS did not differ significantly from the smoking smokers in the control condition. The good news is that the referral aid did not introduce uncertainty about the course of action to be taken. However, the bad news may be that the implementation of the referral aid had such a low level of effect, thus also not resulting in any chances for decisional conflict. Decisional conflict often appears when the choice that has to be made involves a lot of risks or uncertainty or when significant potential gains or losses play a role (238). As most EBSCIs do not really differ on those aspects, this may also explain the lack of conflict. Another study in a similar sample suggested the explanation

that smokers may already made their choice for an EBSCI before addressing smoking cessation to their PN, for example based on experiences from their environment, their own previous experiences and the media (239).

**4.5 Strengths and Limitations**

A strength of this study is that it is one of the first investigating the effect of a referral aid transforming the role of PN from counseling to more a more facilitating role. Previous research showed that HCPs including PNs showed a low consensus on the effectiveness of EBSCIs and might benefit from an inventory on EBSCIs, their effects, characteristics, costs, where to find them and their usage to facilitate better uptake in the PCS (225). Another strength of the study is that it not only focusses on the effectiveness of the referral aid on smoking cessation, but also on the appreciation of the used materials and the process of the recruitment, as previously discussed similar studies already encountered barriers when recruiting participants within the PCS or via the PCS (233-235). We managed to include a relatively high percentage (58%) of smokers with a low education, a group that is often difficult to reach (132) and participating smokers in our study showed a high cessation rate of more than 50%. However, this only concerned the complete case scenario which is likely to be to positive due to the high dropout.

Yet, our study is also prone to limitations. As the limited study sample resulted in an inability to perform multilevel analyses or other statistical analysis while assuring a high statistical validity and possibly preventing type III errors (i.e., correctly rejecting the null hypothesis but for the wrong reasons, for example, when the intervention was not properly implemented) (240). We therefore chose to take on a more descriptive approach to investigate our data, in contrast to the approach described in the protocol paper (228). Other ways to prevent a type III error from happening, other than including a larger sample, is to monitor more strictly how the intervention is implemented by the HCP (241). This can be done through self-reporting by PNs or by observation by a trained researcher. However, valid self-reporting requires a lot of time and effort of the PN and might evoke socially desirable answers, which still evokes a distorted picture. Observation by a trained researcher was not possible because of the COVID-19 pandemic, and the associated distancing measures.

Second, the PNs participating in the present study might have been a select group who are more open to new innovations or are more interested in smoking cessation related health care (selection bias). A consequence might be that the results could be even less positive in a broader population. As PNs often report to non-adhere to the Dutch Cessation Guidelines because of time or costs constraints (54), another explanation for the low participation rate might be that PNs are put off by the burden of the additional research elements associated with RCTs.

Third, the studies suffered from low participation rate and considerable dropout for both PNs as smokers, although this could not be traced back to the study condition. We applied several strategies to prevent attrition such as sending reminder emails for recruiting more smokers (for PN participants) or filling in the questionnaire (for smoking participants) and providing respondents with a €10 voucher for completing all questionnaires (smoking participants), but unfortunately, they did not achieve the intended effect.

Finally, the planned cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA) economic evaluations (228) were not executed because of the small sample size and lack of behavioral results.

### 4.6 Recommendation for practice

In the light of the issues described, we would like to propose three recommendations for practice regarding 1) recruitment within an RCT or other research study, 2) providing smoking cessation counseling and referral to EBSCIs within the PCS and 3) providing smoking cessation counseling and referral to EBSCIs within the PCS outside the PCS.

First off, to facilitate recruitment among both PNs and smokers even more, participation in the study should not create unnecessary ballast on top of the intervention itself. This might be achieved by managing expectations at forehand (informing both groups extensively about all the content and timelines of the elements of the study) (237), keeping actions associated with the research part (e.g., filling in questionnaires) short and to the point and integrating unfamiliar tasks (e.g., registering smokers willing to participate) as much as possible within current daily operations.

Second, when looking at the situation within the PCS, time or costs constraints often play a large role in the adherence of PNs to the smoking cessation guidelines including referral to EBSCIs (54). The PNs primary task is assisting smokers with smoking-related diseases such as asthma or COPD with by providing chronic care, which was also the primary target group of this study. PNs are therefore also mainly reimbursed for performing tasks within chronic care. Although referring smokers not in need of chronic care to external EBSCIs can help PNs save time and money, this transfers their roll more into facilitators rather than only counselors while referral can be viewed as a complicated process when the PN wishes to provide counseling in the PCS. By increasing the reimbursements, they receive for counseling smokers, also those with nonsmoking-related diseases or without disease for which they do not get the same amount of reimbursement, PNs might be more motivated to actively counsel or refer these smokers independent of the time they have to invest in it, which can provide certainty for both PNs and smokers. To achieve this, the current funding systems within the Dutch health care system should be adjusted to make effective counseling possible and attractive within the PCS.

Third, it may be important to explore whether there are additional venues outside the PCS to talk about smoking cessation in order to reach and persuade more smokers to quit,

for example through other HCPs such as dentists or midwives. Although research has found other HCPs also encounter barriers such as lack of time and training (36) a spreading of the workload can help lower the total individual pressure. To achieve this, appropriate educational options, possibly a simplified version of the 5As or Dutch guidelines such as the ask-advise-refer (AAR) strategy (242) which is already been tried out or proven effective in other settings (117, 243-245). Furthermore, HCPs should be able to claim reimbursement for these actions. Again, an adjustment to the current funding system within the Dutch Health care system needs to be made to establish this change, possibly leading to more attention and reimbursements for prevention and innovation in the PCS (246). An additional entryway outside of the healthcare system for discussing smoking cessation might be found in the workplace, as most organizations have direct and prolonged contact with potential quitters (25). Another possible entryway might be the internet. Although often associated with high dropout rates (131), online interventions, for example spread through existing national (social media) campaigns, might result into a high reach, especially targeting younger and relatively healthy populations less likely to come to PCS or other health professionals, against a much lower cost (132). However, this method was not yet found to be effective among high-risk groups (e.g., low socioeconomic status or people with smoking-related health complaints) so additional effort should be put into reaching and including this target group (247) for example by increasing their involvement in the development process (248).

## 5. CONCLUSION

To assist Dutch PNs and other primary care providers in referring their smokers to EBSCIs, a referral aid was developed. The aim of this study was to explore the use and effect of the referral aid from the perspectives of PNs and smokers by investigating the course of recruitment and conducting a process and effect evaluation. Recruitment of both PNs and smokers resulted in low levels of participation. Overall, PNs found the materials clear and understandable. Smokers had similar but (slightly) less positive opinions. However, the referral aid was not intensively used, and the groups of smokers and ex-smokers did only marginally differ on discussion and usage of EBSCIs, nor differed on abstinence. As the main finding concerned a low level of participation and use of the referral aid by PNs, further research should aim at assessing how to better involve PNs and smokers when recruiting for an RCT and at how to foster effective counseling. Additional research should also look deeper into barriers for referral of both PNs and smokers and how to best stimulate referral to EBSCIs and helping smokers make a decision, for example by implementing a simplified strategy such as the AAR, both within the PCS as possibly outside the PCS by involving other HCPs and options outside of healthcare such as the workplace and the internet.

# CHAPTER 5

## How to convince more primary care professionals to adopt a valued smoking cessation tool: Facilitators and barriers

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How to convince more primary care professionals to adopt a valued smoking cessation tool: Facilitators and barriers.

## ABSTRACT

**Aim:** To study the factors associated with the intention of primary care professionals (PCPs) to use or not use a referral aid (RA) in selecting an evidence-based smoking cessation intervention (EBSCI)

**Design:** Cross-sectional study

**Methods:** Participants (n = 85) were recruited from June to September 2020 to complete an online questionnaire based on the I-Change Model to assess the factors associated with the adoption of RA. The differences between non-adopters (n = 48) and adopters (n = 37) in terms of demographics, motivational factors, and post-motivational factors were subsequently assessed. Correlation and logistic regression analyses were conducted to explore the factors associated with the intention to adopt.

**Results:** Both groups indicated that they highly appreciated the RA. However, non-adopters expressed a more negative attitude towards the RA, experienced less social support, showed low self-efficacy, and encountered barriers such as lack of time and skills. The factors most strongly associated with the intention to adopt were advantages, disadvantages, self-efficacy, less barriers, working in a solo practice and age.

**Conclusion:** The adoption of RA can be facilitated in two ways. The first one is by increasing the added value of the tool through a second round of co-creation focusing on the adoptability of the RA in practice. The second approach is by communicating the added value of referring to EBSCIS and thereby using the RA by implementing it in smoking cessation training for PCPs, which could also help to improve the attitude, social support, self-efficacy, and perceived skills in terms of RA usage among PCPs.

**Impact:** This study is the first work in the Netherlands to investigate the willingness of PCPs to actively refer patients to other EBSCIs in addition to providing face-to-face counseling themselves.

## 1. INTRODUCTION

Tobacco use continues to cause a range of noncommunicable diseases, and it is responsible for approximately eight million deaths worldwide every year (6). The prevalence of daily smoking among adults in the Netherlands was approximately 18% in 2017 (6, 249). The primary care setting (PCS) can play a significant role in smoking cessation, as most smokers visit their general practitioner (GP) yearly for a consultation with either the GP or a practice nurse (PN; (224). PNs specialized in the treatment of chronic diseases are usually trained in providing smoking cessation counseling according to the Dutch Smoking Cessation Guidelines (DGSCC:(52, 53); these guidelines are based on the internationally used protocol of 5As, namely Ask, Advise, Asses, Assist, and Arrange (177). According to these guidelines, the PCS is also the main gateway for referral to pharmacotherapy (including nicotine replacement therapy (NRT)) and other evidence-based smoking cessation interventions (EBSCIs), some of which are administered outside of the PCS. Although the use of EBSCIs significantly increases the success rate of smoking cessation attempts (53, 86), EBSCIs are used by only 19–25% of the Dutch smokers who are willing to quit (90). An approach based on informed and shared decision principles, rather than top–down recommendations or very brief advice by a primary care professional (PCP), may increase the referral to and use of EBSCIs. It may also enhance smoking patients' involvement and commitment by providing them with the support that best fits their needs and preferences (103, 104).

Establishing clear guidelines on how to aid smoking patients in deciding the EBSCI that is the most appropriate for them may not only increase the referral to and use of EBSCIs and boost the patients' commitment but may also facilitate the implementation of smoking cessation guidelines in the PCS, reduce the time burden, and may lead to a more efficient process outside of practice in broader geographical areas. Therefore, a referral aid (RA), the "*StopWijzer*" (which can be translated as stop-indicator and stop wisely in Dutch), was developed. The goal of the RA is to optimize the referral to and use of EBSCIs in the PCS and to increase the success rate of smoking cessation attempts.

The RA consisted of an intervention manual with additional materials such as a flow-chart and a poster (described in further detail in the method section), which aims to guide PCPs in discussing smoking cessation with patients and aid them in selecting an EBSCI that fits the patients' individual needs and preferences. The RA was based on a needs assessment comprising a literature review (e.g., (31, 52, 69, 105); individual interviews with respectively GPs, PNs, and smokers; a Delphi study on the referral to EBSCIs in the PCS (225); and input from the advisory board that was installed for the research project. The EBSCIs included in the RA, which are also referred to in the DGSCC (52, 53), are face-to-face counseling (44), online counseling (eHealth) (69, 178), telephone counseling (179), group counseling (74), pharmacotherapy (75-77), and NRT (78). A brief chapter aimed to discourage the use of non-evidence-based interventions such as acupuncture and

e-cigarettes to quit is also included. (For more information on the RA and the associated materials, see (228).)

The first step in the successful dissemination of interventions is successful adoption by the end users, in this case PCPs (106, 107). Theories such as the theory on diffusion of innovations (206), the theory of planned behavior (TPB; (112), and the integrated change model (ICM) (105) are often used as theoretical frameworks to gain insight into the factors influencing the adoption of smoking cessation interventions among healthcare professionals (e.g., (54, 115-118). The diffusion theory of Rogers seeks to explain how an innovation spreads over time among potential adopters. The TPB predicts an individual's intention to perform a certain behavior through motivational factors (attitude, subjective norms, and perceived behavioral control (PBC)). The ICM adds predisposing factors such as behavioral (past attempts of changing the behavior), psychological (personality traits), biological (age or gender), and environmental factors (policies). The ICM further adds (perceived) barriers, action or coping plans, and skills (105, 250-252).

Predisposing factors such as occupation (32), work experience, and time spent on counseling have been associated with adherence to smoking cessation guidelines (54). In addition, Bolman and colleagues (Bolman, de Vries, & Mesters, 2002) have indicated that predisposing factors do not influence the intention to adopt directly when motivational factors are considered. Motivational factors entail attitude (i.e., advantages and disadvantages), self-efficacy, and social support or social norms. Earlier research revealed attitude to be a strong predictor for the intention to adopt (32, 115-117). Self-efficacy has often been associated with the PCPs' adoption of interventions to improve smoking cessation care. In some studies, higher self-efficacy has been associated with a higher adoption rate (54, 114-118). However, other studies found no significant relationship between self-efficacy and adoption (32). Social support or social norms are less often associated with the intention to adopt among GPs, although some studies found an association (32). This association may be explained by the fact that PNs are frequently shown to be the only smoking cessation counseling point of contact within their individual PCS (54), as studies in other health care settings sometimes reported an association (33, 117). Aside from motivational factors, perceiving fewer barriers in adopting a new smoking cessation RA (117) and being comfortable executing the steps that are part of an intervention (32) are found to be related to a higher intention to adopt. Other factors found to be associated with the intention to adopt a smoking cessation counseling aid include the belief that adoption is futile, as most smokers are unwilling to quit (61).

In contrast to the interventions in the aforementioned studies, this intervention focuses not only on smoking cessation counseling administered inside the PCS but also on the willingness of PCPs to actively refer patients outside of the PCS, as this aspect is a crucial innovation of the new RA. In this study, the ICM was used as a theoretical framework to assess the determinants of the intention to adopt (see Figure 1).

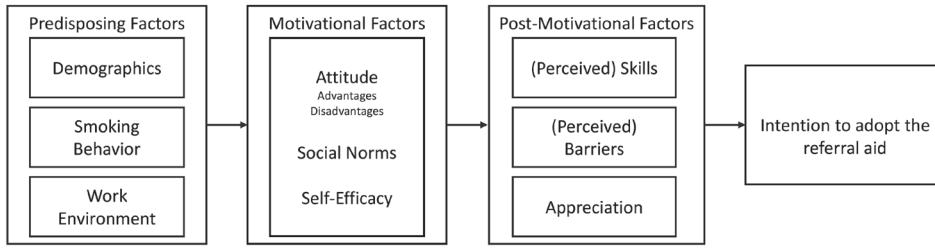


**Figure 1.** The ICM applied to the adoption of the RA by PCPs in the PCS.

## 2. METHODS

### 2.1 Aims

The aim of this study was to explore the factors influencing the PCPs' intention to adopt a smoking cessation intervention that shifts the PCPs' focus from a counseling role to a more facilitating and referring one. First, we wanted to explore the relevant motivational factors related to the intention to adopt, such as experiencing relatively more benefits (e.g., RA is an effective method of bringing EBSCIs to the smokers' attention) and fewer disadvantages (e.g., the belief that the RA would not improve the quality of smoking cessation counseling), higher self-efficacy, and possibly higher social norms. Finally, we explored the PCPs' degree of appreciation for the RA, the perception of PCPs' skills in following the intervention steps, and the PCPs' perceptions of barriers to referring patients to EBSCIs. As some studies indicated some influence of the predisposing factors, we included the factors that measure the PCPs' own smoking behavior and their work environment as well as standard demographic measurements.

### 2.2 Design

A cross-sectional survey was used in this study.

### 2.3 Sample/Participants

Two groups were invited via email, namely all the PCPs who were assigned to the control group in our randomized controlled trial and had therefore not yet worked with the RA (n = 32) (228) and the PCPs who were not involved in our RCT (n = 200). The additional 200 PCPs were recruited throughout the Netherlands using existing mailing lists. The participants received a link to an online questionnaire, a summary of the RAs' content with screen shots of the associated materials, and a link to the RA website where all materials could be viewed. PCPs did not extensively use the RA before completing this study, but they were invited to use the materials in daily practice after the study if they desired to do so.

### 2.4 Referral aid

The RA consisted of a manual that summarizes EBSCIs (i.e., counseling via GP, PN, or coach, eHealth, counseling via telephone, group counseling, NRT, pharmacotherapy) and non-evidence-based methods such as acupuncture and e-cigarettes to quit, their disadvantages, costs, and a list of PCPs within the Netherlands. The manual also encapsulates the steps recommended during a counseling session according to the DGSCC (52, 53), the Dutch healthcare reimbursement system, and some recommendations for planning and conducting a follow-up meeting. Additional materials for the PCP comprised a laminated option grid (designed to be used as a table card) in A3 format, a summarization of the RA protocol in A5 format, and various promotional materials such as a (digital) poster in the practice waiting room, flyers, and business cards (not specifically evaluated during this study).

The RA protocol included five steps (excluding the steps that were only undertaken as part of the data collection for the related RCT study (228). First, the participating PCPs identified patients with smoking-related complaints and asked whether they were motivated to quit smoking. Second, when smoking patients were willing to talk about smoking cessation, PCPs were tasked with explaining the EBSCIs in accordance with the RA materials. Third, when relevant, PCPs were stimulated to explain the Dutch reimbursement system for smoking cessation methods outside of the PCS. Fourth, when smoking patients expressed a preference for one of the recommended EBSCIs, PCPs referred them to the appropriate interventions as described in the RA. Finally, PCPs were advised to schedule a follow-up meeting a few weeks after the decision to talk about the patient's experiences and progress.

### 2.5 Data collection

Data were collected from June until September 2020 via an online questionnaire that could be accessed through an online platform (Formdesk, www.formdesk.nl). The questionnaire took on average 15 minutes to complete, excluding the time that PCPs needed to explore the materials. PCPs who did not respond within seven days were sent a maximum of two reminders. Upon the completion of the questionnaire, participants received a reimbursement of €20 in gift vouchers.

### 2.6 Questionnaire

The questionnaire consisted of 41 questions. These questions concerned PCPs' demographic characteristics (including their own smoking behavior and work environment), intentional factors, motivational factors, and factors regarding perceived skills, perceived barriers, and appreciation (post-motivational factors, explained in more detail below). Questions on motivational factors were based on relevant existing scales (33, 48, 117). Questions to measure the appreciation of the RA were also used in related studies among smoking patients (228, 253) to facilitate the comparison.

### *2.6.1 Demographics and smoking characteristics*

In terms of demographic variables, PCPs were queried about their gender, age, occupation (e.g., practice nurse/nurse specialist, or other) and the number of years they had been active in that occupation. The PCPs' own smoking behavior was assessed using one item (smoker/ex-smoker/non-smoker). The PCPs' work environment (e.g., type of PCS, such as a solo practice; refer to Table 1 for a complete overview) was assessed using six items.

### *2.6.2 Intentional factors*

To compare participants based on their intention to adopt the RA, intention to adopt was assessed using three items (e.g., "I consider it likely that the RA will be implemented in practice"). All intention items were measured using a five-point Likert scale ranging from 1 ("surely not") to 5 ("most certainly yes"). Based on the three items, a mean score was formed (Cronbach's α = .78).

### *2.6.3 Motivational factors*

The advantages of the RA (e.g., "The RA is easy to apply in daily practice") were measured with four items using a five-point Likert scale ranging from -2 ("completely disagree") to 2 ("completely agree"). Moreover, the items were combined into an overall advantages scale using the mean score (α = .73).

The disadvantages of the RA (e.g., "The RA does not improve the quality of providing smoking cessation information in general practice") were measured with four items using a five-point Likert scale ranging from -2 ("completely disagree) to 2 ("completely agree"). Additionally, the items were combined into an overall disadvantages scale using the mean score (α = .80).

Social support towards using the RA in daily practice from GPs, PNs, assistants, and the care group in which the participant worked was assessed using four items (e.g., "When implementing the RA in practice, I expect much opposition or support from my (fellow) PNs"). All social support items were measured using a five-point Likert scale ranging from 1 ("much opposition") to 5 ("much support") and combined into an overall scale using the mean score (α = .74).

Self-efficacy towards using the RA in daily practice was assessed using four items (e.g., "I find difficulty in using the RA when the patient is clearly not motivated to stop smoking"). All self-efficacy items were measured using a five-point Likert scale ranging from 1 ("very difficult") to 5 ("very easy"). The reliability analysis showed a low reliability (α = .52); however, given the exploratory nature of this study, the scale was used in the regression analysis.

### *2.6.4 Post-motivational factors*

Perceived skills necessary to successfully implement the steps as shown by the RA protocol were assessed using five items (e.g., "I think I am able to identify a patient as a smoker who

is motivated to quit smoking") using a five-point Likert scale ranging from 1 ("very difficult") to 5 ("very easy"). Moreover, the items were merged into a mean skills scale (α = .65).

Perceived barriers towards adopting the RA in daily practice were assessed using five items (e.g., "There is too little time to use the referral guide"). All the barriers' items were measured using a five-point Likert scale ranging from 1 ("totally disagree") to 5 ("totally agree") and were merged by forming a scale using mean scores (α = .71) after the exclusion of one item (i.e., "Many patients in our practice have an insufficient command of the Dutch language"). The language item was included as a separate item.

Appreciation was assessed using four items, of which three were measured (i.e., "I found the RA materials clear/understandable/instructive") using a five-point Likert scale (1 = totally disagree; 5 = totally agree). The three items were combined into a mean appreciation scale (α = .86). Participants were additionally asked to rate the intervention materials in total on a scale of 1 to 10 (1 = bad; 10 = very good).

### 2.7 Ethical considerations

The research proposal for this study has been reviewed and approved by the medical ethics committee of Maastricht University Hospital and Maastricht University. According to both institutions, this study did not require medical ethical consent under the rules of the Medical Research Involving Human Subjects Act (WMO–2018-1038). The study was registered at the Netherlands Trial Register (NL7020, https://www.trialregister.nl/trial/7020). Informed consent was obtained by affirmatively answering one question to access the questionnaire; PCPs who did not give consent were excluded from the study.

### 2.8 Data analysis

Descriptive statistics were used for describing the characteristics of the participants. Participants were divided into two groups based on their intention to adopt: non-adopters (surely not, not, and neutral) and adopters (certainly and most certainly). T-tests and chi-square tests were conducted to assess the potential differences between adopters and non-adopters in terms of demographics, motivational factors, and post-motivational factors. To control for multiple testing, we used a significance criterion of $P < .01$.

Next, correlations between all relevant concepts (predisposing, motivational and post motivational variables) and the intention to adopt were tested via Pearson correlation coefficient. Variables that revealed significant correlations with the outcome measure (age, years active in occupation, being an ex- or non-smoker, working in a solo practice or other type of practice (non-group), years active in practice, advantages and disadvantages, social support, and self-efficacy, perceived skills, and barriers) were used in a linear regression analysis using forward stepwise selection to determine predictors of intention to adopt the RA.

## 3. RESULTS/FINDINGS

### 3.1 Demographics and smoking characteristics

The recruitment process resulted in 85 participants (response rate = 34%), from whom n = 18 stemmed from the original control group (response rate = 56%) and n = 67 from the newly approached group (response rate = 34%). The participating group of PCPs consisted of 4 GPs, 46 PNs, 3 practice assistants, 28 nurse specialists, and 4 others. The participants worked on average 25.4 hours (SD = 7.1) per week in the PCS.

Participants were divided into adopters (n = 37, 43.5%) and non-adopters (n = 48, 56.5%). In the group of non-adopters, PCPs were significantly younger, worked for a shorted duration in their described occupation, worked fewer hours, and were less often ex-smokers (for all the study demographics, see Table 1).

### 3.2 Differences between adopters and non-adopters

#### *3.2.1 Motivational factors*

Non-adopters perceived fewer advantages than adopters, as they less often reported that (1) the RA was an effective method of supporting patients in their choices about quitting smoking, (2) the RA was easy to apply in daily practice, and (3) the RA helped them to bring smoking cessation to their patients' attention in a more effective manner. Non-adopters also reported more disadvantages. First, they indicated that the RA was not sufficiently enabling patients to make an informed choice about quitting smoking. Second, they stated that the RA increased the risk that patients no longer want to quit smoking. Third, they believed that the RA was difficult to apply. Furthermore, non-adopters perceived less support from their environment, especially from other PCPs. Finally, non-adopters reported a lower self-efficacy, especially with regard to situations in which they are very busy or when the patient is not motivated to stop smoking. An overview of all the differences is presented in Table 2.

#### *3.2.2 Post-motivational factors and appreciation*

Non-adopters significantly differed from adopters in their rating on the perceived skills scale and their rating on Step 2. Non-adopters perceived significantly more barriers than adopters, except for patients with an insufficient command of the Dutch language, which did not significantly differ between both groups.

With regard to the total scale of appreciation, no significant differences were found between the appreciation of the RA by adopters and non-adopters (see Table 3). Non-adopters gave the RA a slightly lower overall evaluation (8.04 out of 10) than adopters (8.69 out of 10) ($T = 7.13$, $P < 0.05$).

**Table 1.** Comparison of demographics and smoking characteristics between adopters and non-adopters.

| | Total (n = 85) | Adopters (n = 37) | Non-Adopters (n = 48) | T-test | χ2 | P |
|---|---|---|---|---|---|---|
| **Demographics** | | | | | | |
| Gender female (%) | 84 (98.8) | 36 (97.3) | 48 (100) | | | .435† |
| Mean age in years (SD) | 45.5 (11.6) | 48.3 (11.1) | 43.2 (11.7) | -2.041 | | .044 |
| Occupation (%) | | | | | | .521† |
| PN/Nurse specialist | 74 (87.1) | 31 (83.8) | 43 (89.6) | | | |
| Other‡ | 11 (12.9) | 6 (16.2) | 5 (10.4) | | | |
| Mean years active in occupation (SD) | 10.05 (6.4) | 11.7 (7.3) | 8.8 (5.4) | -2.120 | | .037 |
| Smoking behavior (%) | | | | | | |
| smoker | 3 (3.5) | 1 (2.7) | 2 (4.2) | | - | - |
| ex-smoker | 27 (31.8) | 17 (45.9) | 10 (20.8) | | 6.079 | .014 |
| non-smoker | 55 (64.7) | 19 (51.4) | 36 (75.0) | | 5.117 | .024 |
| **Work environment** | | | | | | |
| Type of general practice (%) | | | | | 3.576 | .167 |
| Solo practice | 20 (23.5) | 12 (32.4) | 8 (16.7) | | | |
| Group practice | 40 (47.1) | 17 (45.9) | 23 (47.9) | | | |
| Other§ | 25 (29.4) | 8 (21.6) | 17 (35.4) | | | |
| Mean years active in practice (SD) | 9.68 (7.8) | 10.8 (6.8) | 8.8 (8.4) | -1.179 | | .242 |
| Mean working hours per week (SD) | 25.40 (7.1) | 27.4 (6.7) | 23.8 (7.1) | -2.370 | | .020 |
| Mean number of patients in practice (SD) | 5382.54 (2944.1) | 5250.0 (3196.8) | 5491.5 (2751.1) | 0.368 | | .714 |
| Mean number of smokers per practice who in general receive brief/short smoking cessation advice per month (SD) | 10.94 (8.4) | 11.6 (10.1) | 10.4 (6.8) | -0.667 | | .507 |
| Mean number of smokers per practice who receive smoking cessation counseling per month (SD)¶ | 4.15 (3.7) | 4.9 (5.1) | 3.6 (2.1) | -1.619 | | .109 |

†Fisher's Exact Test reported as numbers are insufficiently high for calculating $\chi^2$.
‡ e.g., Practice assistant, General practitioner or other (individual groups too small to perform separate analyses)
§ e.g., Health center, medical center, general practitioner with dispensing pharmacist
¶This means that we asked PN to estimate the absolute number of active counseling by the PCP according to the Dutch Guidelines for smoking cessation; this might also include the prescription of pharmacotherapy.

**Table 2.** Significant differences in mean scores between adopters and non-adopters on motivational factors (attitude, social support, and self-efficacy)

| | Overall | Adopters | Non-adopters | T-test | P value |
|---|---|---|---|---|---|
| | Mean (SD) | Mean (SD) | Mean (SD) | | |
| **Advantages†** | 0.79 (0.5) | 0.84 (0.5) | 0.73 (0.4) | 3.455 | .001 |
| The referral aid: | | | | | |
| is a good method to support patients in their choices about EBSCIs | 0.99 (0.6) | 1.05 (0.7) | 0.91 (0.5) | 2.092 | .004 |
| is easy to apply in daily practice | 0.93 (0.6) | 0.93 (0.6) | 0.91 (0.6) | 2.680 | .009 |
| helps me to better bring smoking cessation to the attention of smoking patients | 0.30 (0.7) | 0.41 (0.7) | 0.15 (0.7) | 2.993 | .004 |
| helps patients to make a good choice about how they want to quit smoking | 0.95 (0.6) | 0.96 (0.6) | 0.95 (0.5) | 1.982 | .051 |
| **Disadvantages †** | -0.55 (0.6) | -0.57 (0.7) | -0.53 (0.5) | 3.556 | .001 |
| The referral aid: | | | | | |
| does not improve the quality of smoking cessation information in general practice | -0.22 (0.9) | -0.30 (0.9) | -0.16 (1.0) | 0.485 | .006 |
| Does not help patients to make a good choice about quitting smoking | -0.39 (0.8) | -0.46 (0.8) | -0.34 (0.8) | 3.552 | .001 |
| Increase the risk that the patient will no longer wants to quit smoking with my help | -0.68 (0.8) | -0.70 (0.9) | -0.67 (0.8) | 2.577 | .012 |
| Is difficult to apply | -0.90 (0.8) | -0.95 (1.0) | -0.83 (0.6) | 2.559 | .012 |
| **Social support‡** | 3.97 (0.7) | 4.27 (0.7) | 3.7 (0.6) | 3.809 | .000 |
| From the GP (or fellow GPs) | 3.78 (0.9) | 4.14 (0.9) | 3.5 (0.8) | 3.589 | .001 |
| From the PN (or fellow PNs) | 4.26 (0.9) | 4.65 (0.8) | 4.0 (0.9) | 3.701 | .000 |
| From the practice assistant (or fellow practice assistants) | 3.94 (0.9) | 4.14 (0.9) | 3.8 (0.9) | 1.707 | .092 |
| From the care group to which the practice is affiliated | 3.91 (0.9) | 4.16 (0.9) | 3.7 (0.9) | 2.244 | .028 |
| **Self-efficacy§** | 3.07 (0.5) | 3.24 (0.5) | 2.87 (0.5) | 3.33 | .001 |
| I find it difficult to use the RA when… | | | | | |
| If I am very busy | 3.24 (0.8) | 3.49 (0.7) | 3.04 (0.8) | 2.757 | .007 |
| If the patient is not motivated to stop smoking | 2.82 (0.8) | 3.05 (0.9) | 2.65 (0.8) | 2.254 | .027 |
| If the patient is poorly educated | 2.92 (0.9) | 3.11 (0.9) | 2.77 (0.9) | 1.728 | .088 |
| If I think that this means that you can no longer guide the patient yourself in quitting smoking? | 3.14 (0.8) | 3.30 (0.7) | 3.02 (0.8) | 1.685 | .096 |

† -2 = completely disagree; 2 = completely agree
‡ 1 = much discouragement; 5 = much support
§ 1 = very difficult; 5 = very easy

**Table 3.** significant differences in mean scores between adopters and non-adopters on perceived skills, barriers, and appreciation

| | Overall | Adopters | Non-adopters | T-test | P |
|---|---|---|---|---|---|
| | Mean (SD) | Mean (SD) | Mean (SD) | | |
| **Perceived skills†** | 3.87 (0.4) | 4.03 (0.4) | 3.74 (0.3) | 3.524 | .001 |
| **Step 1***:* Identify a patient as a smoker who is motivated to quit smoking | 3.88 (0.6) | 4.00 (0.6) | 3.79 (0.6) | 1.586 | .117 |
| **Step 2:** Explain smoking cessation methods using the referral aid | 3.92 (0.5) | 4.08 (0.5) | 3.79 (0.5) | 2.651 | .010 |
| **Step 3:** Provide an explanation of the reimbursement for external EBSCIs | 3.69 (0.7) | 3.89 (0.7) | 3.54 (0.7) | 2.264 | .026 |
| **Step 4:** Refer the patient to an appropriate EBSCI with the help of the referral aid | 3.81 (0.6) | 4.00 (0.7) | 3.67 (0.6) | 2.429 | .017 |
| **Step 5:** Contact the patient again after a few weeks to follow-up | 4.02 (0.6) | 4.16 (0.5) | 3.92 (0.6) | 2.057 | .043 |
| **Perceived barriers (scale)‡** | 2.22 (0.5) | 1.94 (0.5) | 2.44 (0.5) | -4.898 | .000 |
| In our practice there are not enough smoking patients to use the referral aid meaningfully. | 2.00 (0.7) | 1.73 (0.5) | 2.21 (0.7) | -3.567 | .001 |
| In our practice there is too little time to use the referral aid on smoking patients. | 2.28 (0.8) | 2.03 (0.7) | 2.48 (0.8) | -2.808 | .006 |
| We do not have enough staff in our practice to use the referral aid consistently | 2.28 (0.7) | 2.00 (0.7) | 2.50 (0.7) | -3.378 | .001 |
| Patients in our practice have little interest in discussing smoking cessation possibilities. | 2.33 (0.8) | 2.00 (0.5) | 2.58 (0.8) | -3.676 | .000 |
| Perceived barriers (other) | | | | | |
| Many patients in our practice have insufficient command of the Dutch language. | 1.98 (0.9) | 2.03 (0.9) | 1.94 (0.8) | 0.474 | .637 |
| **Appreciation§** | 3.85 (0.6) | 3.97 (0.7) | 3.75 (0.4) | 1.854 | .067 |
| I think the referral aid materials are clear | 3.93 (0.6) | 4.05 (0.7) | 3.83 (0.6) | 1.663 | .100 |
| I think the referral aid materials are understandable | 3.93 (0.6) | 4.05 (0.7) | 3.83 (0.5) | 1.720 | .089 |
| I think the referral aid materials are educational | 3.68 (0.7) | 3.81 (0.8) | 3.58 (0.6) | 1.550 | .125 |
| I grade the referral aid materials with a mark of (0-10) | 8.48 (1.1) | 8.78 (1.3) | 8.25 (0.8) | 2.302 | .024 |

† 1 = Very difficult; 5 = very easy
‡1 = totally disagree; 5 = totally agree
§ 1 = totally disagree; 5 = totally agree

### 3.3 Factors (uniquely) associated with the intention to adopt

Intention to adopt was most strongly positively correlated with perceived advantages (r=.53), self-efficacy (r=.49), social support (r=.47), skills (r=.33), being an ex-smoker (r=.31), years active in occupation (r=.30), working in a solo-practice (r=.21), years active in practice (r=.19) and age (r=.19). Perceived disadvantages (r=-.54), the perception of (many) barriers (r=-.50), being a non-smoker (r=-.32) and working in another type of practice (not solo or group) (r=-23) had a negative correlation with the intention to adopt. The results of a forward linear regression revealed that factors most strongly associated with the intention to adopt were advantages (β=.39), disadvantages (β=-.36), self-efficacy (β=.35), less barriers (β=-.27), working in a solo practice (β=-.23) and age (β=.01). The overall model explained 63% of the variance.

## 4. DISCUSSION

In this study, the factors influencing the PCPs' intention to adopt a new smoking cessation RA were examined using the ICM as a theoretical framework. Although the appreciation in both groups was high (both groups scored the RA materials higher than an 8), most PCPs did not intend to adopt the RA (n = 48, 56.5%). The non-adopters in the sample reported an overall more negative attitude towards the RA (more disadvantages and fewer advantages) than adopters, experienced less social support and a lower self-efficacy, while also experiencing more barriers to adopt and having less perceived skills, factors that all indicated to correlate with the dependent variable of intention.

A positive attitude (perceiving more advantages and fewer disadvantages) towards an innovation is a well-documented factor of adoption both among PNs (32, 254) and other general practice staff (33, 116) or health professionals outside of the general practice setting (115, 117). In our sample, non-adopters were least convinced that the RA would help them to bring the topic of EBSCI usage to the attention of the smoking patient. This result might be because raising such topic is not part of their current routine or because they feel they have already inquired about the smoking status of most of their patients and therefore are unwilling to discuss this subject any further (61). We were unable to confirm this finding based on our outcomes. The most important disadvantage considered in both groups was the perception that the RA would not improve the quality of smoking cessation information or counseling in general practice. Non-adopters were even significantly more convinced of this idea. As PCPs and especially PNs are expected to provide counseling in accordance with the DGSCC (52, 53), in which referral is already one of the steps, perhaps the PCPs do not see the added value of the RA in their counseling, for example because they do not recognize the added value of EBSCIs themselves, or they are already familiar with the different EBSCI options and thus are substantially knowledgeable about what they

can denote. The DGSCC (52, 53) are designed as an overall guideline, and they do not provide specifics on the availability and costs of EBSCIs. Although they do include information on the effectiveness in the form of evidence tables, these tables might be difficult to understand and use in conversation. As the RA was developed as a facilitating tool for communicating this information (e.g., effectiveness and availability, among others) to smoking patients and rated as such in this study (perceived skills: Step 2), we assume that the RA can be of assistance in their daily routine to discuss EBSCIs with smoking patients. PCPs might have been insufficiently aware of this specific value of the RA. Aside from a positive attitude, a stronger intention to change is, according to the ICM (105), characterized by high levels of social support and self-efficacy.

We found that social support influenced the intention to adopt, especially support from the GP or PNs. Findings on the role of social support are equivocal in other studies, as some studies identify an influence (33), whereas others do not, possibly because of mediation by other factors (32, 115-117). An explanation for the inconsistent findings may be the highly independent working environment of Dutch PCPs and PNs. In the Netherlands, approximately 88% of the PCS employ one or more PNs specialized in smoking cessation (the numbers are lower for solo practices) who work an average of three days a week (139). As this case indicates that often only one PN is working per practice, regular communication with peers may be hindered. However, this research did not investigate the form that this support should assume.

Empirical evidence is inconsistent regarding the influence of self-efficacy on adoption, as some studies report no effect of self-efficacy on adoption (115, 117), whereas others have found an effect of high self-efficacy on adoption rate (54, 116, 118, 255, 256). In our sample, non-adopters reported the lowest self-efficacy to counsel smoking patients using the RA in case they were very busy, which was also reported in earlier research in a similar sample (61). As PCPs get only a limited amount of time for counseling, especially for "healthy" smokers (smokers without smoking-related illnesses), a means of increasing the PCPs' self-efficacy is by making sure that the smoking cessation counseling protocol is as easy and efficient as possible, for example by using the Ask-Advise-Refer strategy (242), in which the time-consuming counseling is conducted by another health care professional. This strategy has been proven effective in Dutch cardiac wards (117). Increasing the timeframe that PCPs can spend per patient under full reimbursement may also help PCPs to overcome the time problem. However, our self-efficacy items turned out to have a low-test score reliability according to Cronbach's alpha.

A regression analysis exploring factors explaining the intention to adopt revealed that intention to adopt is explained by perceiving more advantages, fewer disadvantages, more self-efficacy, less barriers, more often working in a solo practice and, at only a small rate, a higher age. As also found in previous research, the influence of the predisposing factors probably did not influence the intention to adopt directly when motivational factors were

considered (115). The overall model ultimately explained 63% of the variation in the intention to adopt between adopters and non-adopters, which is in line with comparable studies in other target groups (i.e., cardiac nurses, midwives (33, 117). Nonetheless, these results also reveal that a significant proportion of the variance is left unexplained, indicating that other factors are relevant as well, such as occupation (could not be explored in our study because of a low amount of GPs in our sample) or time spent working after following a smoking-cessation counseling training (possibly related to age and time spent working in occupation), which have been found to be associated with adoption in previous studies (32, 114).. It is suggested to identify them, e.g., by conducting qualitative research, as well as performing a longitudinal study to identify predictor of adoption.

**4.1 Limitations**

The added value of this study is the examination of the willingness of PCPs to refer patients outside the PCS rather than solely focusing on smoking cessation counseling administered inside the PCS as also recommended by the DGSCC. However, this study had some limitations. First, as we used a cross-sectional design (one point in time, one measurement per respondent), we cannot draw causal conclusions. Furthermore, we experienced a low response rate that resulted in a low sample size for the complete model testing. However, due to the explorative nature of this study and the strong evidence of using the I-Change model as a basis for explaining the intention to adoption as also seen in other studies (54, 114-118), we decided to test the full model. Second, the sample of potentially more motivated participants selected from the population of Dutch PCPs who were willing to participate in this study and are expected to have seen the RA materials may constitute a limitation. Therefore, the results may not be generalizable to PNs and PCS in general. This is also reinforced by the small number of GPs, which prevented us from exploring the differences between different groups of professionals, thereby also limiting the homogeneity of our sample. Furthermore, as only Dutch PCPs were included in the sample, the results may only be relevant in the Netherlands. Finally, as this study used self-reported data, social desirability might have influenced the PCPs' answers, for example resulting in a higher intention to adopt.

**4.2 Recommendations for future adoption**

To make the RA eligible for widespread adoption, it needs to be enclosed with motivational-enhancing communication to establish a more positive attitude towards the tool. A more positive attitude can be achieved by emphasizing the benefits of the referral tool (e.g., convincing the PCPs of the usefulness of the referral tool in helping smoking patients to choose an EBSCI) when introducing the referral tool to potential users to convince potential adopters of the RA's added value. The prerequisite is that both the RA has added value and that the PCP and the patients alike recognize the added value of the RA compared to usual

care. The proven effectiveness of the RA seems to be necessary in this case to facilitate its adoption and implementation. A means of increasing the added value of the RA is, for example, conducting additional research in the form of co-creation. Although the materials of the RA were created through co-creation sessions with PCPs, a second round of co-creation may be desirable. This round should then specifically focus on further developing the RA in a way that it can be more easily adopted into the PCS.

An approach to the facilitation of RA adoption is through the structural dissemination of the RA via existing sources such as relevant national training programs focused on smoking cessation counseling for the PCS, such as the one provided by the Dutch Quit Smoking Quality Register (kwaliteitsregister stoppen-met-roken, www.kwaliteitsregisterstopmetroken.nl). The quality registry lists qualified PCPs who are specially trained and experienced in providing intensive evidence-based counseling. To be listed in the registry, a training certificate must be obtained. Although the use of EBSCIs is already part of this training, the RA can help to increase (1) the awareness about EBSCIs, (2) the attitude towards referring to EBSCIs, (3) perceived social support among colleague PCPs also referring to EBSCIs according to the RA, and (4) self-efficacy by learning how to best implement the RA. The extent to which the RA already fits within this training or what is needed to implement it can be examined in the previously suggested second co-creation round.

Implementing the RA into the PCP quality training could also aid PCPs in discussing EBSCIs or smoking cessation in general with patients who are not motivated to quit, which is a known barrier in smoking cessation counseling (Blumenthal, 2007) and the most reported barrier in the current study. In the RA, we have endeavored to address the issue of motivating smokers who are unwilling to quit smoking by including one page of information describing the elements of motivational interviewing in our materials (e.g., how to motivate an unmotivated smoker to talk about smoking cessation), a technique that has proven to be effective when talking to non-motivated patients (257). As motivational interviewing is also part of the PCP quality training, it could aid the PCPs' technique in discussing the use of EBSCIs during a smoking cessation attempt. Improving the PCPs' technique might also positively influence their perceived self-efficacy and skillset.

Another well-known and often reported barrier that was also noted in this study is a lack of time to provide more intensive counseling. This barrier fits well with the aim of the RA to reduce active counseling time by the PCP by referring patients to another specialist or EBSCI. Solutions to facilitate the RA usage include increasing the reimbursed time for smoking cessation counseling provided by PCPs, providing additional training to increase efficiency without compromising effectiveness (31, 63, 118, 258), and entrusting intensive counseling to specialized smoking cessation coaches with expertise in addiction care. Providing additional training could also help to strengthen the self-efficacy and perceived skills of non-adopters.

## 5. CONCLUSION

This study examined the factors underlying the PCPs' intention to adopt an RA by comparing potential adopters and non-adopters. Although appreciation in both groups was high (both groups scored the RA materials higher than an 8), most PCPs did not intend to adopt the RA. A regression analysis exploring the factors associated with the intention to adopt revealed that non-adopters perceived fewer advantages, showed lower self-efficacy, experienced less social support, and perceived more disadvantages. Recommendations for future adoption include improving the tool itself through a second round of co-creation focusing on the adoptability of the RA in practice. A second recommendation relates to communicating the added value of referring to EBSCIS and integrating the RA use in smoking cessation training for PCPs. This approach may help to improve the attitude, social support, self-efficacy, and perceived skills in terms of RA usage among PCPs.

# PART TWO

# Future applications and possibilities

# CHAPTER 6

## Decision aids to facilitate decision making around behavior change in the field of health promotion: A scoping review

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## ABSTRACT

**Objective:** To broadly synthesize literature regarding decision aids (DAs) supporting decision making about diet, physical activity, sleeping, and substance use a scoping review was performed.

**Methods:** Multiple sources were used: (1 Scientific literature searches, (2 excluded references from a Cochrane review regarding DAs for treatments and screenings, and (3 results from additional searches. Interventions had to (1 support informed decision making and (2 provide information and help to choose between at least two options. Two researchers screened titles and abstracts. Relevant information was extracted descriptively.

**Results:** Thirty-five scientific articles and four DAs (grey literature) were included. Results were heterogeneous. Twenty-nine (94%) studies described substance use DAs. All DAs offered information and value and/or preference clarification. Many other elements were included (e.g., goal-setting). DA's effects were mixed. Few studies used standardized measures, e.g., decisional conflict (n=4, 13%). Some positive behavioral effects were reported: e.g., smoking abstinence (n=1).

**Conclusions:** This research shows only some positive behavioral effects of DAs. However, studies reported heterogeneous results/outcomes, impeding knowledge synthesis. Areas of improvement were identified, e.g., establishing which intervention elements are effective regarding health behavior decision making.

**Practice Implications:** DAs can potentially be beneficial in supporting people to change health behaviors – especially regarding smoking.

## 1. INTRODUCTION

Noncommunicable diseases continue to be the leading cause of deaths worldwide, inflicting heavy economic burden (259). These diseases' main modifiable risk factors (i.e., blood pressure, blood glucose, cholesterol, and weight) are heavily influenced by individual health behaviors, e.g., tobacco use, physical activity (PA), diet, alcohol use and sleep (duration) (260-263). The occurrence of noncommunicable diseases can therefore be greatly reduced by changing these preventive health-related behaviors (for the sake of readability, we will use this term when referring to tobacco use, PA, diet, alcohol use, and sleep (duration) together).

In all these areas people face decision-making situations, such as deciding to check how well one is meeting behavioral recommendations or deciding whether or not to engage in actions to change an unhealthy behavior. In addition to these decisions, people are confronted with decisions between different possible actions to change their behavior, e.g., people wishing to stop smoking can choose between several effective cessation aids (66, 71, 72, 264, 265).

When multiple options exist and persons need to identify their own values (i.e., how (un)desirable certain options' *characteristics* are (266)) and preferences (i.e., how (un) desirable certain *options themselves* are taking values into account (266)), decisions are referred to as "preference-sensitive" (127). This type of decision requires that people weigh the benefits and harms of each option on basis of their own values and preferences, since no option is objectively better than others (127). In practice, it requires lay persons to gather available evidence, evaluate its quality and incorporate this information to assess which options fit their values and preferences best – tasks which can be difficult (128).

People facing such preference-sensitive decisions about preventive health-related behaviors may profit from support in their decision-making process, for instance by using decision aids (DAs). DAs are typically used to inform users about available options and their respective characteristics (e.g., effect, time investment and availability) in a balanced manner and help users to choose options that are value- and preference-concordant (127, 267), in other words they help users to make informed decisions (268). DAs structure the decision-making process with the help of value clarification methods (VCMs, previously also referred to as value clarification exercises or VCEs) (129) – which can be implicit (i.e., not including overt activity) or explicit (i.e., including overt activity) (269). Such DAs, when applied to treatment or screening decisions (e.g., decisions about cancer treatment options), have shown to have a positive impact on knowledge, accuracy of risk perception, values-concordant choices, decisional conflict, feelings of being undecided, costs and the number of people making a decision (127). However, it is unclear whether this promising approach to decision support can also help individuals make informed decisions about preventive health-related behaviors.

The most comprehensive knowledge synthesis in the field of DAs excluded studies conducted around DAs focusing on lifestyle (127). However, a systematic review by Moyo et al. (270) has shown that DAs could be a promising approach to smoking cessation, as have individual studies (e.g., (91)). Currently, there is a lack of concrete knowledge of DAs in the broader area of preventive health-related behaviors. To the best of our knowledge, no knowledge synthesis of any kind has been carried out to fill this knowledge gap. We therefore do not know for which preventive health-related behaviors DAs actually exist. In the recent past, studies have been carried out to examine intervention elements (271) of DAs in general and the theoretical basis (272) of treatment and screening DAs in more detail. Effects of DAs focused on treatment and screening decisions are also routinely synthesized in the aforementioned comprehensive knowledge synthesis in the form of a Cochrane review (127) and at least one systematic review has investigated DAs cost-effectiveness in general (273). However, all of this information is not available regarding DAs aimed at making decisions about changing preventive health-related behaviors *specifically*.

Consequently, our aim was to broadly synthesize existing literature in the form of a scoping review by reviewing information regarding DAs supporting informed decision making about these behaviors, focusing on their characteristics, intervention elements, theoretical foundations and (cost-)effectiveness. The synthesized knowledge will be of value to guide future research directions, but also to inform (clinical) practice and to better understand the usefulness of DAs that focus on preventive health-related behavior change.

## 2. METHODS

The methodological framework developed by Arksey & O'Malley (274), the Joanna Briggs Institute Reviewers' Manual (275) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) (276) guided the study protocol – which can be found on the Open Science Framework (https://osf.io/9xkbv/) (277). However, one change was made: We decided to gather descriptive data instead of quantitative data as the heterogeneity of the results hindered us to conduct quantitative analyses. This made it impossible to calculate Cohen's kappa (however, other measures were taken to ensure reliability, see *2.2 Study and DA selection*). Consequently, the data are therefore presented descriptively in text and/or tabular form. The completed PRISMA-ScR checklist can be found in *Appendix A*.

### 2.1 Information sources

Multiple sources were used to gather data: (1 Scientific literature search results, (2 the excluded publications from the Cochrane review on DAs for people facing health treatment

or screening decisions (127) (mentioned in the introduction) and (3 results from additional searches, such as a literature search on Google Scholar and a grey literature search on the Ottawa Hospital Research Institute Patient Decision Aid inventory (DALI) (278).

### 2.1.1 Scientific literature searches

Systematic literature searches were conducted in three relevant databases (i.e., PubMed, PsycINFO, and CINAHL) with search strings related to the aforementioned behaviors combined with "decision aid" (for the full overview see tables B.1 and B.2 in Appendix B) in October 2018. Terms were included to exclude papers that focus on policy decision making as the focus of this scoping review was on individual decision making. Searches were restricted to publications pertaining to humans (again, due to the focus on individual human decision making) between January 2008 and October 2018 (to synthesize the most recent literature). Search strategies were specified to each database and discussed with a scientific information specialist.

### 2.1.2 Excluded publications from the Cochrane review

As noted in the introduction, the most comprehensive knowledge synthesis in the field of DAs (the systematic review by Stacey et al. (127)) excluded articles describing DAs focusing on lifestyle – hence, those which were of interest for this scoping review. Therefore, all of those excluded publications were retrieved.

### 2.1.3 Additional searches

Using Google Scholar, we applied a systematic search (see *table B.3* in *Appendix B* for the search strings). Publications within the first 50 hits were screened for each search string. Again, this search was limited to the last 10 years (January 2008 and October 2018). We also created a Google Scholar Alert to inform us of any other relevant publications. Subsequently, we searched through the DALI (278) using all the search terms described above.

Finally, we tried to identify any DAs (in development) that were missed. For this purpose additional strategies were: (1 Cross-referencing included articles and articles *only* selected for full text screening (see *2.2 Study and DA selection*, e.g., (270)), (2 checking the publications from first authors of included articles, (3 using Google Scholar's "related articles"-function and (4 using our existing professional network (e.g., by making use of newsletters of professional associations) and contacting authors of known DAs in development or with currently unpublished findings.

## 2.2 Article and DA selection

Retrieved titles and abstracts were screened by TG and DZ by using the following inclusion criteria: Articles had to describe interventions that (1 supported informed decision making

in relation to preventive health-related behaviors and (2 provided information about the decision at hand and helped to choose between at least two options (e.g., by including VCMs) (279, 280). Articles describing (clinical) treatment DAs were excluded. Inconsistencies between the two reviewers were resolved by discussion. If an agreement could not be reached, CH helped to come to a conclusion. The selected full articles were assessed by DZ and TG, after which TG extracted all relevant information descriptively which was charted within an Excel spreadsheet developed a priori. After completion of the data extraction by TG, DZ reviewed 10% of the articles to ensure reliability. Inconsistencies were discussed between TG and DZ. The same procedure was applied to the DAs not found in scientific literature (i.e., grey literature), except for a change in author responsibilities, i.e., DZ initially abstracting the data and TG reviewing 10%. The charting of the information was based on the Cochrane review on treatment and screening DAs (see *Appendix C)* (127). Authors of the included articles were not contacted to clarify or add information.

## 3. RESULTS

### 3.1 Scientific literature

#### *3.1.1 Descriptives and study characteristics*

Through this scoping review 35 articles (281-315) were identified, including four study protocols (289, 296, 299, 302). It was not possible to determine the exact number of DAs described in the 35 articles due to a lack of clear identification of DAs by name or other distinguishing characteristic in the majority of the articles. Therefore, the units of analysis for this scoping review were individual studies (not DAs) with the exception of protocol papers which were analyzed together with their associated effect papers. More than half of the studies were of American origin (n=16, 52%) (282, 289, 294-298, 304-309, 312-315). The main focus was on substance use (n=29, 94%) (283-315) with 11 DAs solely focusing on smoking (35%) (302-309, 311-313, 315). All studies described DAs that included both information provision and value clarification or described such DA content without explicitly using the terms. All developed DAs contained a multitude of other intervention elements, such as personal stories (306) or encouragement to set a quit date (302, 303). For an overview of the included articles see *table 1*, for an overview of intervention elements see *table 2*, and for a flow diagram depicting the selection process see *figure 1*.

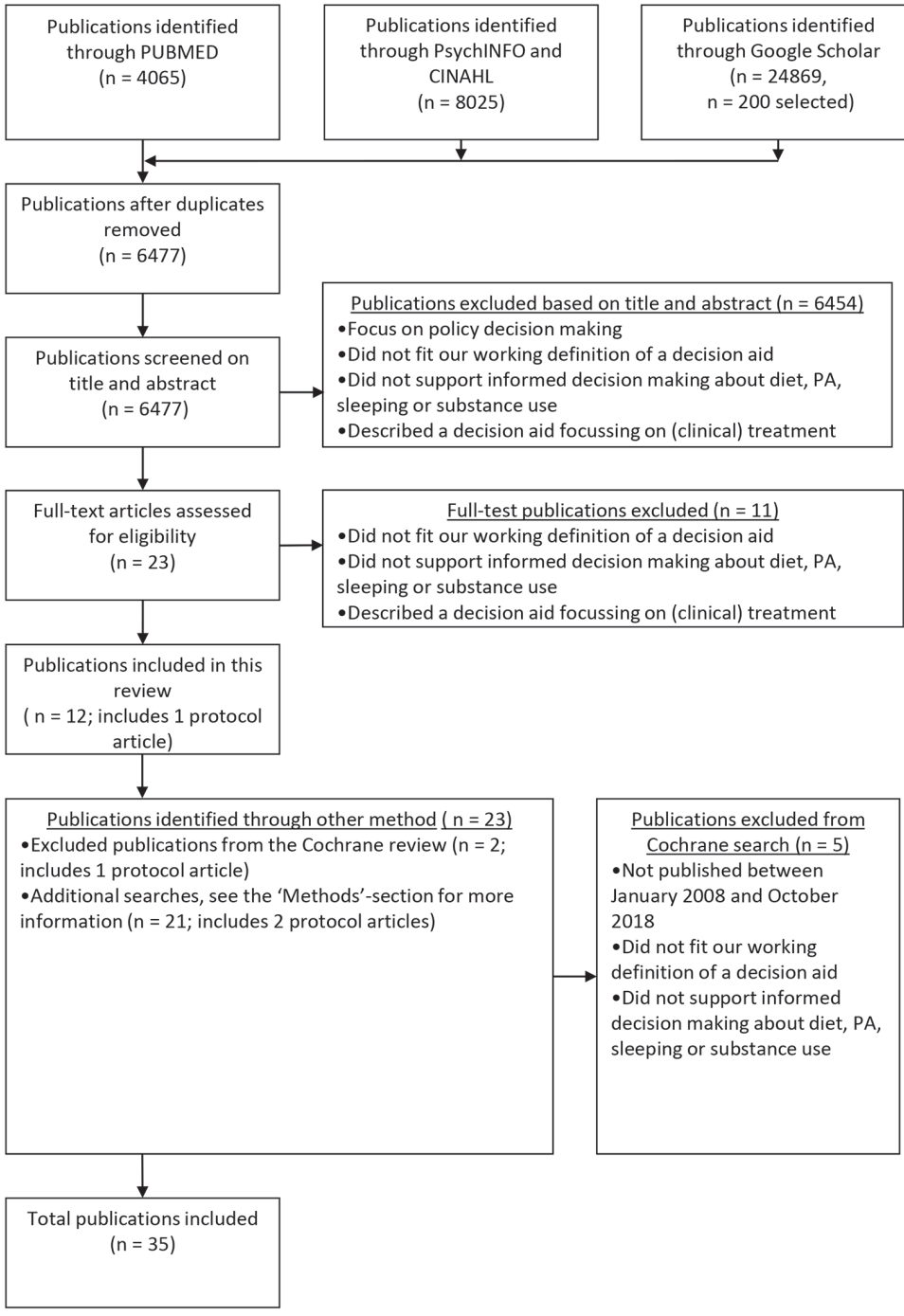


**Figure 1.** Flow diagram.

**Table 1.** Article characteristics

| Article | Study design/ methodology | Study population | Study aims and purposes | Country of origin |
|---|---|---|---|---|
| Cupples et al. (2018) (281) | Mixed method feasibility study | Patients aged ≥18 years with (or at risk of) coronary heart disease (CHD) | To test the feasibility of using a novel, paper-based decision tool, to facilitate shared decision making (SDM, between HP and patient) in the process of initiating behavior change for cardiovascular disease (CVD) prevention among patients with, or at high risk of, CHD in general practice | United Kingdom (UK) |
| Geller et al. (2012) (282) | Not explicitly mentioned, probably pre-post pilot study | Older ethnically diverse population adults visiting two community housing sites in Hawaii | To test the implementation of a decisional balance sheet PA program and fruit and vegetable program, specifically describing the efficiency and effectiveness of the programs adapted for older adults residing in community living homes | United States of America (USA) |
| Hirsch et al. (2010) (283) | Pragmatic cluster randomized controlled trial (CRT) | Patients who had their cholesterol levels measured during a period of 4 weeks | To evaluate the satisfaction level of both patients and physicians in a reciprocal relationship of SDM using a structured tool for cardiovascular prevention contrasted to the results of a control group | Germany |
| Hirsch et al. (2011) (285) | Mixed method evaluation study | German patients that visited their GP and had to make a decision which was covered by the decision aid (DA) | To evaluate the acceptance of SDM with reference to an interactive, transactional, and evidence-based library of DAs by patients and physicians in the primary care context | Germany |
| Hirsch et al. (2011) (284) | Pragmatic CRT | Patients who had their cholesterol levels measured during a period of 4 weeks | To evaluate methodological difficulties in calculating the correspondence between patient and physician satisfaction ratings and to show the relevance for SDM research | Germany |
| Hirsch et al. (2012) (287) | Mixed method evaluation study | German patients that visited their GP and had to make a decision which was covered by the DA | To evaluate associations between the use of an interactive, transactional, and evidence-based library of DAs and communication and decision making in patients and physicians in the primary care context | Germany |
| Hirsch et al. (2012) (286) | Mixed method evaluation study | German patients that visited their GP and had to make a decision which was covered by the DA | To evaluate the uptake of an interactive, transactional, and evidence-based library of DAs and its association to decision making in patients and physicians in the primary care context | Germany |
| Hirsch et al. (2012) (288) | Not explicitly mentioned, analyses of log data | German patients that visited their GP and had to make a decision which was covered by the DA | To examine user interactions of primary-care physicians and their patients with the electronic library of DAs used during consultations, on the basis of log data | Germany |
| Koelewijn-van Loon et al. (2008) (Protocol paper) & Koelewijn-van Loon et al. (2009) (Effect paper) (289, 290) | CRT | Adult patients eligible for cardiovascular risk management who met one or more of the following criteria blood pressure ≥ 140 mm Hg or receiving treatment for high blood pressure; total cholesterol ≥ 6.5 mmol/L or receiving treatment for high cholesterol; smoker aged ≥ 50 years (men) or ≥ 55 years (women); diabetes; a positive family history of cardiovascular disease; and visible obesity (based on the physician's opinion) | To investigated whether a nurse-led intervention in primary care had a positive effect on lifestyle and 10-year cardiovascular risk | Netherlands and the UK |

| | Behavior (general) | Behavior (specific) | DA Delivery | Duration to complete the DA | Sources of funding |
|---|---|---|---|---|---|
| | Dietary behavior & physical activity (PA) | Not described | Paper-based, used during consultation with their general practitioner (GP) | Approximately 15 minutes (whole consultation) | Northern Ireland Chest Heart & Stroke (UK) |
| | Dietary behavior & PA | Increasing PA and/or (daily) fruit and vegetable consumption | Combination of paper-based materials and group discussions, delivered in community housing sites, used in groups (see other included elements for more information) | 30-40 minutes | The National Cancer Institute (USA) |
| | Included multiple cardiovascular prevention strategies,<br>three of which were preventive health-related behaviors (dietary behavior, PA & substance use) | Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Paper-based, used during consultation at the GPs | Not reported | Federal Ministry of Education and Research (Germany) |
| | Modular library that contained multiple DAs: The DA for cardiovascular prevention was the only one that focused on preventive health-related behaviors, it included dietary behavior, PA & substance use | Ambiguous, but in all likelihood the same as in Krones et al. (292): Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Digital-based, used during consultation at the GP | Not reported | Federal Ministry of Education and Research (Germany) |
| | Included multiple cardiovascular prevention strategies,<br>three of which were preventive health-related behaviors (dietary behavior, PA & substance use) | Ambiguous, but in all likelihood the same as in Krones et al.(292): Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Ambiguous, but in all likelihood paper-based, used during consultation at the GPs | Not reported | Federal Ministry of Education and Research (Germany) |
| | Modular library that contained multiple DAs: The DA for cardiovascular prevention was the only one that focused on preventive health-related behaviors, it included dietary behavior, PA & substance use | Ambiguous, but in all likelihood the same as in Krones et al. (292): Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Digital-based, used during consultation at the GPs | Not reported | Federal Ministry of Education and Research (Germany) |
| | Modular library that contained multiple DAs: The DA for cardiovascular prevention is the only one that focused on preventive health-related behaviors, it included dietary behavior, PA & substance use | Ambiguous, but in all likelihood the same as in Krones et al. (292): Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes), smoking (cessation) | Digital-based, used during consultation at the GPs | Approximately 8 minutes on average | Federal Ministry of Education and Research (Germany) |
| | Modular library that contained multiple DAs: The DA for cardiovascular prevention was the only one that focused on preventive health-related behaviors, it included dietary behavior, PA & substance use | Ambiguous, but in all likelihood the same as in Krones et al. (292): Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Digital-based, used during consultation at the GPs | Approximately 8 minutes on average | Federal Ministry of Education and Research (Germany) |
| | Substance use, dietary behavior & PA | Smoking, alcohol use, saturated fat intake, fruit, and vegetable consumptions & PA | Paper-based, delivered during a primary care consultation, had to be read at home (between two consultations) | Not reported (for the DA alone) | Netherlands Organisation for Health Research and Development (ZonMw, Netherlands) and Maastricht University (Netherlands) |

**Table 1.** Continued

| Article | Study design/ methodology | Study population | Study aims and purposes | Country of origin |
|---|---|---|---|---|
| Koelewijn-van Loon et al. (2010) (291) | CRT | Adult patients eligible for cardiovascular risk management who met one or more of the following criteria blood pressure ≥ 140 mm Hg or receiving treatment for high blood pressure; total cholesterol ≥ 6.5 mmol/L or receiving treatment for high cholesterol; smoker aged ≥ 50 years (men) or ≥ 55 years (women); diabetes; a positive family history of cardiovascular disease; and visible obesity (based on the physician's opinion) | To investigate the short-term effect of their nurse-led intervention on patients' risk perception and lifestyle, in comparison with usual nurse-led care | Netherlands and the UK |
| Krones et al. (2008) (292) | Pragmatic CRT | Patients who had their cholesterol levels measured during a period of 4 weeks | To evaluate the effectiveness of the DA as judged by patients | Germany and Austria |
| Krones et al. (2010) (293) | Pragmatic CRT | Patients in whom discussion of preventive measures seemed indicated | To assess the feasibility and outcome of measuring the theory of planned behavior (TPB) in patients receiving routine counselling versus counselling with a DA during primary care consultation on cardiovascular risk prevention | Germany and Austria |
| Sheridan et al. (2013) (Protocol paper) & Keyserling et al. (2014) (Effect paper) (296, 298) | Comparative effectiveness trial | Patients at participating practices (seen for an office visit within the past 2 years), age 35–79, and at high risk for CHD (angina, MI, or CHD death) defined by a Framingham risk score of ≥10% or known CVD | To assess the effectiveness, acceptability, and cost-effectiveness of a combined lifestyle and medication intervention to reduce CHD risk offered in counselor-delivered and web-based formats | USA and Singapore |
| Tinsel et al. (2017) (Protocol paper) & Tinsel et al. (2018) (effect paper) (299, 300) | Two-arm, randomized, controlled pilot study | Patients with at least one cardiovascular risk factor (hypertension, hypercholesteremia, diabetes, arteriosclerosis, smoking, obesity, high stress level or drug prescription against hypertension, high cholesterol) | To test the intervention regarding its usability, acceptance, and potential effects in primary care and to test the feasibility of the randomized study design | Germany |
| Van Steenkiste et al. (2008) (301) | Cross-sectional study | Patients (aged 40–75 years) without established CVD who were at high, or at potentially high-cardiovascular risk | To assess patients' responsiveness to a decision support tool for primary prevention of CVDs | Netherlands |
| BinDhim et al. (2014) (Protocol paper) & BinDhim etl al. (2018) (Effect paper) (302, 303) | Automated, double-blind randomized controlled trial (RCT) | Self-selected adult (≥ 18 years old) daily smokers from the USA, Australia, Singapore, and the UK | To test the efficacy of an interactive smoking cessation DA app compared with a smoking cessation static information app on quit rates | Saudi Arabia and Australia |
| Brunette et al. (2011) (304) | Quasi experiment | Adult smokers with severe mental illnesses who were receiving supported housing and comprehensive psychiatric services at two settings within a large, urban, psychosocial rehabilitation center | To test the effectiveness of the first version of their motivational tool | USA |

| | Behavior (general) | Behavior (specific) | DA Delivery | Duration to complete the DA | Sources of funding |
|---|---|---|---|---|---|
| | Substance use, dietary behavior & PA | Smoking, alcohol use, saturated fat intake, fruit, and vegetable consumptions & PA | Paper-based, delivered during a primary care consultation, had to be read at home (between two consultations) | Not reported | Netherlands Organisation for Health Research and Development (ZonMw , Netherlands) and Maastricht University (Netherlands) |
| | Included multiple cardiovascular prevention strategies, three of which were preventive health-related behaviors (dietary behavior, PA & substance use) | Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Ambiguous, but in all likelihood paper-based, used during consultation at the GPs | Not reported | Federal Ministry of Education and Research (Germany) |
| | Included multiple cardiovascular prevention strategies, three of which were preventive health-related behaviors (dietary behavior, PA & substance use) | Ambiguous, but in all likelihood the same as in Krones et al.(292): Eating fish 2x per week (or Omega-3 fatty acids), exercise 2-3x per week > 30 minutes, smoking (cessation) | Ambiguous, but in all likelihood paper-based, used during consultation at the GPs | Not reported | Ambiguous, but in all likelihood the same as in Krones et al. (292): Federal Ministry of Education and Research (Germany) |
| | Included multiple cardiovascular prevention strategies, three of which were preventive health-related behaviors (dietary behavior, PA & substance use) | Changing diet (e.g., eating polyunsaturated fats rather than reducing total fat content), increasing PA, smoking (cessation) | Digital-based, used with the assistance of a health counselor | Not reported | U.S. Centers for Disease Control and Prevention (USA) and National Institutes of Health (USA) |
| | Included multiple cardiovascular prevention strategies, three of which were preventive health-related behaviors (PA, dietary behavior, substance use, sleep-related behaviors) | Ambiguous, but in all likelihood smoking, PA, alcohol use, changing diet and changing sleeping behavior | Paper-based, received at the GP | Not reported | German Heart Foundation (Germany) |
| | Included multiple cardiovascular prevention strategies, probably three of which were preventive health-related behaviors (dietary behavior, PA & substance use) | Ambiguous, but in all likelihood smoking, PA, alcohol use and changing diet | Paper-based, was presented during a consultation at the GP, participants were asked to complete it at home | 22 minutes (SD 12 minutes) | Ambiguous, but in all likelihood The Netherlands Organization for Health Research and Development (ZonMw, Netherlands) (316) |
| | Substance use | Smoking (cessation) | App-based, freely available | Not reported | Ministry of Education (Saudi Arabia) |
| | Substance use | Smoking (cessation) | Digital- and web-based | 30-90 minutes | The West Family Foundation (USA) and the Segal Foundation (ambiguous, but in all likelihood the USA) |

**Table 1.** Continued

| Article | Study design/ methodology | Study population | Study aims and purposes | Country of origin |
|---|---|---|---|---|
| Brunette et al. (2013) (305) | RCT | Daily smokers with a mood or psychotic disorder with persisting functional disability, but without other current substance dependence | To assess whether a single session of a computerized motivational decision support system with carbon monoxide and health checklist feedback would lead to higher rates of initiating smoking cessation treatment than a version of the system with health checklist feedback alone (no carbon monoxide feedback) | USA |
| Brunette et al. (2015) (306) | Pre-post pilot study, with a randomly selected control group (for which not all measures were assessed) | Safety net clinic patients between 18–70 years who smoked four cigarettes or more per day | To assess whether this web-based, motivational, decision-support system could engage smokers who were not motivated to use treatment in a primary care 'safety net' clinic that serves disadvantaged people | USA |
| Cupertino et al. (2010) (307) | Pre-test, post-test assessment with no control group | Underserved, low-literacy smokers (46.7% Latinos) | To assess the feasibility and preliminary outcomes of a computerized DA to improve knowledge and utilization of smoking cessation resources among underserved, low-literacy smokers | USA |
| Ferron et al. (2011) (308) | Mixed method usability test | Convenience sample of smokers between the age of 18 and 65 | To test the usability of the intervention | USA |
| Ferron et al. (2012) (309) | Secondary analysis of data from an RCT | Adult smokers with serious mental illness who were receiving care at an urban psychiatric rehabilitation center | To study whether cognitive functioning, clinical characteristics and computer experience predict time spent using a web-based DA and whether these variables predict the main proximal outcome, engagement in smoking cessation treatment, and other quit behaviors | USA |
| Hollen et al. (2013) (310) | Prospective RCT | Adolescents (14-19 years) survivors of childhood cancer who had a history of cancer diagnosed between birth and 12 years but had been disease-free for at least 5 years (no treatment during the past 2 years) | To test a DA for adolescent survivors of childhood cancer that is aimed at difficult decisions related to engaging in substance use risk behaviors | USA |
| Lee et al. (2016) (311) | CRT | Adult (≥ 18 years old) smokers visiting an outpatient clinic of a Department of Family Medicine and a Health Screening Center | To develop a culturally tailored DA for smoking cessation and to evaluate its effect on deciding to use smoking cessation medication | Republic of Korea |
| McDonnell et al. (2014) (312) | Prospective, one-group repeated measures design | Smokers (at least 21 years) motivated to quit that were scheduled for surgery for a suspicious thoracic mass or known cancer, with a household family member that also smoked and was also motivated to quit | To test the feasibility of a multidisciplinary, multicomponent, theory-based DA | USA |

| | Behavior (general) | Behavior (specific) | DA Delivery | Duration to complete the DA | Sources of funding |
|---|---|---|---|---|---|
| | Substance use | Smoking (cessation) | Digital-based, used together with a research assistant | 30-90 minutes | U.S. Department of Education, National Institute on Disability and Rehabilitation Research (USA); the Substance Abuse and Mental Health Services Administration, Center for Mental Health Services and Consumer Affairs Program (USA) and the Bristol-Myers Squibb Foundation (USA) |
| | Substance use | Smoking (cessation) | Digital and web-based, used with a research assistant present | 45-90 minutes | Dartmouth SYNERGY (USA) |
| | Substance use | Smoking (cessation) | Digital-based, delivered in safety-net clinics and community health fairs | Not reported | The Healthcare Foundation of Greater Kansas City (USA) |
| | Substance use | Smoking (cessation) | Digital and web-based, used with a researcher present | 47 minutes (SD=24.6) in the third and final version | The Foundation for Informed Medical Decision Making (USA) |
| | Substance use | Smoking (cessation) | Digital-based, delivered in a clinic office with research staff present | 32.12–190.3 minutes (M=92.27, SD=32.77) | U.S. Department of Education, National Institute on Disability and Rehabilitation Research (USA); the Substance Abuse and Mental Health Services Administration, Center for Mental Health Services and Consumer Affairs Program (USA) and the Bristol-Myers Squibb Foundation (USA) |
| | Substance use | Smoking, alcohol consumption, and illicit drug use | As the DA consistent of multiple components, it was delivered in multiple ways: See other included elements *(table 2)* for more information | Different modules varied in length, from 10 to 60 minutes, the whole intervention involved approximately 7.5 contact hours (including measurements) | National Institute of Nursing Research (USA) |
| | Substance use | Smoking (cessation) | Video-based (presented on a tablet computer), was watched before a consultation at a department of family medicine | 7 minutes | Pfizer (USA) |
| | Substance use | Smoking (cessation) | As the DA consistent of multiple components, it was delivered in multiple ways: See other included elements *(table 2)* for more information | Different modules varied in length, face-to-face visits lasted about 45 minutes, while optional booster sessions lasted less than 15 minutes | The American Cancer Society (USA) |

**Table 1.** Continued

| Article | Study design/ methodology | Study population | Study aims and purposes | Country of origin |
|---|---|---|---|---|
| McDonnell et al. (2016) (313) | Prospective, one-group repeated measures, mixed-method feasibility study | Smokers (at least 21 years) motivated to quit that were scheduled for surgery for a suspicious thoracic mass or known cancer, with a household family member that also smoked and was also motivated to quit | To determine the feasibility and acceptability of a multidisciplinary, theory-based DA, for patients scheduled to undergo thoracic surgery and for their family members who smoke | USA |
| Rhee et al. (2008) (314) | Prospective RCT | Rural adolescents (14-20 years old) with asthma without learning disabilities | To determine the feasibility of the decision-making program for adolescents with asthma and to conduct preliminary testing of the following hypothesis: Adolescents receiving the intervention, framed within the context of engaging in risk behaviors and asthma and its treatment, would report improved quality decision making, reduced risk motivation, and reduced risk behaviors at 2, 4, and 6 months post-intervention compared with the control group and to examine whether intervention effects would vary by gender or race | USA |
| Sheridan et al. (2010) (294) | RCT | Convenience sample of men and women from a registry of participants interested in decision support testing between (≥ 45 years old) who were likely to be at moderate to high risk of heart diseases | To determine whether adding an explicit VCM* to a DA on heart disease prevention improved decision-making outcomes, including decisional conflict, intent for screening, perceived value concordance, and self-efficacy | USA |
| Sheridan et al. (2011) (295) | RCT | Patients between the ages of 40-79 years presenting for routine care with no prior history of cardiovascular disease, diabetes mellitus, or other serious medical condition; and were at moderate or high risk of CHD over 10 years | To test the feasibility of delivering the intervention in clinical practice and the effect of the intervention on important efficacy outcomes | USA |
| Sheridan et al. (2014) (297) | RCT | Patients between the ages of 40-79 years presenting for routine care with no prior history of cardiovascular disease, diabetes mellitus, or other serious medical condition; and were at moderate or high risk of CHD over 10 years | To further understand earlier found effects | USA |
| Warner et al. (2015) (315) | Randomized, two-group pilot study | Smoking patients (≥ 18 years old) scheduled for elective surgery | To develop and pilot test a DA to increase patient involvement in decisions regarding smoking behavior of cigarette smokers scheduled for elective surgery | USA |

**Note.** Articles are sorted thematically, alphabetically, and chronologically. Ambiguous information was not verified with the original authors. *Called a value clarification exercise (VCE) in their article

| | Behavior (general) | Behavior (specific) | DA Delivery | Duration to complete the DA | Sources of funding |
|---|---|---|---|---|---|
| | Substance use | Smoking (cessation) | As the DA consistent of multiple components, it was delivered in multiple ways: See other included elements *(table 2)* for more information | Not reported | The American Cancer Society (USA) and the Oncology Nursing Society Foundation (USA) |
| | Substance use | Smoking, alcohol consumption, and illicit drug use | As the DA consistent of multiple components, it was delivered in multiple ways: See other included elements (*table 2*) for more information | Different modules varied in length, from 10 to 90 minutes | National Institute of Nursing Research (USA) |
| | Included multiple cardiovascular prevention strategies, only one of which was a preventive health-related behavior (substance use) | Smoking (cessation) | Digital and web-based, participants got access to either the DA with or without an explicit VCM* alongside a hypothetical scenario | Without explicit VCM = 5 minutes (range 1 to 12 minutes), with explicit VCM = 11 minutes (range 4 to 21 minutes) | The American Heart Association (USA), the National Heart Lung and Blood Institute (USA), and the National Cancer Institute (USA) |
| | Included multiple cardiovascular prevention strategies, only one preventive health-related behavior (substance use) | Smoking (cessation) | Digital and web-based, used in one university internal medicine practice, before a consultation | 12 minutes (range: 1-45 minutes) | The American Heart Association (USA), the National Heart Lung and Blood Institute (USA), and the National Cancer Institute (USA) |
| | Included multiple cardiovascular prevention strategies,<br>only one of which was a preventive health-related behavior (substance use) | Smoking (cessation) | Digital and web-based, used in one university internal medicine practice, before a consultation | 12 minutes (range: <1-45 minutes) | The American Heart Association (USA), the National Heart Lung and Blood Institute (USA), and the National Cancer Institute (USA) |
| | Substance use | Smoking (cessation) | Paper-based, delivered in an examination room of a preoperative evaluation center by clinicians that regularly staff the center | 5-10 minutes | The National Cancer Institute (USA) |

**Table 2.** Intervention elements included

| Article | Intervention elements | | |
|---|---|---|---|
| | **Information provision** | **Value and/or preference clarification (explicit or implicit)** | **Other** |
| Cupples et al. (2018) (281) | Yes | Yes, explicit | Questions regarding barriers and facilitators, goal setting, problem solving, action planning, practical and emotional social support |
| Geller et al. (2012) (282) | Ambiguous, but in all likelihood yes | Yes, explicit | Group discussions in which participants were encouraged to share personal experiences, participants were also guided through the process of completing the intervention (not specifically described) |
| Hirsch et al. (2010) (283) | Yes | Yes, ambiguous if explicit or implicit | Calculation of individual absolute risk for stroke and/or myocardial infarction, exploration of subjective risk, assessment of individual risk factors, risk comparison to the population with identical sex and age, planning course of action |
| Hirsch et al. (2011) (285) | Yes | Yes, ambiguous if explicit or implicit | Discussion of the individual risk, discussion of treatment options and plan for future actions |
| Hirsch et al. (2011) (284) | Yes | Yes, ambiguous if explicit or implicit | Ambiguous, but in all likelihood the same as in Krones et al. (292): Calculation of individual absolute risk for stroke and/or myocardial infarction, exploration of subjective risk, assessment of individual risk factors, risk comparison to the population with identical sex and age, planning course of action |
| Hirsch et al. (2012) (286) | Yes | Yes, ambiguous if explicit or implicit | Discussion of the individual risk, discussion of treatment options and plan for future actions |
| Hirsch et al. (2012) (287) | Yes | Yes, ambiguous if explicit or implicit | Discussion of the individual risk, discussion of treatment options and plan for future actions |
| Hirsch et al. (2012) (288) | Yes | Yes, ambiguous if explicit or implicit | Discussion of the individual risk, discussion of treatment options and plan for future actions |
| Koelewijn-van Loon et al. (2008) & Koelewijn-van Loon et al. (2009) (289, 290) | Yes | Yes, explicit | The DA was one part of an intervention mix, the other parts being: Risk assessment, graphical risk communication tool, (adapted) motivational interviewing |
| Koelewijn-van Loon et al. (2010) (291) | Yes | Yes, explicit | The DA was one part of an intervention mix, the other parts being: Risk assessment, graphical risk communication tool, (adapted) motivational interviewing |
| Krones et al. (2008) (292) | Yes | Yes, ambiguous if explicit or implicit | Calculation of individual absolute risk for stroke and/or myocardial infarction, exploration of subjective risk, assessment of individual risk factors, risk comparison to the population with identical sex and age, planning course of action |
| Krones et al. (2010) (293) | Yes | Yes, ambiguous if explicit or implicit | Ambiguous, but in all likelihood the same as in Krones et al. (292): Calculation of individual absolute risk for stroke and/or myocardial infarction, exploration of subjective risk, assessment of individual risk factors, risk comparison to the population with identical sex and age, planning course of action |
| Sheridan et al. (2013) (Protocol paper) & Keyserling et al. (2014) (Effect paper) (296, 298) | Yes | Yes, implicit | The DA was one part of an intervention mix and included: Calculation of participants' CDH risk, showing participants how much their CHD risk might be reduced by one or more of the following: Changes in diet, increased PA, smoking cessation, initiation of aspirin (for men only), or initiation or intensification of treatment with statins or hypertension medication; encouragement to choose risk-reducing strategies, the other part being: Either counselor-delivered and web-based intervention sessions that included 4 intensive sessions (each up to 60 min in duration depending on participants' individual pace in the web or counselor-delivered sessions) at monthly intervals, followed by 3 maintenance sessions (each 15–30 minutes in duration) delivered at 2 month intervals, the intensive sessions included content related to self-assessment of lifestyle and barriers, tips to circumvent self-identified barriers, creation of first steps toward self-identified actionable goals, the content of maintenance sessions was tailored according to participants' success in adhering to their chosen risk reducing strategy or strategies, which were assessed at the beginning of the first maintenance visit. Messages focused on the following basic topics: Relapse prevention, problem solving and lessons for long-term maintenance, all participants received ancillary resources including a cookbook, pedometers, and physical activity logs for self-monitoring of exercise and an illustrated community resource guide that specified local resources for healthy eating (e.g., farmers markets) and physical activity (e.g., walking trails) |

**Table 2.** Continued

| Article | Intervention elements | | |
|---|---|---|---|
| | **Information provision** | **Value and/or preference clarification (explicit or implicit)** | **Other** |
| Tinsel et al. (2017) (Protocol paper) & Tinsel et al. (2018) (299, 300) | Yes | Yes, ambiguous if explicit or implicit | The DAs were one part of the intervention, the other parts being: Two printed booklets which contained the DAs but also self-monitoring elements such as protocols; a homepage with further information about cardiovascular risks and diseases and structured consultations by GPs which include risk calculation (at the start and after 4 months); SDM and goal setting; support individual action planning and self-monitoring. The control group received everything except the brochures. |
| Van Steenkiste et al. (2008) (301) | Yes | Yes, implicit | The DA was given to patients at a first consultation after which they could complete it and come back for a second consultation, the DA also included: Risk charts for CVD prevention, case histories, smokers were questioned about their smoking behavior, worksheet to summarize patient's risk assessment, preferences for risk reduction and invitation to participate in the decision-making process on personal cardiovascular risk management plan |
| BinDhim et al. (2014) (Protocol paper) & BinDhim etl al. (2018) (Effect paper) (302, 303) | Yes | Yes, implicit | Intervention group: Compulsory notification (e.g., daily motivational messages), quitting diaries, (visual) quitting benefits tracker; Control group: No other elements |
| Brunette et al. (2011) (304) | Yes | Yes, explicit | (Optional) tutorial on how to use a computer mouse, users could choose to receive more elaborate information, video-recorded narrator who identified as smoker, a smoking assessment (incl. carbon monoxide meter) followed by feedback, video of a smoker that used a nicotine patch during a cessation attempt, printout report that included: Summary of smoking level, individual pros and cons of smoking, treatment interests and a referral to a smoking cessation specialist, sign-up sheet for meeting with smoking cessation specialist |
| Brunette et al. (2013) (305) | Yes | Yes, explicit | Same elements as described in Brunette et al. (304), however only the intervention group received carbon monoxide feedback, the control group received the DA only |
| Brunette et al. (2015) (306) | Yes | Yes, explicit | Culturally diverse patient program guides, five interactive educational modules, video-based patient quit stories, function to evaluate both the financial costs as well as the health impact of smoking, tailoring of information, text-to-speech function, direct access to chosen treatment options at the study side, tailoring for pregnant women (e.g., different information) |
| Cupertino et al. (2010) (307) | Yes | Yes, explicit | Presentation of information in two languages (English and Spanish), bilingual narrator, smoking behaviors query, combination of video and audio, involvement of well-known community members, printed three page tailored printout that included: Summary of reported reason for quitting, level of interest in quitting, treatment preferences, personalized recommendations for behavior change, for participants that were interested in stopping smoking: A cessation plan, for participants that were not interested in stopping smoking: Small changes to stop smoking, prompt to discuss smoking cessation with a health care provider, report and tips for health care providers, fax referral form for a quit line, for participants that were interested in using medication: Provision of nicotine patches or a coupon and prescription for bupropion |
| Ferron et al. (2011) (308) | Ambiguous, but in all likelihood yes | Ambiguous, but in all likelihood yes; ambiguous if explicit or implicit | Ambiguous, but in all likelihood the same elements as the DA mentioned in Brunette et al. (304): (Optional) tutorial on how to use a computer mouse, users could choose to receive more elaborate information, video-recorded narrator who identified as smoker, a smoking assessment (incl. carbon monoxide meter) followed by feedback, video of a smoker that used a nicotine patch during a cessation attempt, printout report that included: Summary of smoking level, individual pros and cons of smoking, treatment interests and a referral to a smoking cessation specialist, sign-up sheet for meeting with smoking cessation specialist |
| Ferron et al. (2012) (309) | Yes | Yes, explicit | Same elements as the DA mentioned in Brunette et al. (304) and Brunette et al. (305), additionally a read-aloud function and the possibility to choose between different models |

**Table 2.** Continued

| Article | Intervention elements | | |
|---|---|---|---|
| | **Information provision** | **Value and/or preference clarification (explicit or implicit)** | **Other** |
| Hollen et al. (2013) (310) | Yes | Yes, explicit | There were five modules on: Decision making (a 17-minute video on decision making in general based on Janis and Mann's conflict model of decision making), smoking (a 11-minute, video on why some teens start smoking and why it is hard to stop), alcohol/drug use (a 10-minute videos about alcohol use), an interactive substance use module (a 30-60 minute interactive practice in how to handle difficult situations with substance use), and a health status module (15-minute discussion with an health professional), they also provided one-on-one counseling sessions, telephone calls for people with a high risk and web-based support |
| Lee et al. (2016) (311) | Yes | Yes, implicit | Introduction to outpatient clinic, proactive smoking cessation counseling and prescription |
| McDonnell et al. (2014) (312) | Yes | Yes, explicit | The DA was one part of the intervention and included: Brief decision-making tutorial (incl. a graphical handout and a CD), the other parts being: Brief smoking cessation counselling by a surgeon or other team member, a smoking cessation program booklet plus four face-to-face sessions and up to six optional booster sessions via the telephone and/or online, stress management mediation CD, and medication management |
| McDonnell et al. (2016) (313) | Yes | Yes, explicit | The DA was one part of the intervention and included: Brief decision-making tutorial (incl. a graphical handout and a CD), the other parts being: Brief smoking cessation counselling by a surgeon or other team member, a smoking cessation program booklet plus four face-to-face sessions and up to six optional booster sessions via the telephone and/or online, stress management mediation CD, and medication management |
| Rhee et al. (2008) (314) | Yes | Yes, ambiguous if explicit or implicit | Brief counseling session guided by Risk Behavior Fact Sheets, digital decision-making module (discussing basic principles of decision making) which depicted 17 decisions using cartoon and real teen actors, digital risk behavior module with information about smoking and alcohol use, intervention boosters which included a repetition of the decision-making module and a workbook to provide reinforcement and an opportunity to apply information in a real life situation, interactive CD-ROM booster to practice substance use decisions, telephone follow-up interviews to assess and ensure compliance |
| Sheridan et al. (2010) (294) | Yes | Yes, both (tested the added value of an additional explicit VCM*) | Same elements as in Sheridan et al. (295), except for the tailored adherence messages that were not included in this study |
| Sheridan et al. (2011) (295) | Yes | Yes, explicit | The DA was one part of the intervention and included: Calculation of patients' overall risk of CHD events in the next 10 years, encouragement to choose risk-reducing strategies, and coaching to communicate their decisions with their physicians for this audio clips about ways to overcome common communication barriers were provided, the other part being: Tailored adherence messages to help patients to circumvent self-identified barriers and gain the resources and skills for adherence |
| Sheridan et al. (2014) (297) | Yes | Yes, explicit | The DA was one part of the intervention and included: Calculation of patients' overall risk of CHD events in the next 10 years, encouragement to choose risk-reducing strategies, and coaching to communicate their decisions with their physicians for this audio clips about ways to overcome common communication barriers were provided and a summary of their DA session to initiate discussion with their provider, the other part being: Tailored adherence messages to help patients to circumvent self-identified barriers and gain the resources and skills for adherence |
| Warner et al. (2015) (315) | Yes | Yes, implicit | Simple graphic illustrating the effects of smoking on the body, and a motivational phrase |

**Note.** Articles are sorted thematically, alphabetically, and chronologically. Ambiguous information was not verified with the original authors. *Called a value clarification exercise (VCE) in their article

### 3.1.2 Theoretical foundations

Twenty-two studies (71%) (281-283, 285, 286, 292-295, 297, 299-306, 309-314) reported using theoretical frameworks, most commonly to identify relevant outcome measures (n=15, 48%) (283, 285, 286, 292-295, 297, 301-305, 309, 310, 314). Janis' and Mann's conflict theory of decision making was used most often (n=6, 19%) (294, 297, 310, 312-314) – however, largely the same researchers were involved. An overview over the theoretical foundations can be seen in *table 3*.

### 3.1.3 Effectiveness and cost-effectiveness of the identified DAs

Most effects where tested in either a cluster (n=7, 23%) (283, 284, 289-291, 311) or a randomized controlled trial (n=8, 26%) (294, 295, 297, 302, 303, 305, 309, 310, 314). In this result section null effects are defined as insignificant findings that reflect neither an increase nor a decrease.

**Table 3.** Use of theories

| **Has a theory been used at all?** | Yes<br>Not reported | n = 22<br>n = 9 |
|---|---|---|
| Specific theories/frameworks used* | Conflict theory of decision making | n = 6 |
| | Social cognitive theory | n = 5 |
| | Transtheoretical model of change | n = 5 |
| | Glyn Elwyn's model of shared decision making | n = 5 |
| | Theory of planned behavior | n = 4 |
| | Self-Determination theory | n = 2 |
| | Ottawa Decision Support Framework (ODSF) | n = 1 |
| | Integrative Theory | n = 1 |
| | Protection Motivation Theory | n = 1 |
| | Hersey-Blanchard Model | n = 1 |
| | Behaviour change wheel | n = 1 |
| | Prospect theory | n = 1 |
| | Expectancy value theory | n = 1 |
| | Health action process approach (HAPA) | n = 1 |
| | Other/model developed by authors for the study | n = 1 |
| Ways theories were used* | Theories' concepts used as outcome measure | n = 15 |
| | To guide content development | n = 14 |
| | Part of the DA | n = 3 |
| | To guide study design | n = 1 |
| | To compare study groups at baseline | n = 1 |

Note. *In some studies, multiple theories have been used for multiple purposes. Therefore, the absolute amount exceeds 31.

*3.1.3.1 Effects on the attributes of the choice made*

In six studies, knowledge (19%) was assessed (292, 297, 300, 303, 305, 315), but only one (297) reported a significant increase in knowledge as compared to baseline measurement. In three studies (10%), null effects were reported regarding knowledge (292, 305, 315). All other studies examined knowledge only as part of another overarching concept (300, 303), e.g., informed choice. Effects on risk perception were examined in two studies (6%) (291, 297), both found an increase in appropriateness of risk perceptions, however in one study the effects disappeared after correction for baseline characteristics (291) and in the other effects were not compared to a control group (297). Value-congruency was tested in four studies (13%) (293, 294, 297, 303). In one of those studies value-congruency was not examined in isolation (303). Sheridan et al. (294) found that adding an explicit VCM (called a VCE in their article) did not increase value-consistency. In one study an increased attitude towards the chosen option (i.e., "actual" value-consistency) was reported that was compared to a control group (293), while in another study positive effects on perceived value-consistency that were not compared to a control group were reported (297). The one article that reported on the measurement of regret reported a significant positive effect (i.e., a decrease in regret) (292).

*3.1.3.2 Effects on the attributes of the decision-making process*

The most commonly investigated attribute was patient-practitioner communication (n=12, 39%) (284-286, 291, 297, 301, 304, 305, 307, 309, 312, 315). However, mixed effects were found: Decrease in communication (n=1) (307), increase in communication (n=2, 6%) (297, 304), increase in satisfaction with the communication (n=1) (291), and null effects (n=1) (315). Other studies mainly reported descriptive characteristics, e.g., that most of the exposed patients were satisfied (285). In four (13%) out of seven (23%) studies in which participation in decision making was investigated positive effects compared to a control group were found (283, 285, 292, 315) (the majority came from similar researchers), in one study null effects were reported (297). Positive effects were found regarding decisional conflict, assessed in four studies (13%) (294, 297, 303, 315); null effects were only reported in one study (294) on the added value of an explicit VCM. Positive effects were both observed compared to a control group (n=2, 6%) (303, 315), and not compared to a control group (n=1) (297). While the proportion of undecided people was reported in six studies (19%) (281, 285-287, 293, 315) (again, the majority came from similar researchers), only in one the effect was tested (293). They found a positive effect compared to a control group (293). No study reported effects on decisional satisfaction.

*3.1.3.3 Effects on behavior*

In 18 (58%) articles an assessment on the impact of the DA on behavior was reported (281, 282, 285, 286, 290, 291, 298, 300, 303-307, 309, 311, 312, 314, 315).

*3.1.3.3.1 Dietary behavior*

In one study in which differences between two study groups were tested, positive effects due to the interventions on fat and vegetable intake were found (290). However, effects on fat and vegetable intake were not replicated in multilevel analyses (290). In another study with a control group (same researchers) null effects for fat, fruit and vegetable consumption were found (291), while in another study negative effects on overall diet were reported (300). In one study mixed effects in terms of fruit and vegetable intake were reported (282) which were not compared to a control group. In this study two different versions of a DA were tested: One targeting PA, the other fruit and vegetable intake (282). Interestingly, only the version targeting PA resulted in an increase in fruit and vegetable consumption, the fruit and vegetable version resulted in a small decrease in fruit and vegetable consumption (282). In another study the same DA was compared alongside counseling or a web-based lifestyle intervention (thus, both study arms received the same DA): Positive effects were found for fat quality, fruit, and vegetable intake (298). One article simply reported that diet changed without further details (281).

*3.1.3.3.2 Physical activity (PA)*

In two of the three studies (6%) (290, 291) comparing effects to a control group no effects on PA were found (same researchers), the one that did (300) was a pilot study that only reported descriptive analyses. Within the study that tested two different versions of the same DA (one for PA, one for fruit and vegetables): Positive effects regarding PA were found in both groups (282). Strikingly, the effects were stronger in the non-PA version. In another study without control group positive effects on weekly PA time and sedentary behavior were found (281), negative effects were found for minutes of PA and daily number of steps (281). The study that compared the effects of the DA alongside counseling or a web-based lifestyle intervention found positive effects for weekly walking time and daily number of steps. However, the effect for weekly walking time was only observed in the counselor group (298).

*3.1.3.3.3 Substance use*

In studies including a control group positive effects on smoking cessation aid uptake (n=3, 10%) (303, 304, 306) and smoking abstinence (n=1) (303) were found, while null effects were found on perioperative smoking behavior (n=1) (315), smoking cessation medication (n=1) (311), smoking abstinence (n=3, 10%) (290, 291, 311) and smoking, alcohol and illicit drug uptake (n=1) (314). Only in one study that included a control group negative effects regarding smoking were found, however positive effects on alcohol consumption were found as well (300). Interestingly, in one study both an effect on smoking cessation aid uptake and abstinence was found, but they researchers did not find that the DA's effect on abstinence was mediated by the quitting method (303). In another study (290) a difference

between intervention and control group was found, however the difference was already present at baseline. In the one study without control group, positive effects were found on smoking cessation aid uptake and number of cigarettes, while negative effects were found on planning of a quit date and talking to health-care providers about smoking cessation (307). Other effects that were found: Adding carbon monoxide feedback to a DA did not make it more effective (n=1) (305), a DA for dyads (patient plus family member) seemed to be more effective for patients' quitting behavior than family members' quitting behavior (n=1) (312) and in the study (298) that compared the effects of the DA alongside counseling or a web-based lifestyle intervention positive effects for smoking were found in both groups.

#### *3.1.3.4 Effects on adherence to the chosen option*

Adherence was assessed in four (13%) studies (281, 295, 303, 315). Three (10%) compared the effects to a control group; one reported null (315), one positive effects (i.e., increased adherence) (295), and one reported that 97.7% adhered to their chosen option regardless of the assigned group (303).

#### *3.1.3.5 Effects on economic impact*

Cost-effectiveness was assessed in one study, however not the cost-effectiveness of the DA itself was tested but rather of a counseling or a web-based intervention used next to the DA (298).

#### 3.1.3.6 Effects on health outcomes

Health status was assessed in five studies (16%) (290, 292, 295, 298, 300), both null (n=3, 10%) (290, 292, 300) and positive effects (n=2, 6%) (295, 298) (both from similar research teams) were found. Quality of life (298) and anxiety (291) were only assessed once, in both cases significant improvements were found. No study reported effects on depression and emotional distress.

### 3.2 Results grey literature

The initial search into the DALI resulted in 10 DAs (dietary behavior n=5 and substance use n=5). Only four DAs were still available online at the time of the search (317-320). All DAs stemmed from the same developer (www.healthwise.org), a nonprofit organization aimed at providing digital health education. All DAs shared a similar design. Theory application was not described.

All DAs made use of information provision and explicit elements to clarify values and preferences. Other elements were personal stories, a knowledge quiz, and a summary. Duration to complete the DAs was not reported.

The DAs were not reported in any scientific publications. No effects were reported. An overview of currently online accessible DAs can be seen in table 4.

**Table 4.** DA characteristics grey literature

| Name | Behavior (general) | Behavior (specially) |
|---|---|---|
| Healthwise: Quitting Smoking: Should I Use Medicine? (317) | Substance use | Smoking (cessation) |
| Healthwise: Obesity: Should I Use a Diet Plan to Lose Weight? (318) | Dietary behavior | Diet |
| Healthwise: Weight Management: Should I Use Over-the-Counter Diet Aids? (319) | Dietary behavior | Use of diet aids |
| Healthwise: Sleep Apnea: Should I Have a Sleep Study? (320) | Sleep-related behaviors | General sleep management |

## 4. DISCUSSION AND CONCLUSION

### 4.1 Discussion

With this scoping review we aimed to synthesize the literature on DAs that focus on preventive health-related behaviors by reviewing available information regarding their characteristics, intervention elements, theoretical foundations and (cost-)effectiveness. We identified 35 scientific papers describing DA development and/or evaluation and four DAs that focus on preventive health-related behaviors in the grey literature. We will focus on three key areas in this discussion: (1 Characteristics and intervention elements of identified DAs, (2 theoretical foundations of the identified DAs, and (3 effectiveness of the identified DAs.

#### *4.1.1 Characteristics and intervention elements of the identified DAs*

Identified DAs focused most often on substance use, primarily smoking. This could be due to the fact that smoking cessation trajectories show similarities with clinical treatment and screening trajectories, which is where the majority of DAs traditionally have been applied (127). For example, one of the options that is regularly named in smoking cessation DAs is pharmacological support (e.g., (303)).

DAs were often combined with additional intervention elements. Therefore, it was difficult to ascertain the impact of the DA independent from these other components, as the additional components often had their basis in behavioral change theories, rather than informed decision making. Consequently, tested outcomes varied widely among studies, limiting the current evidence base for any behavior- or decision-related outcome.

Future studies should examine which intervention elements are effective regarding informed decision making in the area of preventive health-related behaviors. Furthermore, studies should be conducted to disentangle which intervention elements can be deployed to support which processes. To this end, however, consensus should be reached on which outcomes are relevant to be tested in studies investigating DAs that focus on preventive health-related behaviors. This would not only allow different intervention elements to be tested using the same criteria but would also enable developers of DAs that focus on preventive health-related behaviors to develop DAs that are even more rooted in evidence

than current DAs. Ultimately, this could result in a taxonomy as used in behavior change (321) which clearly describes the purpose of most often applied intervention elements. Theoretical work to understand VCMs' effects and how those effects can be accomplished have recently been undertaken (271, 322).

#### *4.1.2 Theoretical foundations of the identified DAs*

Around 70% of the studies reported that they used a theory, most commonly to identify relevant outcome measures. Multiple studies used theories such as the Self-Determination Theory (323) or the Theory of Planned Behavior (112); theories meant to explore motivation or behavior (change). We also found studies that used decision-making—focused theories, such as the Conflict Theory of Decision Making (122), however these are not explicitly designed to support people in changing behavior. Given the dual purpose of DAs that focus on preventive health-related behaviors, insights from multiple theories should be used to develop these DAs.

There are two possible approaches to integrate insights from both areas when developing DAs that focus on preventive health-related behaviors: (1 Developers could flexibly integrate insights from multiple theories on respectively behavioral change and informed decision making as proposed by Peters & Crutzen (324), (2 or attempts could be made to establish an integrative framework that can be applied in multiple (unrelated) DA development projects. The second approach could be particularly helpful for developers that are not familiar with both research fields.

#### *4.1.3 Effectiveness of the identified DAs*

Studies reported positive effects such as uptake of effective smoking cessation aids and smoking abstinence, however interpretation is somewhat difficult as not all studies followed an RCT protocol and as we could not synthesize the effects quantitatively. Also, a formal analysis of the quality of the evidence has not taken place in this scoping review as this form of knowledge synthesis (often) does not include quality assessments in the same form as systematic reviews (276). However, our findings are in line with a systematic review (270) in which it was found that smoking cessation DAs can be effective, but that there was major heterogeneity within studies and DAs. Beneficial effects were also identified regarding PA and nutritional behavior, however, due to the relatively low numbers of studies and the mixed findings found in the included studies, no clear conclusions can be drawn at this time.

Interestingly, the majority of the identified studies failed to report effects on decisional outcomes. Future studies should investigate how DAs that focus on preventive health-related behaviors affect those decisional outcomes as well and how these outcomes relate to behavior (change). Insights from Self-Determination Theory (323), for example, would suggest that the offering of choices (i.e., what DAs do inherently) can support individuals in becoming autonomously motivated towards self-chosen options, which in turn can lead to greater behavioral maintenance (325, 326).

### 4.2 Limitations

A possible limitation was the focus on studies as the units of analysis rather than individual DAs. However, not all studies that referred to similar DAs clearly described how they related to one another, which made it impossible to report results per DA. To minimize the impact of this on our results, we highlighted if studies were conducted by the similar author(s). Another possible limitation would be that we decided to exclude all treatment DAs, including those aimed at preventing secondary diseases or complications (e.g., cardiovascular disease due to diabetes mellitus). However, our working definition of DAs that focus on preventive health-related behaviors has only focused on primary disease prevention and we are convinced that DAs aimed at primary, secondary and tertiary prevention should be explored separately. Hence, the focus on DAs that focus on primary prevention.

### 4.2 Future research directions

Based on the discussion above, we have identified three main areas of interest for further research: (1 Establishing which intervention elements are effective regarding decision making in the domain of preventive health-related behaviors, and for which processes, (2 strengthening the integration between theoretical insights from behavior change and informed decision making, by either adopting a flexible approach or by establishing an integrative framework, and (3 conducting more randomized trials to enable systematic reviews and meta-analyses in order to draw stronger conclusions regarding behavioral and decisional outcomes and how those relate to one another.

### 4.3 Practice Implications

While scoping reviews do not allow for strong conclusions to be drawn (compared to other forms of knowledge syntheses), our results show that DAs can potentially be beneficial in supporting people to change preventive health-related behaviors – especially regarding smoking (particularly when taken together with other evidence (270). As such, DAs might be one potential approach to counteract the rise of noncommunicable diseases. However, further research is needed to substantiate this.

### 4.4 Conclusions

This study was the first attempt to broadly synthesize knowledge regarding DAs aimed at preventive health-related behavioral decisions. Findings regarding the effects on behavior were potentially promising, especially regarding smoking (particularly when taken together with other evidence (270)). However, while certain beneficial effects could be identified, interpretation was hindered by heterogenous reporting. Certain areas of improvement were identified, such as establishing which intervention elements are effective regarding decision making in the domain of preventive health-related behaviors.

# APPENDIX A - PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES EXTENSION FOR SCOPING REVIEWS (PRISMA-SCR) CHECKLIST

**Table A.1.** PRISMA-ScR Checklist

| Section | Item | PRISMA-ScR Checklist item | REPORTED ON PAGE # |
|---|---|---|---|
| Title | | | |
| Title | 1 | Identify the report as a scoping review. | 106/Title page |
| Abstract | | | |
| Structured Summary | 2 | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives. | 107/Abstract |
| Introduction | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach. | 108-109 |
| Objectives | 4 | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | 109 |
| Methods | | | |
| Protocol and Registration | 5 | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | 109 |
| Eligibility criteria | 6 | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale. | 110 |
| Information sources | 7 | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | 109-110 |
| Search | 8 | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated. | 109-110, appendix B |
| Selection of sources of evidence | 9 | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review. | 110-111 |
| Data charting Process | 10 | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 110-111, appendix C |
| Data items | 11 | List and define all variables for which data were sought and any assumptions and simplifications made. | Appendix C |

**Table A.1.** Continued

| Section | Item | PRISMA-ScR Checklist item | REPORTED ON PAGE # |
|---|---|---|---|
| Critical appraisal of individual sources of evidence | 12 | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate). | Not applicable |
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | 109 |
| Results | | | |
| Selection of Sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | Figure 1 |
| Characteristics of sources of Evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | 111-130 |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | Not applicable |
| Results of Individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | 111-130 |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | 111-130 |
| Discussion | | | |
| Summary of Evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | 130-132 |
| Limitations | 20 | Discuss the limitations of the scoping review process. | 132 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | 133 |
| Funding | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | 106/Title page, Table 1 |

## APPENDIX B - SEARCH STRINGS

**Table B.1.** Search Strings for PubMed

| Behavior | Search terms |
|---|---|
| Dietary behavior | ((“Decision Support Techniques”[Mesh] OR “Decision Support Techniques” [tiab] OR “Decision model”[tiab] OR “decision aid*”[tiab]) AND (“Diet”[Mesh] OR “Diet*”[tiab] OR “dietary behavio*”[tiab] OR “Eating”[Mesh] OR “Eating”[tiab] OR “food restriction”[tiab] OR “Weight Loss”[Mesh] OR “Weight Loss”[tiab] OR “Weight Gain”[tiab] OR “Diet, Food, OR Nutrition”[Mesh] OR “food”[tiab] OR “weight reduction plan”[tiab] OR “weight reduction”[tiab])) NOT (“Policy Making”[Mesh] OR “Policy Making”[tiab] OR “Public Policy”[Mesh] OR “Public Policy”[tiab] OR “Health Policy”[tiab]) |
| Physical activity | ((“Decision Support Techniques”[Mesh] OR “decision aid*”[tiab] OR “Decision Support Techniques” [tiab] OR “Decision model”[tiab]) AND (“Exercise”[Mesh] OR “Exercise*”[tiab] OR “Physical Activity”[tiab] OR “movement”[tiab] or “sport*”[tiab] or “active behavio*”[tiab] OR “fitness”[tiab])) NOT (“Policy Making”[Mesh] OR “Policy Making”[tiab] OR “Public Policy”[Mesh] OR “Public Policy”[tiab] OR “Health Policy”[tiab]) |
| Sleep-related behaviors | ((“Decision Support Techniques”[Mesh] OR “decision aid*”[tiab] OR “Decision Support Techniques” [tiab] OR “Decision model”[tiab]) AND (“Sleep”[Mesh] OR “Sleep*”[tiab] OR “Sleep hygiene”[MeSH] OR “Sleep hygiene”[tiab] OR “Sleep habit”[tiab] OR “Rest”[Mesh] OR “Rest*”[tiab])) NOT (“Policy Making”[Mesh] OR “Policy Making”[tiab] OR “Public Policy”[Mesh] OR “Public Policy”[tiab] OR “Health Policy”[tiab]) |
| Substance use | ((“Decision Support Techniques”[Mesh] OR “decision aid*”[tiab] OR “Decision Support Techniques” [tiab] OR “Decision model”[tiab]) AND (“Alcohol Drinking”[Mesh] OR “Alcohol Drinking”[tiab] OR “alcohol*”[tiab] OR “Alcoholism”[Mesh] OR “Ethanol”[MeSH] OR “Ethanol”[tiab] OR “Alcoholic Beverages”[MeSH] OR “Alcoholic Beverages” [tiab] OR “Smoking”[Mesh] OR “Smok*”[tiab] OR “Smoking Cessation”[Mesh] OR “Smoking Cessation”[tiab] OR “Smoking Reduction”[Mesh] OR “Smoking Reduction”[tiab] OR “Tobacco Use Cessation Products”[Mesh] OR “Tobacco Use Cessation Products”[tiab] OR “Smoking Devices”[Mesh] OR “Smoking Devices”[tiab] OR “Tobacco”[Mesh] OR “Tobacco Use”[Mesh] OR “Tobacco Use”[tiab] OR “Tobacco Use Cessation”[Mesh] OR “Tobacco”[tiab] OR “cigarette*”[tiab] OR “e-cigarette*”[tiab] OR “Drug Misuse”[Mesh] OR “Drug*”[tiab] OR “Substance-Related Disorders”[Mesh])) NOT (“Policy Making”[Mesh] OR “Policy Making”[tiab] OR “Public Policy”[Mesh] OR “Public Policy”[tiab] OR “Health Policy”[tiab]) |

**Table B.2.** Search Strings for PsycINFO and CINAHL

| Behavior | Search terms |
|---|---|
| Dietary behavior | (SU Decision Support Systems OR TI "Decision Support Systems" OR AB "Decision Support Systems" OR TI "decision aid*" OR AB "decision aid*" OR TI "Decision Support Technique*" OR AB "Decision Support Technique*" OR TI "Decision model" OR AB "Decision model") AND (SU Diets OR TI "Diet*" OR AB "Diet*" OR SU Eating Behavior OR TI "Eat*" OR AB "Eat*" OR SU Food Intake OR SU Food OR TI "food" OR AB "food" OR SU Nutrition OR SU Weight Control OR SU Weight Gain OR TI "Weight Gain" OR AB "Weight Gain" OR SU Weight Loss OR TI "Weight Loss" OR AB "Weight Loss" OR TI "dietary behavio*" OR AB "dietary behavio*" OR TI "eat*" OR AB "eat*" OR TI "food restriction" OR AB "food restriction" OR TI "weight reduction plan" OR AB "weight reduction plan") NOT (SU Policy Making OR TI "Policy Making" OR AB "Policy Making" OR TI "public policy" OR AB "public policy" OR TI "health policy" OR AB "health policy") |
| Physical activity | (SU Decision Support Systems OR TI "Decision Support Systems" OR AB "Decision Support Systems OR TI "decision aid*" OR AB "decision aid*" OR TI "Decision Support Technique*" OR AB "Decision Support Technique*" OR TI "Decision model" OR AB "Decision model") AND (SU Physical Activity OR SU Physical Fitness OR TI Exercise* OR AB Exercise* OR SU Physical Activity OR TI Physical Activity OR AB Physical Activity OR TI movement OR AB movement OR SU Sports OR TI Sport* OR AB Sport* OR TI active behavio* OR AB active behavio* OR TI fitness OR AB fitness) NOT (SU Policy Making OR TI "Policy Making" OR AB "Policy Making" OR TI "public policy" OR AB "public policy" OR TI "health policy" OR AB "health policy") |
| Sleep-related behaviors | (SU Decision Support Systems OR TIX "Decision Support Systems" OR AB "Decision Support Systems OR TI "decision aid*" OR AB "decision aid*" OR TI "Decision Support Technique*" OR AB "Decision Support Technique*" OR TI "Decision model" OR AB "Decision model") AND (SU Sleep OR TI Sleep* OR AB Sleep* OR TI Rest* OR AB Rest*) NOT (SU Policy Making OR TI "Policy Making" OR AB "Policy Making" OR TI "public policy" OR AB "public policy" OR TI "health policy" OR AB "health policy") |
| Substance use | (SU Decision Support Systems OR TIX "Decision Support Systems" OR AB "Decision Support Systems OR TI "decision aid*" OR AB "decision aid*" OR TI "Decision Support Technique*" OR AB "Decision Support Technique*" OR TI "Decision model" OR AB "Decision model") AND (SU Drinking Behavior OR TI Alcohol* OR AB Alcohol* OR SU Drug Usage OR SU Ethanol OR TI Ethanol OR AB Ethanol OR SU Alcoholic Beverages ORTI Smok* OR AB Smok* OR SU Smoking Cessation OR SU Nicotine OR TI Tobacco* OR AB Tobacco* OR TI Nicotine* OR AB Nicotine* OR SU Drug Withdrawal OR TI Cigarette* OR AB Cigarette* OR TI e-cigarette* OR AB e-cigarette* OR TI drug*OR AB drug* OR TI substance*OR AB substance*) NOT (SU Policy Making OR TI "Policy Making" OR AB "Policy Making" OR TI "public policy" OR AB "public policy" OR TI "health policy" OR AB "health policy") |

**Table B.3.** Search Strings for Google Scholar

| Behavior | Search terms |
|---|---|
| Dietary behavior | (("Decision Support Techniques" OR "Decision model" OR "decision aid*") AND ("Diet*" OR "Eat* OR "food*" OR "Weight*")) -policy |
| Physical activity | (("Decision Support Techniques" OR "Decision model" OR "decision aid*") AND ("Exercise*" OR "Physical Activity" OR "move*" or "sport*" or "active behavio*" OR "fitness")) -policy |
| Sleep-related behaviors | (("Decision Support Techniques" OR "Decision model" OR "decision aid*") AND ("Sleep*" OR "Rest*")) -policy |
| Substance use | (("Decision Support Techniques" OR "Decision model" OR "decision aid*") AND ("alcohol*" OR "Ethanol" OR "Ethanol" OR "Smok*" OR "Tobacco*" OR "cigarette*" OR "e-cigarette*" OR "Drug*" OR "Substance*")) -policy |

## APPENDIX C - EXTRACTED INFORMATION

**Table C.1.** Extracted information

| Questions | Sub questions |
|---|---|
| On which behavior did the DA (under study) focus, both in general (e.g., dietary behavior) and specifically (e.g., weight loss)? | |
| How was the (studied) DA delivered to the user? | |
| How long did it take to complete the DA (under study)? | |
| Of which elements did the DA (under study) consist? | • Did the DA contain information provision elements?<br>• Did the DA contain elements to clarify values and preferences?<br>o Were those elements explicit or implicit?<br>• Which other intervention elements were employed? |
| Was the DA (under study) scientifically published (and was certain necessary information described)? | • If it was, what was/were the:<br>o study design and methodology?<br>o study population?<br>o aims/purposes?<br>o origin/country of origin?<br>o author(s)?<br>o year of publication? |
| How were theories used? | • Specifically:<br>o Has a theory been used at all?<br>o From which field does the theory come?<br>o Which theory has been used specifically and how was it used?<br>o Was there an impact on the outcomes through the use of theory? |
| What were the effects on the attributes of the choice made? | • Specifically, the effects on:<br>o knowledge?<br>o accurate risk perceptions?<br>o value congruency?<br>o regret? |
| What were the effects on the attributes of the decision-making process? | • Specifically, the effects on:<br>o decisional conflict?<br>o proportion undecided?<br>o decisional satisfaction?<br>o patient-practitioner communication, if applicable?<br>o participation in decision making, if applicable? |
| What were the effects on behavior? | • Specifically, the effects on:<br>o (actual) behavior after the choice has been made?<br>o adherence to chosen option (time of adherence)? |
| What were the results regarding economic impact? | • Specifically, the effects on:<br>o costs?<br>o cost effectiveness? |
| What were the effects on health outcomes? | • Specifically, the effects on:<br>o health status?<br>o quality of life?<br>o anxiety?<br>o depression?<br>o emotional distress? |

# CHAPTER 7

## The usability of an online tool to promote the use of evidence-based smoking cessation interventions

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## ABSTRACT

**Introduction:** To increase usage of evidence-based smoking cessation interventions (EBSCIs) among smokers, an online decision aid (DA) was developed. The aims of this study were 1) to conduct a usability evaluation; 2) to conduct a program evaluation and evaluate decisional conflict after using the DA and 3) to determine the possible change in the intention to use EBSCIs before and directly after reviewing the DA.

**Methods:** A cross-sectional study was carried out in September 2020 by recruiting smokers via the internet (N = 497). *T*-tests and chi-square tests were conducted to test the differences between smokers who differed in perceived usability of the DA on the program evaluation and in decisional conflict. The possible changes in intention to use EBSCIs during a cessation attempt before and after reviewing the DA were tested using *t*-tests, the McNemar test and $\chi^2$ analysis.

**Results:** Participants evaluated the usability of the DA as moderate (MU; n = 393, 79.1%) or good (GU; n = 104, 20.9%) GU smokers rated higher on all elements of the program evaluation and experienced less decisional conflict but also displayed a higher intention to quit. After reviewing the DA, participants on average had a significantly higher intention to use more EBSCIs, in particular in the form of eHealth.

**Conclusions:** Recommendations to make the DA more usable could include tailoring, using video-based information and including value clarification methods. Furthermore, a hybrid variant in which smokers can use the DA independently and with the guidance of a primary care professional could aid both groups in choosing a fitting EBSCI option.

## 1. INTRODUCTION

With eight million deaths occurring worldwide as a result of several types of cancer, cardiovascular diseases and respiratory diseases (6), smoking is the most important cause of preventable death (6, 10). In the Netherlands alone, this represents approximately 20,000 mortality cases (11) but also results in other losses for society, such as work loss because of illness or absence and higher healthcare costs (12). Beyond added costs, smoking is also one of the factors responsible for greater inequality between high socioeconomic status (SES) and low-SES households (13), as people from low-SES households are more likely to smoke but have fewer material and social resources (327). Therefore, a decrease in smoking prevalence is a significant goal for the Dutch public health domain (22).

Currently, approximately 20.2% of the Dutch population smokes (9). Among less-educated groups, this percentage is higher, at 23.9% (9). In 2020, 35.6% of all Dutch smokers made a serious attempt at quitting (9). However, only 3-5% of smokers who attempt to quit without help succeed in their first effort (137), and, on average, as many as 30 or more quit attempts may be required before smokers are successful for longer than 12 months (138). To help smokers in their smoking cessation attempts, several evidence-based smoking cessation interventions (EBSCIs) have been developed. EBSCIs are proven to double the likelihood of successful smoking cessation (86).

There are two principal forms of EBSCIs: behavioral and pharmacological support. Behavioral support can include face-to-face counseling by a healthcare professional (HCP) in the GP setting, such as a general practitioner (GP) or a practice nurse (PN). Other forms of behavioral support outside the GP setting include counseling by a trained stop coach outside the GP-setting (44, 57, 62-65), tailored online counseling known as eHealth (69, 178), telephone counseling (179) and group counseling (74). Effectiveness rates of behavioral support range between one and three percent for very brief advice on quitting (57, 242) by a GP and seven to 14 percent for more extensive forms of counseling, in contrast to unassisted quit attempts (73, 74). Pharmacological support includes nicotine replacement therapy (NRT; e.g., nicotine gum or patches) and pharmacotherapy. NRT has an effectiveness rate of 50-60%, if correctly used, in comparison with no treatment or a placebo (79). For pharmacotherapy, the effectiveness rate ranges from 55 to 77% in comparison with no treatment or a placebo (80, 81). A combination of behavioral and pharmacological support is recommended and required when the smoker wants to be entitled to reimbursement from a health insurer (22, 52, 53). In addition to EBSCIs, there is also non-evidence-based cessation assistance, for which no firm evidence base has yet been found. Examples of non-evidence-based cessation assistance include acupuncture, laser therapy and electrostimulation (85). These options are not usually reimbursed by health insurers. Providing smokers with information and guidance to help them decide which EBSCI would best fit their needs and preferences might increase their involvement

in and commitment to their own treatment processes (103, 104). However, only 25-30% of smokers report having used behavioral counseling methods (88, 89).

Reaching smokers, motivating them to quit and educating them on EBSCIs are difficult to achieve. The primary care setting (PCS) offers an entry point for reaching smokers, as most people who smoke visit their PCS yearly, often for related complaints such as asthma and COPD (39, 96, 328). Within the PCS, practice nurses (PNs) provide the majority of smoking cessation counseling (182), based on the Dutch guideline for smoking cessation care (DGSCC) (52, 53). This guideline is based on an evidence-based counseling method, the minimal intervention smoking cessation strategy (MIS) (44), which is similar to the internationally-used 5A protocol of ask, advise, asses, assist, and arrange (177). However, PNs do not always adhere to these guidelines, particularly the assist and arrange aspects, in which they are asked to provide smoking cessation counseling or refer smokers to other EBSCIs. This might be due to a lack of knowledge or low self-efficacy related to helping their patients make informed decisions (44, 52, 225). An overview of effective evidence-based smoking cessation tools might help counselors and smokers decide on the most preferred cessation method (127).

The usability of such an overview among PNs and smoking patients willing to quit smoking has been explored in earlier research, revealing a high appreciation for but low uptake of the materials (228, 253). However, due to a low recruitment rate during the present randomized controlled trial, which evaluated interventions among smokers recruited via the PCS (253), this study retested the usability of the materials among a larger group of smokers to explore whether the materials with minimal modifications were suitable to be offered as an online intervention. This study explored the perceptions of smokers by using an adapted standalone version of the decision aid (DA), which could be accessed online without the assistance of PNs. To explore whether the DA was also suitable for use without the guidance of PNs, the first aim of this study was to assess the overall usability of the standalone version of the DA. To assess the factors that could possibly be associated with smokers' views on usability, the second aim was to compare groups who differed in their usability score by focusing on their evaluations of the program and their levels of decisional conflict in making a choice. As the main aim of the DA was to increase the use of EBSCIs, the third aim of this study was to explore a possible change in the intention to use EBSCIs during a potential cessation attempt. This was achieved by measuring intention to use EBSCIs before and directly after reviewing the DA.

## 2. METHOD

### 2.1 Study design and procedure

A cross-sectional study was carried out in September 2020 via an online research recruitment agency (www.panelclix.nl). The recruitment agency provided a database with

potential participants who could decide for themselves whether they would take part in the study. After accepting the study invite, participants were automatically transferred to the online questionnaire. At the start of the questionnaire, participants received a brief explanation of the aim of the intervention, followed by the first part of the questionnaire. After filling in the first part of the questionnaire, the participants were asked to review the DA materials, followed by the second part of the questionnaire (all questions are described below). If they completed the entire questionnaire, they received compensation from the recruitment agency. Inclusion criteria were as follows: 1) participants were above the age of 18; 2) participants had smoked (primarily cigarettes) in the past seven days and 3) participants were able to understand Dutch and had the necessary internet literacy skills to use the DA. Intention to stop smoking was not an inclusion criteria, but participants had to be willing to consider smoking cessation options. Informed consent was provided prior to the start of the questionnaire by asking if participants wanted to take part in the study and whether they gave the research team permission to use their data for scientific research.

### 2.2 Materials

The DA was named "*StopWijzer*," which can be translated as either "stop-guide" or "stop-smarter," and it was based on a needs assessment consisting of a literature review (e.g., (31, 69, 105), individual semi-structured interviews among general practitioners (GPs) (*n* = 5), practice nurses (PNs) (*n* = 20) and smokers (*n* = 9), a Delphi study on referral to EBSCIs (52, 225) and the input of an advisory board consisting of experts representing various Dutch smoking cessation related organizations, six of which were actively involved. After the intervention was pilot-tested, the DA was originally deployed to be used in primary care (228, 253).

In keeping with the DGSCC (52, 53), EBSCIs included in the DA were 1) face-to-face counseling (44); 2) counseling via internet (eHealth) (69, 178); 3) telephone counseling (179); 4) group counseling (74); 5) pharmacotherapy and 6) nicotine replacement therapy. Participants were strongly recommended to use pharmacotherapy and nicotine replacement therapy only in combination with a form of behavioral counseling, as also described in the DGSCC (52, 53).

Using non-evidence-based methods, such as acupuncture and e-cigarettes, was also discussed in the DA to address potential questions by smokers about their effectiveness, risks, costs, and availability. The DA discouraged use of these non-evidence-based methods and promoted using EBSCIs as suitable alternatives.

#### *2.2.1 DA components*

The online DA consisted of the following elements (see also (228)

1. an introduction, which explained the goals and relevance of the DA and summarized the EBSCIs and the other elements of the DA: (see Figure 1).

2. an overview of the different EBSCIs, in the following order: face-to-face counseling; eHealth; counseling via telephone; group counseling; nicotine replacement therapy; pharmacotherapy and the non-evidence-based “cessation” methods of acupuncture (85), laser therapy (188), auriculotherapy (189), hypnosis (190) and e-cigarettes (49);
3. an overview of possible reimbursements of EBSCIs by health insurers, with a calculation tool to help patients provide insight into how much money they could save by quitting smoking.
4. The website also contained an overview of the options, which could also be download. The overview listed the EBSCIs mentioned above and gave an outline of their target groups, strengths and weaknesses, effectiveness, and costs (see Figure 2).

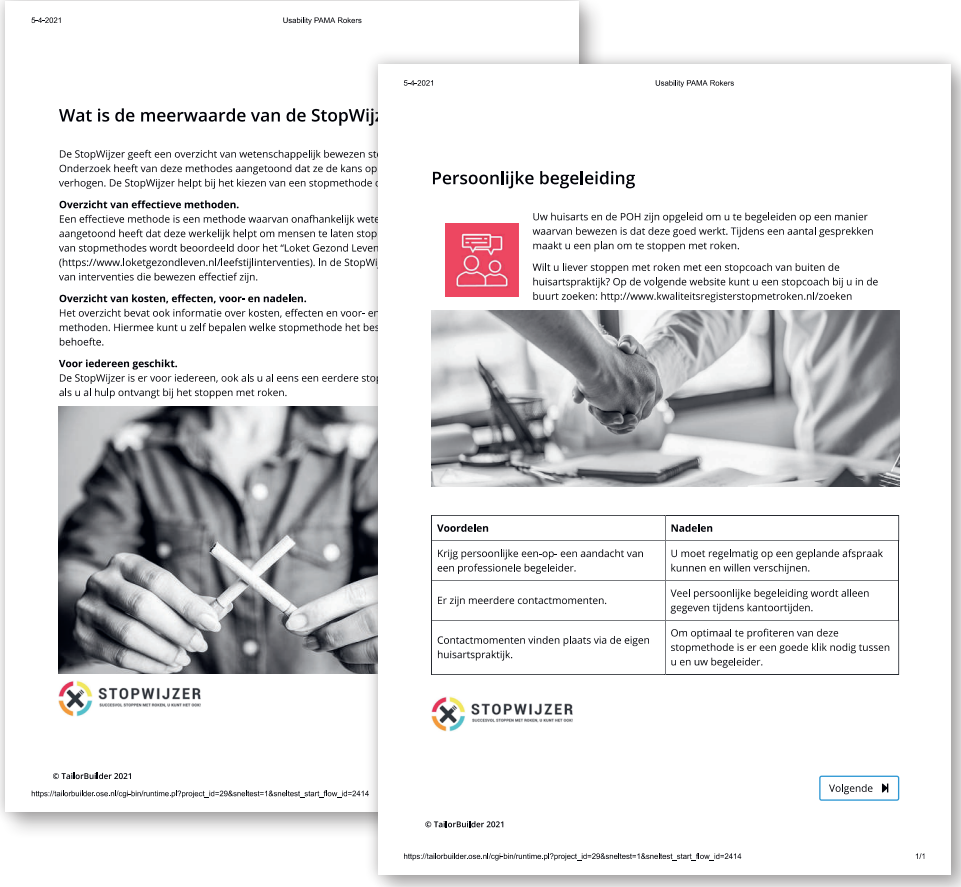
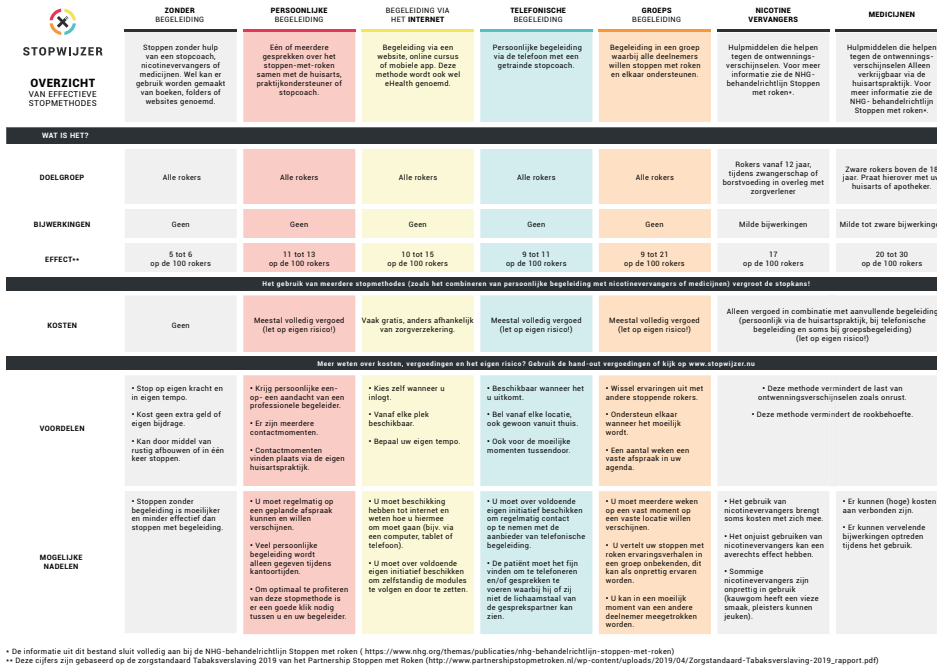



**Figure 1.** Excerpts from the DA website



STOPWIJZER

**OVERZICHT** VAN EFFECTIEVE STOPMETHODES

| | ZONDER BEGELEIDING | PERSOONLIJKE BEGELEIDING | BEGELEIDING VIA HET INTERNET | TELEFONISCHE BEGELEIDING | GROEPS BEGELEIDING | NICOTINE VERVANGERS | MEDICIJNEN |
|---|---|---|---|---|---|---|---|
| | Stoppen zonder hulp van een stopcoach, nicotinevervangers of medicijnen. Wel kan er gebruik worden gemaakt van boeken, folders of websites genoemd. | Eén of meerdere gesprekken over het stoppen-met-roken samen met de huisarts, praktijkondersteuner of stopcoach. | Begeleiding via een website, online cursus of mobiele app. Deze methode wordt ook wel eHealth genoemd. | Persoonlijke begeleiding via de telefoon met een getrainde stopcoach. | Begeleiding in een groep waarbij alle deelnemers willen stoppen met roken en elkaar ondersteunen. | Hulpmiddelen die helpen tegen de ontwennings-verschijnselen. Voor meer informatie zie de NHG-behandelrichtlijn Stoppen met roken*. | Hulpmiddelen die helpen tegen de ontwennings-verschijnselen Alleen verkrijgbaar via de huisartspraktijk. Voor meer informatie zie de NHG- behandelrichtlijn Stoppen met roken*. |
| **WAT IS HET?** | | | | | | | |
| **DOELGROEP** | Alle rokers | Alle rokers | Alle rokers | Alle rokers | Alle rokers | Rokers vanaf 12 jaar, tijdens zwangerschap of borstvoeding in overleg met zorgverlener | Zware rokers boven de 18 jaar. Praat hierover met uw huisarts of apotheker. |
| **BIJWERKINGEN** | Geen | Geen | Geen | Geen | Geen | Milde bijwerkingen | Milde tot zware bijwerkingen |
| **EFFECT**** | 5 tot 6 op de 100 rokers | 11 tot 13 op de 100 rokers | 10 tot 15 op de 100 rokers | 9 tot 11 op de 100 rokers | 9 tot 21 op de 100 rokers | 17 op de 100 rokers | 20 tot 30 op de 100 rokers |
| **Het gebruik van meerdere stopmethodes (zoals het combineren van persoonlijke begeleiding met nicotinevervangers of medicijnen) vergroot de stopkans!** | | | | | | | |
| **KOSTEN** | Geen | Meestal volledig vergoed (let op eigen risico!) | Vaak gratis, anders afhankelijk van zorgverzekering. | Meestal volledig vergoed (let op eigen risico!) | Meestal volledig vergoed (let op eigen risico!) | Alleen vergoed in combinatie met aanvullende begeleiding (persoonlijk via de huisartspraktijk, bij telefonische begeleiding en soms bij groepsbegeleiding) (let op eigen risico!) | |
| **Meer weten over kosten, vergoedingen en het eigen risico? Gebruik de hand-out vergoedingen of kijk op www.stopwijzer.nu** | | | | | | | |
| **VOORDELEN** | • Stop op eigen kracht en in eigen tempo.<br>• Kost geen extra geld of eigen bijdrage.<br>• Kan door middel van rustig afbouwen of in één keer stoppen. | • Krijg persoonlijke een-op- een aandacht van een professionele begeleider.<br>• Er zijn meerdere contactmomenten.<br>• Contactmomenten vinden plaats via de eigen huisartspraktijk. | • Kies zelf wanneer u inlogt.<br>• Vanaf elke plek beschikbaar.<br>• Bepaal uw eigen tempo. | • Beschikbaar wanneer het u uitkomt.<br>• Bel vanaf elke locatie, ook gewoon vanuit thuis.<br>• Ook voor de moeilijke momenten tussendoor. | • Wissel ervaringen uit met andere stoppende rokers.<br>• Ondersteun elkaar wanneer het moeilijk wordt.<br>• Een aantal weken een vaste afspraak in uw agenda. | • Deze methode vermindert de last van ontwenningsverschijnselen zoals onrust.<br>• Deze methode vermindert de rookbehoefte. | |
| **MOGELIJKE NADELEN** | • Stoppen zonder begeleiding is moeilijker en minder effectief dan stoppen met begeleiding. | • U moet regelmatig op een geplande afspraak kunnen en willen verschijnen.<br>• Veel persoonlijke begeleiding wordt alleen gegeven tijdens kantoortijden.<br>• Om optimaal te profiteren van deze stopmethode is er een goede klik nodig tussen u en uw begeleider. | • U moet beschikking hebben tot internet en weten hoe u hiermee om moet gaan (bijv. via een computer, tablet of telefoon).<br>• U moet over voldoende eigen initiatief beschikken om zelfstandig de modules te volgen en door te zetten. | • U moet over voldoende eigen initiatief beschikken om regelmatig contact op te nemen met de aanbieder van telefonische begeleiding.<br>• De patiënt moet het fijn vinden om te telefoneren en/of gesprekken te voeren waarbij hij of zij niet de lichaamstaal van de gesprekspartner kan zien. | • U moet meerdere weken op een vast moment op een vaste locatie willen verschijnen.<br>• U vertelt uw stoppen met roken ervaringsverhalen in een groep onbekenden, dit kan als onprettig ervaren worden.<br>• U kan in een moeilijk moment van een andere deelnemer meegetrokken worden. | • Het gebruik van nicotinevervangers brengt soms kosten met zich mee.<br>• Het onjuist gebruiken van nicotinevervangers kan een averechts effect hebben.<br>• Sommige nicotinevervangers zijn onprettig in gebruik (kauwgom heeft een vieze smaak, pleisters kunnen jeuken). | • Er kunnen (hoge) kosten aan verbonden zijn.<br>• Er kunnen vervelende bijwerkingen optreden tijdens het gebruik. |

* De informatie uit dit bestand sluit volledig aan bij de NHG-behandelrichtlijn Stoppen met roken ( https://www.nhg.org/themas/publicaties/nhg-behandelrichtlijn-stoppen-met-roken)
** Deze cijfers zijn gebaseerd op de zorgstandaard Tabaksverslaving 2019 van het Partnership Stoppen met Roken (http://www.partnershipstopmetroken.nl/wp-content/uploads/2019/04/Zorgstandaard-Tabaksverslaving-2019_rapport.pdf)

**Figure 2.** Decision overview (option grid)

### 2.3 Measurements

In terms of demographic variables, we asked the participants about their gender (0 = man, 1 = woman), age and highest completed education level (1 = low; 3 = high).

Smoking behavior was measured with two items asking, “How many regular cigarettes and/or rolling tobacco do you smoke on average per day?” and, “Have you used an e-cigarette in the past 7 days?” (1 = no; 2 = yes, with nicotine; 3 = yes, without nicotine; 4 = yes, but I don’t know with or without nicotine).

Smoking addiction was measured by using the six items on the Fagerström test for nicotine dependence (FTND), such as, “Do you smoke more often in the first hours after getting up or do you smoke more often during the other hours of the day?”. The answers were converted to an overall sum score in which 0 = not addicted and 10 = highly addicted (209). Previous quit attempts were measured by asking whether the participant had tried to quit smoking in the past year.

Intention to quit was measured on a five-point Likert scale with one item asking participants if they had the intention to quit (1 = no, definitely not; 5 = yes, definitely).

Readiness to quit smoking was measured on a six-point scale with one item asking participants whether they intended to quit smoking within a certain period of time (6 = yes, within the next month; 5 = yes, within 1-3 months; 4 = yes, within 4-6 months; 3 = yes, within 1 year; 2 = yes, within 1-5 years; 1 = yes, but not within the next 5 years) (329, 330).

### *2.3.1 Usability, program evaluation and decisional conflict*

Two items were used to verify whether participants 1) looked at and 2) read the DA materials (1 = all the materials; 5 = none of the materials).

The usability of the DA was measured by using the system usability scale (SUS) (331), consisting of the sum of 10 items (e.g., "I found the DA complex"), which could be rated on a five-point Likert scale (1 = strongly disagree; 5 = strongly agree), forming a sum score from 0 = bad usability to 100 = good usability (Cronbach's α = .66).

The program evaluation was measured by seven constructs of program evaluation, as also used in previous research (30). Each construct originally consisted of three items measured on a five-point scale (1 = totally disagree; 5 = totally agree). Negatively-worded items were reverse coded. Table 1 summarizes the concepts measured, example questions and their internal consistency. Based on an unsatisfactory Cronbach's alpha score, one item was deleted from the comprehension subscale. In addition, the adaptation and dose-inflicted subscales were omitted from the final scale.

The program evaluation was supplemented with one item enquiring whether participants would recommend the DA to other people willing to stop smoking (1 = totally disagree; 5 = totally agree) and one item asking the participant to rate the overall DA on a scale from one to 10.

Decisional conflict was measured with the decisional conflict scale (DCS) (238, 332), consisting of 16 items (e.g. "I feel I have made an informed choice") on a five-point Likert scale (1 = strongly disagree; 5 = strongly agree). Table 1 summarizes the concepts measured, example questions and their internal consistency.

### *2.3.3 Intention to use EBSCIs*

The main goal of the DA was to promote the use of EBSCIs in order to potentially increase their use among smokers when undertaking a quit attempt. Therefore, at the start of the questionnaire and directly after reviewing the DA, participants were asked if they intended to use an EBSCI if they decided to quit smoking. Participants were presented with 10 options (face-to-face via GP; face-to-face via PN; face-to-face via stop coach; eHealth; in groups; via telephone; NRT; pharmacotherapy; non-evidence-based methods and none), to which their response was measured on a dichotomous scale (0 = no; 1 = yes).

## 2.4 Data analysis

Descriptive statistics were used to describe the characteristics of the recruited participants. Participants were divided into two groups based on their scoring of the usability of the DA using the SUS. As a SUS score above 68 is considered above average for web-based interventions (333), this score was used as a cutoff mark between groups: moderate usability (MU) (mean SUS between 51 and 68) and good usability (GU) (mean SUS above 68). *T*-tests and Chi-square tests were conducted to test the differences between both

**Table 1.** Constructs of the program evaluation scale and decisional conflict scale

| | Example questions | Cronbach's α |
|---|---|---|
| **Program evaluation scale constructs** | | |
| Attention | 'The DA held my attention' | .81 |
| Comprehension | 'In my opinion the DA was clear' | .81[1] |
| Adaptation | 'The DA applied to me personally' | .44[2] |
| Appreciation | 'The DA was interesting' | .81 |
| Processing | 'The DA contains good tips on the best way to quit smoking' | .87 |
| Dose infliction | 'The DA provides a nice overview of the available evidence-based smoking cessation methods' | .46[2] |
| Persuasion | 'The DA was convincing' | .80 |
| Complete scale | - | .93 |
| **Decisional conflict scale constructs** | | |
| | By using the DA, …. | |
| Uncertainty | I know what the best choice is for me | .84 |
| Informed | I know which options are available to me | .85 |
| Value clarity | I am clear about which benefits matter most to me | .84 |
| Support | I have enough support to make a choice | .75 |
| Effective decision | I am satisfied with my choice | .78 |
| Complete scale | - | .94 |

[1] With one item deleted from scale
[2] Subscale was omitted in total program evaluation scale

groups on program evaluation and decisional conflict after reviewing the DA's materials. For the intention to use EBSCIs, changes were examined before reviewing the materials (pre-test) and after reviewing the materials (post-test), both in the MU and in the GU group. A paired-sample *t*-test was used to test the pre- and post- difference in the total number of EBSCIs that participants intended to use. The McNemar test was used to assess the intention to use individual forms of EBSCIs (yes/no), pre- and post- reviewing the materials. To assess whether the intention to use EBSCIs after reviewing the materials differed significantly between the MU and GU groups, Δ-scores were constructed indicating the differences pre- and post-reviewing the materials. These scores were compared by means of a *t*-test (total number of EBSCIs) and $\chi^2$ analysis (individual EBSCIs).

## 3. RESULTS

### 3.1 Study sample characteristics

The recruitment resulted in 497 participants, most of whom evaluated the DA as moderately usable (MU; *n* = 393; 79.1%). Participants were on average 41 years of age, slightly more

often male than female, had mostly a medium-to-high level of education, had a low-to-moderate level of nicotine addiction, smoked an average of 12.5 cigarettes per day, and generally did not use e-cigarettes (Table 2). Although both groups indicated readiness to quit, in the group of GU smokers this intention was significantly higher. However, smokers from the GU group were not significantly more ready to quit, as both groups indicated being ready to quit within six to 12 months on average.

**Table 2.** Characteristics of the sample including smoking behavior

| Study sample characteristics | Total (N = 497) | MU (n=393) | GU (n=103) | T | $X^2$ | P value |
|---|---|---|---|---|---|---|
| Age (years), mean (SD) | 41.23 (13.9) | 41.06 (13.9) | 41.96 (12.6) | -0.597 | | .551 |
| Female, n (%) | 225 (45.3) | 172 (43.8) | 53 (51.5) | | 1.947 | .163 |
| Educational level, n (%) | | | | | 0.174 | .916 |
| Low | 59 (11.9) | 47 (12) | 11 (10.7) | | | |
| Medium | 229 (46.1) | 180 (45.8) | 49 (47.6) | | | |
| High | 209 (42.1) | 166 (42.2) | 43 (41.7) | | | |
| FTND score[1], mean (SD) | 4.24 (2.4) | 4.32 (2.5) | 3.94 (2.4) | 1.412 | | .159 |
| Number of cigarettes smoked/day, mean (SD) | 12.51 (7.7) | 12.56 (7.8) | 12.38 (7.1) | 0.215 | | .830 |
| Use of e-cigarettes, n (%) | | | | | 4.421 | .219 |
| No | 306 (61.6) | 246 (62.6) | 59 (57.3) | | | |
| Yes, without nicotine | 40 (8.0) | 35 (8.9) | 5 (4.9) | | | |
| Yes, with nicotine | 144 (29.0) | 107 (27.2) | 37 (35.9) | | | |
| Yes, do not know with or without nicotine | 7 (1.4) | 5 (1.3) | 2 (1.9) | | | |
| Previous quit attempt undertaken, n (%) | 309 (62.2) | 248 (63.1) | 61 (59.2) | | .414 | .520 |
| Intention to quit[2] | 3.97 (0.9) | 3.88 (0.9) | 4.29 (0.8) | -4.334 | | .000 |
| Readiness to quit[3] | 3.19 (1.3) | 3.20 (1.9) | 3.12 (1.4) | 0.579 | | .563 |

[1]Range 1-10, 0 = not addicted; 10 = highly addicted
[2]1 = no, definitely not; 5 = yes, definitely
[3]1 = yes, not within the next 5 years; 6 = yes, within the next month

### 3.2 Program evaluation & decisional conflict

Both groups mostly appreciated the DA's being comprehensive but expressed least appreciation for the extensive amount of information that the DA contained. Participants from the GU group scored significantly higher on all factors of the program evaluation scale ($P < .001$), indicating that they found the DA more attractive, understandable, suited to their own needs, useful, valuable in making their decision and persuasive, in comparison to the MU group (Table 3). They also found the level of information provided by the DA of better dosed than the MU group. Participants from the GU group also indicated significantly more

**Table 3.** Comparison of mean scores on usability, program evaluation, recommendation to others and grading mark of MU and GU smokers.

| | **Total (N = 497)** | **MU (n=393)** | **GU (n=103)** | **T** | **P value** |
|---|---|---|---|---|---|
| Program evaluation scale[2] | 2.42 (0.4) | 3.47 (0.6) | 4.27 (0.5) | -12.674 | .000 |
| Attention subscale | 3.47 (0.8) | 3.30 (0.8) | 4.12 (0.7) | -9.835 | .000 |
| Comprehension subscale | 3.94 (0.7) | 3.77 (0.7) | 4.59 (0.6) | -11.301 | .000 |
| Comprehension: difficult | 3.79 (1.0) | 3.60 (0.9) | 4.53 (0.8) | -9.191 | .000 |
| Adaptation: fitted situation | 3.45 (0.9) | 3.32 (0.9) | 3.97 (0.8) | -6.581 | .000 |
| Adaptation: lacked information | 3.19 (1.0) | 3.05 (0.9) | 3.72 (1.0) | -6.605 | .000 |
| Adaptation: to general | 3.50 (1.0) | 3.36 (0.9) | 4.05 (1.0) | -6.435 | .000 |
| Appreciation subscale | 3.59 (0.8) | 3.43 (0.8) | 4.20 (0.6) | -9.386 | .000 |
| process subscale | 3.53 (0.8) | 3.37 (0.7) | 4.16 (0.6) | -9.741 | .000 |
| Dose subscale | 3.76 (0.8) | 3.59 (0.8) | 4.46 (0.5) | -11.126 | .000 |
| Dose: much information | 3.77 (0.8) | 2.69 (1.0) | 3.57 (1.2) | -7.518 | .000 |
| Persuasion subscale | 3.74 (0.7) | 3.57 (0.7) | 4.38 (0.5) | -9.051 | .000 |
| Recommendation[3] | 3.75 (0.9) | 3.55 (0.8) | 4.52 (0.6) | -10.606 | .000 |
| Mark [1 – 10] | | 7.27 (1.3) | 8.56 (0.9) | -11.531 | .000 |

[1] 0 = low system usability, 100 = high system usability
[2] 1 = totally disagree, 5 = totally agree
[3] 1= would not recommend, 5 = would recommend

often that they would recommend the DA to others who were willing to undertake a smoking cessation attempt and gave the DA a significantly higher mark on a scale from one to 10, namely an 8.6 (good to very good).

Participants from the GU group reported significantly less decisional conflict, both overall and for the subscales, in comparison with participants from the MU group (Table 4). Both groups reported feeling the most conflicted by a feeling of uncertainty (e.g., “I feel sure about what to choose”). For the MU group, their score on this scale exceeded the cutoff point of 37.5, which is associated with decision delay or feeling unsure about implementation (334). Smokers from the GU group reported being the least conflicted on their level of being informed, but all their scores fell below the cutoff point of 25 (334), indicating that they perceived themselves as having an adequate overview of the options available to them after reviewing the DA materials (60). The MU group of smokers experienced the least conflict about their level of effective decision making (e.g., “I feel like I have made an informed choice”), although their score did not meet the cutoff point of less than 25, indicating no substantial certainty to their level of decision making.

**Table 4.** Comparison of mean scores on decisional conflict of MU and GU smokers

| | Total (n = 497) | MU (n=393) | GU (n=103) | T | P value |
|---|---|---|---|---|---|
| Decisional conflict scale, Mean (SD)[1] | 31.73 (14.8) | 35.56 (13.3) | 17.13 (10.6) | 13.060 | .000 |
| Uncertainty subscale | 34.17 (18.0) | 38.13 (16.7) | 19.09 (14.2) | 10.583 | .000 |
| Informed subscale | 29.60 (17.9) | 34.01 (16.2) | 12.78 (13.5) | 12.224 | .000 |
| Value clarity subscale | 32.88 (17.9) | 36.70 (16.4) | 18.28 (15.7) | 10.218 | .000 |
| Support subscale | 32.34 (17.6) | 36.28 (16.7) | 17.31 (12.3) | 10.792 | .000 |
| Effective decision subscale | 30.18 (15.0) | 33.40 (13.9) | 17.90 (12.7) | 10.255 | .000 |

[1]5 = no decisional conflict, 100 = a lot of decisional conflict

### 3.4 Intention to use EBSCIs

The third aim of this study was to explore a possible change in the intention to use EBSCIs during a potential cessation attempt. Participants in both groups reported an overall and significant higher intention to use more EBSCIs after they had reviewed the DA materials, in comparison to their intention before reviewing the materials. Regarding individual forms of EBSCIs, this difference was specifically significant for their intention to use eHealth. The intention of the participants to not use any EBSCI when making a quit attempt significantly decreased. No differences were found regarding the usage of non-EBSCIs (NEBSCIs).

Furthermore, participants from the GU group had showed a significantly higher increase in intention to use more EBSCIs eHealth after reviewing the materials in comparison with the MU group.

**Tabel 5.** Comparison of the intention to use EBSCIs measured before and after reviewing the DA

| | MU (n=393) | | GU (n=103) | | Comparison of changes between MU and GU |
|---|---|---|---|---|---|
| | Pre | Post | Pre | Post | |
| Intention amount of EBSCI to use, mean (SD)[1] | 1.47 (1.1) | 1.59 (1.1)** | 1.89 (1.4) | 1.91 (1.1) | NS |
| Behavioural counseling, % (n) | | | | | |
| via GP | 10.2 (40) | 9.9 (39) | 17.5 (18) | 17.5 (18) | NS |
| via PN | 15.8 (62) | 18.3 (72) | 24.3 (25) | 23.3 (24) | NS |
| via stop coach | 12.7 (50) | 16.0 (63) | 15.5 (16) | 15.5 (16) | NS |
| eHealth | 9.9 (39) | 16.3 (64)*** | 12.6 (13) | 30.1 (31)*** | Δ GU > Δ MU** |
| in groups | 7.1 (28) | 8.1 (32) | 1.9 (2) | 4.9 (5) | NS |
| via telephone | 7.6 (30) | 9.9 (39) | 6.8 (7) | 10.7 (11) | NS |
| NRT | 25.2 (99) | 24.9 (98) | 47.6 (49) | 40.8 (42) | NS |
| Pharmacotherapy | 13.0 (51) | 15.8 (62) | 25.2 (26) | 23.3 (24) | NS |
| NEBSCI[2] | 8.7 (34) | 7.9 (31) | 11.7 (12) | 8.7 (9) | NS |
| None | 37.2 (146) | 31.8 (125)*** | 26.2 (27) | 16.5 (17)** | NS |

[1] other category excluded
[2] e.g., acupuncture, hypnotherapy, or laser therapy
* P<0.05, ** P<0.01, ***P<0.001

## 4. DISCUSSION

The aims of this study were to 1) investigate the overall usability; 2) compare groups who rated the DA with, respectively, a moderate and good usability on their evaluation of the program and 3) to explore a potential change in the intention to use EBSCIs before and directly after reviewing the DA.

With regard to the first objective, the results suggest that most participants found the DA moderately usable in the form in which it was presented, whereas smokers willing to quit scored the DA's usability as good. Although both groups had an intention to quit smoking, this intention was significantly higher in the participants from the GU group. A higher intention to quit might also indicate greater interest in the materials, given that according to socio-cognitive models such as the health belief model (335), the theory of planned behavior (112) and the I-change model (105), a person's beliefs about the effectiveness and perceived benefits—among other factors, such as perceived susceptibility, severity, and barriers—might regulate a person's interest in a behavior change. Furthermore, research has shown that smokers contemplating quitting within the next six months, but not within the coming month (336), might benefit the most from information about the intended behavior and from self-efficacy-enhancing information (337). Therefore, smokers from the GU group may have regarded the information as more

relevant for them, which might have resulted in more information retention and absorption and a higher usability score.

The second aim of this study was to compare groups who scored the DA with moderate and good usability on their evaluation of the program (measured by a program evaluation scale, willingness to recommend the DA to others and scoring the program with an overall mark ranging from one to 10) and their level of decisional conflict. Both groups differed on all aspects, which gives indication for a possible relationship between usability, program evaluation and DCS; these factors also displayed a significant but medium correlation in relation to each other. As the DCS measures the perceived conflict in the decision-making process, more conflicted feelings might also regulate the level of usability and appreciation of the DA. Further research is needed to explore the possible relationship between these three concepts in order to provide more in-depth insight into these connections. Both groups found the DA to be comprehensive, although they also indicated that the materials contained an extensive amount of information. Extensive information can be effective for higher educated users, such as those in our sample, as they may benefit from the processing of more in-depth information (338). However, to also reach less-educated groups of users, it is important in stimulating comprehension and attracting attention that this information be made accessible, and these aspects of the DA were less well-rated in this study. Overall, the DA was positively received, with both groups giving it a satisfactory grade.

Regarding decisional conflict, both groups expressed a high level of uncertainty about how to make the actual decision for an EBSCI (e.g., "I feel sure about what is the EBSCI for me"), even though they also reported that they had an adequate overview of the available EBSCIs. This might indicate that even though the participants felt informed about the EBSCIs, they were not sure how to make a balanced decision that aligned with their own preferences. As DAs are designed to aid in the informed decision-making process, they should not only provide all relevant information on the available options but also include values clarification exercises or methods (e.g., exercises aimed at helping users evaluate a wide range of options in their own specific contexts) to determine which of the options is most fitting to their needs (127, 129, 130). Another explanation for this might be that not all smokers had the intention to quit at the time of reviewing the materials and did not yet, therefore, think deeply about this part of the decision-making process.

The third aim of this study was to explore a possible change in the intention to use EBSCIs during a potential cessation attempt by measuring intention before and directly after reviewing the DA. A slight but significant increase was found in the total number of EBSCIs that participants intended to use. The number of participants willing to use eHealth after reviewing the DA materials also increased. Although systematic research about the (cost-)effectiveness of existing eHealth interventions is still scarce (70, 71), available studies that report on its effectiveness are positive (67-69, 178, 339-341). The demand for eHealth interventions, as found in this study, necessitates a greater supply of validated (i.e.,

evidence-based, and effective) eHealth interventions. Furthermore, since there are also numerous internet interventions available that are not evidence-based (70), the potential establishment of a certification by which smokers could recognize validated eHealth interventions might further increase the willingness to use eHealth, as this would help the smoker in the decision-making process.

The results also indicated a significant decrease in the number of participants who stated that they would make a cessation attempt without the help of EBSCIs. This finding is consistent with the aim of the DA, as EBSCIs are proven to double the likelihood of successful smoking cessation (86). A significant decrease in the intention to use other non-evidence-based smoking cessation interventions such as acupuncture and laser therapy was not found (85). As research has shown that smokers use NEBSCIs almost as often as they use EBSCIs (91), more attention should be paid to understanding why ineffective methods are still preferred by some smokers and which information they may need to steer them away from these options.

### 4.1 Potential strengths and limitations of the study

One of the strengths of this research was the use of validated questionnaires to measure the relevant constructs. Another strength was the inclusion of a large proportion of smokers who were willing but not yet ready to quit (those in the contemplation phase), in contrast to other studies that usually include self-selected smokers who were ready to make a quit attempt. This factor yielded the added advantage that smokers were likely not to have sought information on EBSCIs prior to the study or had decided on a form of EBSCI beforehand. However, this also included a limitation, as smokers with no intention to quit might look for other information during that phase. However, all smokers were informed of the aim of the study in advance and were instructed to take on the mindset of someone who was willing to quit smoking within a short period before and after reviewing the materials and during the questionnaire.

The second limitation was that the DA was primarily developed to be used with the aid of a PCP, such as a PN, in the PCS (228, 253). The content of the DA, however, was developed using a theoretical grounding based on relevant constructs from previous studies (31, 52, 69, 105), a needs assessment in the form of a Delphi study (225) and the input of an advisory board. The DA used in this study was adapted by rewriting the materials to fit within the smokers' frame of reference, taking into account patients' potentially low health literacy and rewriting the information using clear and comprehensible language, in accordance with the applicable Dutch guidelines (Language level B1) (186).

The third limitation was using a cross-sectional design (342) instead of a more longitudinal design, such as an randomized controlled trial, as was used in previous research on the DA materials (253). Therefore, conclusions on the effectiveness of the intervention in a real-life setting could not be drawn. However, as the main aim of this study was to

explore the usability of the materials, this study serves as a pilot test for potential further development of the DA materials.

The last limitation was the use of an online research agency, which resulted in the recruitment of a relatively highly educated participant sample. An additional consequence might be that participants only took part for the compensation they would receive from this agency and, therefore, did not complete the questionnaire carefully. This was guarded against by including a warning that participants who did not fill out the questionnaire would not receive a reward. The researchers also screened the data for time of completion and to exclude participants who fell below the average completion time, but this did not result in the exclusion of any participant.

**4.2 Practical implications**

As almost 80% of the group of participants rated the materials of the DA only moderately usable, the researchers can cautiously conclude that the materials in their current form are not usable as a standalone DA. To adapt the DA in a way that best fits its potential users, qualitative studies such as read-aloud interviews or pilot groups could aid in pinpointing concrete facilitators and barriers for the usage and reception of the DA. To draw conclusions on the effectiveness of the DA on EBSCI usage and effectiveness, randomized controlled trials conducted in ways described in similar research (343) are recommended. In order to decrease the amount of information within the DA, information provided to users could be tailored to their prior knowledge or levels of interest (341, 344). A further communication strategy to also reach a greater number of less-educated smokers might be including more video-based information, as previous studies suggested the advantages of using video-based over text-based communication (69, 345, 346). Last, as participants in this study indicated that they found it difficult to make a firm decision, the use of values clarification methods could aid in steering the decision-making process by helping users explore their preferences (127, 129, 266).

Furthermore, based on the findings of this study and their own experiences with the DA in the primary care setting (253), the researchers suggest that the utilization of a hybrid version (i.e., blended care) that could be used both within the PCS and as a standalone option could be a feasible option for further development of the DA. As mentioned above, PCPs in the PCS work with the DGSCC (52, 53), which are based on the 5A protocol (i.e., ask, advise, assess, assist and arrange) (177). However, as time within the PCS is very limited, an abbreviated version of this protocol has been proposed, the ask-advise-refer (AAR) strategy (242), which can be used to structure very brief advice by a PCP and has already been proven in Dutch cardiac wards (117). PCPs can use the DA as a reference during the referral part of this strategy, while smokers can use the online materials to further explore the available EBSCI options after their consultation with the PCP. Another advantage of adapting the DA into a hybrid variant is that it may benefit from internet interventions'

broad reach but could also have the advantage of the higher adherence rate of interventions used in healthcare settings (132). Another advantage of so-called blended care is that it allows the combination of personal attention and synchronous communication with the online advantages of high accessibility (50, 347). Given that the primary care setting prominently reaches smokers who are more motivated to quit (132, 348), using a mass media approach might reach a greater absolute number of smokers, even those who are still in a (pre-)contemplating phase (132), as was also the case in this study.

## 5. CONCLUSION

As the use of EBSCIs can double the likelihood of a successful smoking cessation attempt, this study investigated the usability of a DA aimed at increasing the use of EBSCIs. As the DA was originally designed to be used in general practice with the guidance of a PN, the aim of this study was to explore the usability of an adapted standalone version of the aid among a large group of smokers. Most participants found the DA only moderately usable, although those who intended to quit found it more usable. Participants who found the usability of the RA to be good rated higher on all elements concerning the evaluation of the DA, including the recommendation to others and overall mark, and experienced less decisional conflict. Furthermore, after reviewing the DA, participants on average had a significantly higher intention to use more EBSCIs, in particular in the form of eHealth. Recommendations to make the DA more usable and well-received among a broader group of smokers could include tailoring, transforming text-based information into video-based information and including values clarification methods. Furthermore, as the DA was found to be only moderately usable in the standalone version, a hybrid variant that would allow smokers to use the DA both on their own and with the guidance of PCPs could aid both groups in choosing a fitting EBSCI option.

# CHAPTER 8

General discussion

The overall aim of this dissertation was to explore the potential of a referral aid (RA) regarding evidence-based smoking cessation interventions (EBSCIs) in the primary care setting (PCS). The goal of the RA was to increase the number of referrals to EBSCIs by educating primary care professionals (PCPs), particularly practice nurses (PNs), about the effectiveness of these interventions and by facilitating the referral process. In Section 1 of this chapter, the main findings of all studies described in this dissertation are summarized and discussed. This section is divided into Part I, which explores the potential of RA in the PCS, and Part II, which explores further applications of the RA partially outside of the PCS. We then turn to methodological and practical considerations of the studies described in Section 2, followed by implications and recommendations for future research in Section 3. Finally, general conclusions are presented in Section 4.

## 1. SUMMARY OF THE MAIN FINDINGS

**Part I: The potential of an RA for the PCS**

The first part of the dissertation examined the potential of an RA intended to increase the use of smoking cessation interventions for smoking patients within the PCS.

### 1.1 Health-care professionals benefitted from an overview of available EBSCIs in their doctor–patient communication

Chapter 2 described a systematic exploration and consensus (Delphi) study, which focused on obtaining an overview of the knowledge, experiences, and viewpoints of smoking cessation experts (researchers and PCPs) on the effectiveness and use of EBSCIs. Although a wide range of EBSCIs with a strong evidence base are already available to refer to in daily practice (142), referral by PCPs to these EBSCIs is often limited and interventions often remain underused (12). The use of evidence-based interventions to support smoking cessation can significantly increase the success rate of quit attempts (86). We conducted this study to identify the existing knowledge and perceptions of PCPs and smoking cessation researchers regarding the effectiveness of EBSCIs as well as to explore possible gaps in that knowledge. Both groups were in high agreement on what patient characteristics should be considered when choosing an appropriate EBSCIs, the most crucial of which were considering the patient's needs and previous cessation attempts; furthermore, both groups scored highly on agreement concerning the use of special protocols for high-risk groups of patients. However, these groups did not reach a consensus on the effectiveness and value of e-cigarettes as a means of quitting. Furthermore, we found a lower degree of consensus regarding the effectiveness of EBSCIs among PCPs. We therefore concluded that identifying the needs of PCPs with respect to EBSCIs and their use can provide insights into how to promote higher intervention uptake in primary care. Furthermore, information

on the effectiveness and use of EBSCIs should be made available in a format that is easily referable for PCPs. Based on these findings, we developed an RA for the PCS with information on EBSCIs, including their effectiveness, advantages, disadvantages, mode of use, and costs. The aim of the RA was to promote the use of EBSCIs among smokers who want to quit smoking and thus to increase smoking cessation success rates.

**1.2 Caregivers were relatively positive about the use of an RA for smoking cessation interventions in primary care, but adherence and usage did not reflect this**

Previous studies have found that PNs' adherence to smoking cessation guidelines (54, 58-60), particularly the step that entails the referral of patients to EBSCIs, is suboptimal (31, 58, 59). Therefore, we developed an RA to aid PNs in adhering to this step. The newly developed RA was named "StopWijzer," which translates to "Stop guide" or "Stop smarter." Chapter 3 described the study design of the development and evaluation of this information and decision tool for supporting PNs in guiding smoking patients and referring them to EBSCIs. The RA was then tested in the PCS through a randomized controlled trial (RCT). The process of recruitment among both PNs and smokers was tracked, as was intervention appreciation, level of informed decision making, and cessation effectiveness. As described in Chapter 4, recruitment of both PNs and smokers resulted in low numbers of participants. In the PN group, only 73 approached PNs were willing to participate, which was a small percentage (4.4%) of those approached. Furthermore, of those who participated, 20 PNs did not recruit a single patient. Ultimately, 285 smokers were recruited to participate in the study. Of the total 285 participants registered by the PNs, 157 (55%) filled in the baseline questionnaire. There was also a high dropout between the baseline questionnaire and the 6-month follow-up questionnaire (nearly 48.1%), which is quite common in patient trials with minimal (and prominently online) personal contact with the research team (349). Although PNs and smokers were relatively positive about the referral and rated the materials an 8 (smokers) and an 8.6 (PNs), the aid was not used intensively, and no significant effects on the discussion and use of EBSCIs nor on abstinence could be found when comparing these outcomes with the control condition, in which smokers did not receive an RA. Furthermore, we assessed whether the range of EBSCIs outlined in the decision aid (DA) might induce or reduce decisional conflicts among patients. The findings revealed that the RA did not result in additional decisional conflict in the experimental group. Although Chapter 3 also proposed a plan for conducting a cost-effectiveness study, this sub-study was not included in Chapter 4 due to the low response rate and a lack of effects in smoking cessation. Since the RA was well-received by both PNs and smokers and a higher number of EBSCIs were used in the experimental condition (especially in the form of eHealth, group counseling, and nicotine replacement therapy, where this increase was significant), the RA is potentially suitable for implementation in the PCS. We concluded that further research should determine how to facilitate the adoption of the RA within the PCS as well as how to better involve PNs and smokers in recruitment to an RCT.

**1.3 Although the RA was positively received by PCPs, intention to adopt was low**

To explore facilitating factors and barriers that influence the potential willingness of PCPs to adopt the RA in its current form in their daily practice, we conducted a cross-sectional study among PCPs. To recruit a sufficient sample of PCPs, and to ensure that all PCPs with the same level of experience with the RA, we had to include PCPs who had not yet worked with the RA in previous studies. Our findings were presented in Chapter 5, which described the factors underlying the PCPs' intention to adopt the RA determined by assessing the differences between PCPs in charge of smoking counseling in the general practice with or without the intention to adopt. Although appreciation in both groups was high (both groups scored the RA materials higher than an 8), most PCPs did not intend to adopt the RA. Nonadopters had a more negative attitude toward the RA (i.e., they perceived fewer advantages and more disadvantages), experienced less social support, had low self-efficacy, and faced barriers such as a lack of time and skills. Recommendations for facilitating the adoption of the RA in the PCP are as follows: First, the RA itself should be improved through a second round of co-creation focused on the adoptability of the tool in practice; second, the added value of referring patients to EBSCIs should be better communicated through implementing the RA in smoking cessation training for PCPs. Making the RA part of this training could also increase PCPs' attitude, social support, self-efficacy, and perceived skills regarding the use of the RA.

**Part II: Future applications and possibilities**

Because a lack of time for using the materials in practice was a frequently reported barrier in Chapter 5 as well as in previous research (61), we sought to explore the usefulness of a standalone or hybrid version of the RA. Thus, the RA could be used in the way that the original RA was intended, but also by smokers in a standalone version (with no counseling by a PCP) or as a strategy for preparing smokers for their counseling session with a PCP, which could also help to reduce potential time barriers for PCPs. To explore this further, we examined the use of DAs for making a decision about a health behavior and conducted a usability study with a large group of smokers outside of the PCS, investigating whether the RA materials were usable without guidance from the PCP.

**1.4 Although most DAs included behavior change elements, only some reported behavioral effects**

To explore the potential of interventions designed to aid the decision-making process aimed at behavior change, we conducted a scoping review (Chapter 6). The aim of the scoping review was to broadly synthesize literature regarding DAs for supporting decision making about diet, physical activity, sleeping, and substance use. We found that all included DAs offered information about the behavior; approximately 70% of the studies reported that they used behavioral explanation and change theories such as self-determination theory

(350) or the theory of planned behavior (112), value and/or preference clarification models, and many other elements (e.g., goal-setting) to assist users in making a choice. However, effects were mixed and only a few studies used standardized measures, such the decisional conflict scale, to measure outcomes. Some positive behavioral effects were reported, especially on smoking cessation (as demonstrated by previous research (270)). We concluded that DAs are potentially beneficial for supporting people to change health behaviors, including and especially smoking cessation.

**1.5 The RA seemed useful in a standalone variant**

As the number of smoking patients recruited in our main study (described in Chapters 3 and 4) was very low, we were unable to fully investigate the usability of the RA because of our limited sample of participating smokers. To draw meaningful conclusions on the actual usability of the RA materials among smokers, and to simultaneously examine whether the RA had potential to be used as a standalone intervention (taking more of a DA form), we conducted an additional usability study among smokers. By using an online research recruitment agency, we included 497 smokers from the general population. Intention to quit smoking was not an inclusion criterion. The materials for the DA used in this study were adapted by rewriting the materials to fit the smokers' frame of reference (e.g., the information was directed at a smoker rather than a PCP). Smokers from this sample were instructed to review the materials and subsequently evaluate them directly before and after reviewing the materials by means of an online questionnaire. They were asked to give their opinion on the RA in case they made a quit attempt. The aims of this study (as described in Chapter 6) were as follows: (1) to conduct a usability evaluation; (2) to conduct a program evaluation (on whether the program holds the attention, is comprehensive, adapts to user needs, is appreciated, is easily processed, holds a fitting amount of information, and is persuasive) and to evaluate decisional conflict after using the RA; and (3) to determine a possible change in intention to use EBSCIs before and directly after reviewing the DA. Most smokers only evaluated the DA as moderately usable (n = 393, 79.1%). Smokers who rated the usability as good scored higher on all elements of the program evaluation and experienced less decisional conflict, but also displayed a higher intention to quit. After reviewing the DA, participants on average had a significantly higher intention to use EBSCIs, and specifically indicated being more willing to use eHealth. Recommendations for making the DA more usable and well-received among a broader group of smokers are as follows: First, the DA could provide more targeted communication by tailoring the content specifically to the user's prior knowledge or interests (337). This may decrease the amount of information provided per user and increase relevance and information processing (341, 344). Second, text-based information could be transformed into video-based information to make the information more understandable and absorbable, as described in other studies for a similar research sample (69, 345). Third, value

clarification methods should be included to support smokers in the decision process without the help of PNs (127, 129, 266). Furthermore, the DA was evaluated as useful by smokers who were ready to quit; this tool may be useful for guiding their smoking cessation process. Yet, smokers who were less ready to quit found the DA only moderately usable and further development is thus relevant. A more in-depth exploration of the needs of this particular target group is required as well as a more thorough co-creation process that involves them. A potential outcome could be a hybrid variant where smokers can use the DA on their own and with the guidance of PNs, which could aid both groups in choosing a fitting EBSCI option. This could represent a feasible future application.

## 2. METHODOLOGICAL AND PRACTICAL CONSIDERATIONS

As evidenced by numerous international and national studies in the field of smoking cessation in primary care, recruitment, and implementation of research in the PCS is a challenging task. During our studies, we encountered several methodological and practical considerations regarding research conducted among PNs in the field of smoking cessation, which are outlined in the following subsections.

### 2.1 Facilitating recruitment and adherence of PCPs in research

PNs were introduced in the PCS more than 25 years ago (41). The aims of this new profession within the PCS were to reduce the workload of GPs and to provide protocol-based patient education, disease management and prevention, and lifestyle counseling for chronic conditions (42, 351, 352). This led to a shift in responsibilities, where the GP was still the first point of contact for smokers as they often focus on providing brief quitting advice and referring smokers who want to quit to the PN for more intensive counseling. However, a study by the Netherlands Institute for Health Services Research (Nivel) demonstrated that, because of the more intensive care that PNs provide, PNs now also suffer from a high workload (42, 353). This problem negatively affected the recruitment of PNs and patients in our research. This was not only the case for the main part of the study (Chapters 3 and 4) but also for the other studies among PNs and PCPs (Chapters 2 and 5) and during other communication attempts with this group (during the developmental process and during the main study).

#### *2.1.1 Getting into contact with the PCS*

To recruit a sufficient sample of PNs in our studies, we employed multiple methods of approaching them (described in Chapter 3 and 4) based on earlier projects in the PCS (28, 31, 65, 69, 252, 354). However, none of these methods were particularly effective as only 73 out of all 1663 approached PNs (4.4%) were willing to participate in our study. Initial

attempts to contact PNs by telephone were sometimes cut off by the practice operator or assistant, and as there was a very low response rate to our emails (less than 1%), this was the only route for direct contact with the target group. In the other studies where PCPs had to be recruited, response rates varied between 27.7% (in the largest round of the Delphi study described in Chapter 2) and 34% (recruitment of new PCPs for the adoption study, as described in Chapter 5), and they were recruited by sending emails to the general practice where the PCP worked. These response rates can be explained by the time and effort required for participation being lower than in our main study. When contact was made with PNs, the reasons they provided for not participating in our main study concerned having other priorities than smoking cessation interventions and research, lacking time, being on special leave, or being otherwise disposed. A few PNs mentioned that they had already participated in other studies or were presently participating in a study concerning smoking cessation and were therefore not eager to participate in our study. This is similar to responses that GPs give when asked to participate in studies, with the addition that GPs also report a gap between the general practice setting and research, which was also described in Chapter 2 of this dissertation (355). Although this is not uncommon for research studies conducted in the PCS (31, 134, 233-235), it did lead to a lower statistical power and generalizability of the results obtained in this study (236).

#### *2.1.2 Managing expectations*

One way to fit participation in research into the daily routine of PNs is to manage expectations in advance, such as by informing potential participants extensively about all of the content and timelines of the elements of the study; thus, they would be able to make an educated assessment of whether they are able to participate in the study and what it entails (237). During the recruitment process of this study, potential participating PNs were informed about the actions that they were expected to perform with respect to the RA and the research by means of an information letter. In this letter, we also outlined the timeframe of the study and provided a scenario of what working with the RA might likely look like in practice based on estimates from experts involved in the pilot test. However, to include a more accurate description of the actions, more thorough pilot testing had to be conducted among PNs who actually worked with the materials. Thus, a more accurate estimate and more detailed pinpoints could be provided in the information letter, for example, regarding how to ensure that PNs would not forget the study during their daily routine.

#### *2.1.3 Nonusage attrition*

Thoroughly informing the PNs of the actions that they are required to perform for the purposes of the study might also help to decrease nonusage attrition, which our study also suffered from. Nonusage attrition refers to participants remaining in the study but not actively participating. In our study, a proportion of the PNs (27.4%) did not recruit any

smokers during the trial and thus did not use the RA (219). When PNs in our main study were asked why their adherence was low (by means of qualitative questions asked in the study, as described in Chapter 5), they named barriers such as lacking time, forgetting to bring up the materials, and lacking patients, which are known reported barriers to program implementation (356, 357). As many PNs indicated that their nonusage attrition stemmed from forgetting to use the RA during their counseling sessions, we attempted to use periodic emails and phone calls as reminders of their participation in the study. Although reminders have been proven to be effective at facilitating behavior change, providing too many reminders can be perceived as excessive interference and can reduce their effectiveness as PNs tend to block them (358). To counteract this, we attempted to increase engagement by, for example, inviting PNs to send in tips and tricks for recruitment to our monthly newsletter (359). We aimed to keep nonusage attrition to a minimum by making the recruitment of smoking participants as easy as possible, which we did most crucially by providing sufficiently informative materials to patients to inform them about the study. These materials could be discussed during the consultation or taken home by the patients to return to at a later date.

#### *2.1.4 The role of reimbursement*

In all of the studies described in this dissertation that dealt with the recruitment of PCPs, we offered reimbursement in the form of gift cards to stimulate participation. In the case of the studies described in Chapters 2 and 5, participants received a gift card of a fixed value after completing the study. In our main study, to prevent attrition and stimulate active recruitment by the PNs, the amount of money that PNs could earn was directly in line with the number of patients they recruited (ranging from €20 for recruiting at least one participant to €100 for recruiting at least five participants). However, this approach was not particularly effective, as 20 PNs did not recruit a single patient and PNs who did recruit patients only recruited an average of five smokers each (no differences existed between the experimental and control conditions). Other methods that we used to stimulate PNs to recruit smoking patients are discussed in Section 2.2.

In sum, to facilitate the recruitment of PNs and their adherence during the study, in addition to minimizing the tasks associated with the research, it is important to thoroughly inform them of the time commitment expected of them. Doing so will enable them to accurately assess whether participating is feasible within their daily routine. Financial incentives as rewards for participation did not seem to be effective in our study. In addition, to facilitate the research becoming part of the PNs' daily routine, regular reminders should be sent to them to keep the research fresh in their minds. Further research should be conducted to determine the most appropriate number of reminders and the format in which they should be sent to PNs.

**2.2 Facilitating recruitment and adherence of smoking participants in research**

As mentioned previously, recruitment of smokers during the RCT was also lower than expected (see Chapter 4). As PNs do not pause their routine to perform actions purely for research (e.g., explaining the rationale behind a questionnaire or filling in the questionnaire during the time that could be used for cessation counseling), to facilitate the recruitment of smokers, researchers should aim to make this process as easy as possible. Although we used minimal exclusion criteria to include a large and varied range of patients, the recruitment rate by PNs remained low. Furthermore, a recent study indicated that equipping PCPs with the knowledge and skills required to refer patients and motivating health care provides to discuss various counseling options with patients can be potentially successful strategies for reaching smokers to provide smoking cessation counseling (360). The main reasons that the PNs gave for the low recruitment were as follows: (1) not seeing any smoking patients during the study; (2) lacking the time to recruit smoking patients; and (3) mostly encountering smokers who are not motivated to quit or to participate in research.

***2.2.1 Encountering smokers***

First, we found the PNs' statements that they did not encounter smoking patients during the recruitment stage of the RCT (a period of 6–12 months, depending on when the PNs entered the study) to be somewhat peculiar, as this would not be expected given the prevalence of smoking in the Netherlands and the frequency with which Dutch smokers visit their GP (37). One explanation may therefore be that the PNs meant that they did not encounter smoking patients to whom they had not already provided brief cessation advice, probably without resulting in an intention to quit, or whom they otherwise would encounter more often during counseling sessions (61). An example of the latter are smokers with COPD who visit the PCS regularly for routine COPD management checkups (361). Because of their regular contact with PNs, smokers with COPD tend to receive more advice on smoking cessation than smokers without COPD. However, research suggests that they do not undertake more attempts to quit, which might demotivate PNs to continually provide them with smoking cessation advice and counseling (361). In addition, a study conducted among smokers with respiratory disease discovered an "advice limit," after which smokers got tired of the repeated messaged and "blocked" the advice out (362). However, as most smokers find it difficult to become motivated to quit without the guidance of a PCP, such as that provided by the RA, this is a missed opportunity (363, 364).

Using a more passive form of recruitment might be suitable for smokers who have already received cessation advice at an earlier date but were at the time not yet ready to quit smoking. Placing recruitment and advertising materials in the general practice without the active recruitment efforts of a PCP has been proven effective for recruitment in another study (64). During the recruitment phase of the main study (described in Chapters 3 and 4), we already used such materials in the RCT by providing PCS (digital) posters and flyers,

which could be exhibited in the waiting room. As we did not investigate the way in which smokers were notified of the RCT in depth, we are not able to report the success rate of these materials. Furthermore, although this method would not reach smokers who are unwilling to quit smoking, it would allow scientists and PNs to reach a broader group of patients without actively putting in time and energy themselves.

### *2.2.2 Addressing the limited time frame*

With regards to the limited time frame PNs could be spending on the recruitment process during their daily routine, we tried to limit the time burden for both PNs and patients as much as possible. We provided questionnaire packages (containing an information letter, the baseline questionnaire, and an envelope with return postage) to all participating PCSs so they could be handed out to smokers who did not have the Internet or a form of technology to fill in the online questionnaires. We also provided the PCSs with business cards so they could redirect smokers with questions concerning the research to the research team. To register smokers for the study, we required only their name, date of birth, and email address and/or phone number from the patient to be submitted by the PCP through our website (submitting the information by email or telephone was also possible but was only used sporadically). Most smokers chose to provide us with their email address, which we used to give them automatic access to the information on the closed section of the website without having to sign up separately. Patients who did not make use of the paper-based questionnaires also received their questionnaires by email, which allowed the research team to send multiple reminders using an automated system. The online questionnaires were designed to be viewed on multiple platforms (PC, smartphone, or tablet), making it easy for participants to fill them in (365). By requesting only minimal contact information, we hoped to reduce the privacy concerns of potential participating smokers. However, this also had drawbacks as it left us with minimal patient contact information, which made follow-up contact more difficult since we did not have the ability to communicate more personally than by email, which we could only do by name (349, 365, 366). A potentially high level of perceived anonymity might also have made it easier for patients to drop out of the trial (219).

### *2.2.3 Readiness to quit*

Lastly, a large proportion (67%) of our sample of smokers was ready to quit within 1 month. Only a small percentage (smaller than 1%) was only willing to quit within 6–12 months, or even after a longer time period. This is in line with previous research, which suggested that patients who are not yet sufficiently motivated to quit often do not receive the same level of smoking cessation counseling as those who do, and might therefore not have been asked to participate in the study by the PN (61). Although the RA described in this dissertation might be used as a new approach to open the conversation about smoking cessation, we

suspect that the RA would not be highly effective in groups of smokers who do not have the intention to quit smoking yet. This is because the main focus of the aid is not on motivating smokers to quit smoking (steps 1 t/m 4 of the DGSCC) but rather on the discussion of EBSCIs in particular (step 5 of the DGSCC) (52, 53). Therefore, instead of focusing on include nonmotivated smokers, an alternative and perhaps more fruitful strategy might be to recruit motivated smokers and keep patients motivated to continue participation, not only in the intervention but also in the entire study (6 months after). Other research found that motivation to quit smoking, indirect recruitment methods, and longer follow-up assessments are associated with a lower retention rate (348). We attempted to increase retention by promising smokers a financial incentive for participating in the study and filling in both questionnaires (baseline and 6 months). Another method for making smoking patients feel that they are participating is by sending them more reminders about their participation in the study (e.g., by making use of social media outlets or newsletters) (64). Another method of recruiting motivated smokers is by attempting to form a personal relationship using a personal approach, thus increasing goodwill with smoking patients (61), such as through scheduling regular follow-up meetings with their PN. Thus, PNs could assume the role of case manager, discussing progress and additional actions when required. In this role, they are also able to intervene earlier when a quit attempt proves unsuccessful. However, due to several factors, such as keeping the workload and questionnaires as brief as possible among others, we were unable to track to what extent these follow-up meetings were executed and what form they took. Toward the end of the main study, the COVID 19 pandemic increased the workload of PCPs further, and therefore, we suspect that this part of the research was not implemented in most cases.

#### *2.2.4 Facilitating the recruitment of smokers with smoking-related complaints or those from lower SES groups*

As mentioned earlier, smokers with smoking-related complaints often visit the PCS (37, 222); however, this is a difficult population to motivate to quit smoking. Smokers with COPD, for example, experience higher levels of cigarette dependence and depression, while also having lower levels of self-efficacy. They report the same number of quit attempts despite receiving more triggers from their environment to undertake a cessation attempt (e.g., more social support) (361, 367). This results in a negative attitude toward smoking cessation among this group, which consequently makes it a frustrating group for PNs to counsel. This can have far-reaching consequences for giving cessation advice and providing additional counseling to this group, such as stigmatization and a lower provision of smoking cessation counseling (368, 369). A recent systematic review revealed a combination of mediation with behavioral support to be the only effective treatment (370). To address smokers with smoking-related complaints compared with smokers in the general population, the RA can be adapted for this group by providing extra information on making the most use of a

combination of EBSCIs or information about any side effects or possible mismatches with commonly prescribed medications. Additional guidance should be provided in the form of specifically targeting their lower levels of self-efficacy, using a social-support group, and adjusting their attitudes toward making another quit attempt.

Because of the preconceived purpose of the study, combined with a strict time period for the development of the RA and the Dutch nationality of the research team, the materials comprising the RA were only available in Dutch. However, as described in Chapter 5, not all patients had sufficient command of the Dutch language. This might have been a threshold for non-native speakers of Dutch, patients with a migrant background, or lower educated (illiterate) patients. Although these groups of patients often have a lower socioeconomic status (SES), they also suffer from higher smoking rates and encounter more challenges in quitting (16). Potential language barriers also make them a difficult group for PNs to provide counseling to in accordance with the DGSCC (52, 53), and most interventions seem to be effective among higher-SES rather than lower-SES smokers (371, 372). We aimed to facilitate this by providing the materials in clear and comprehensible language in accordance with the applicable Dutch guidelines (Language level B1) in order for them to be understandable for less-educated patients.

In conclusion, this section discussed three considerations for recruiting smokers in smoking cessation research and encouraging PNs to keep patients involved in the cessation process, namely (1) using passive recruitment strategies for smokers who have been informed at an earlier time about smoking cessation; (2) keeping the recruitment process of new patients as short as possible (for both PCPs and smokers) and asking for sufficient contact information from the smokers to keep in touch during the trial; and (3) focusing primarily on rerouting motivated smokers and keeping them in the study. Furthermore, the RA can play a role in reaching smokers from lower SES groups, but to recruit them into the study and benefit from the study materials, the materials need to be more customized, both for smokers and PNs, so that they better meet their specific needs and preferences.

**2.3 How to determine smoking cessation effects in research and in practice**

During the RCT, PNs were randomized at the practice level. This meant that participants from the same practice were randomized in the same treatment group to avoid spill-over from the different interventions between patients and different PNs working at the same practice (e.g., patients from the control condition receiving information from the materials distributed in the experimental condition). The power analysis that we conducted to calculate the sample size of the RCT was based on the intra-cluster correlation design mentioned earlier and on a 7-day point prevalence abstinence effect size of 10% between the control and experimental conditions. However, this design would require a larger sample of smoking participants (n = 600 during the recruitment phase, accounting for 50% dropout

between recruitment and filling in of the baseline questionnaire, resulting in n = 300 at baseline; see Chapter 3 for our power analysis), and therefore, would lead to a more complex design, logistics, and analysis. As we only managed to recruit n = 285 patients, of whom only n = 157 (55.1%) filled in the baseline questionnaire during the recruitment period, we could not conduct a cluster randomized trial. It is also possible that selection bias occurred here, as those who agreed to participate in our study might have differed from those who declined to participate, for example, based on their motivation to quit smoking. Furthermore, based on the limited sample, we could not draw significant conclusions on the effects of the RA on smoking abstinence. We also measured decisional conflict to examine whether exposure to the RA may have affected users' decisional process. These two topics are discussed in more detail in the following subsections.

#### *2.3.1 Measuring smoking abstinence in small samples*

Our RCT found no differences in 7-day point prevalence abstinence and 6-month prolonged abstinence. Given the study design, in which care was provided by a PN in both conditions while it was supplemented by the RA in the experimental condition, whether it was realistic to expect a large difference in smoking cessation rates between the two conditions is questionable. Given the generally low success rates of smoking cessation attempts and to increase the motivation of both PNs and smokers, it may be valuable to reevaluate the measures used for determining when to count a cessation attempt as a (small) success when dealing with a small sample size, or to base effectiveness on reductions in smoking rather than on complete cessation. Future research might therefore consider examining effect measures other than smoking cessation, such as a decrease in the number of cigarettes smoked (per day), decrease in cigarette dependence as assessed via the Fagerström Test for Cigarette Dependence (208, 209), multiple serious quit attempts, a shift in willingness ('I intend to quit smoking') or readiness to change ('I intend to quit smoking within 6 months' (e.g. 193, 207), or perhaps even switching to e-cigarettes (fully or slowly phased), some of which have already been found to be prerequisites for a successful quit attempt (373). The change in motivation could be measured over time, for example, during subsequent consultations with their PNs. In the context of this study, the intention to use EBSCIs could also be seen as a potential measure of effectiveness, as it was part of one of the aims of the study. By using multiple forms of measurements when evaluating an intervention such as the RA, more information about its overall effectiveness can be distilled. Finally, as the RA is aimed at improving the use of EBSCIs, it may also be of particular interest to determine whether its effects are notable among smokers who do not use these ESCBIs. However, this will require a different experimental study.

During our RCT (Chapter 4), all tobacco abstinence measures were assessed through self-reporting as well as with a 'fake lead' question ('Do you object if we come and perform a saliva test to check your smoking status?'). This question would reduce socially desirable

responses by incorporating the threat of biochemical testing (194, 195). We chose this method of validating abstinence measures rather than biochemical measurements to minimize the effort required for participating in the study for both PNs and smokers. Voluntary appointments by smokers with their PNs are typically used for biochemical validation where a saliva sample is collected using a swab stick to test for the presence of cotinine. However, the response rate to these voluntary appointments in a similar study was low (28), and orchestrating the distribution of cotinine tests, collecting the results, and providing feedback raised doubts about their feasibility. Another way to conduct cotinine research is to collect samples from smokers' homes by, for example, sending a research assistant (69). This would require more sensitive information from participants, which could raise privacy concerns and another barrier to participation. In retrospect, however, both forms of validation would have been impossible because the COVID-19 pandemic overwhelmed PNs and did not allow personal contact. Moreover, previous studies have suggested that the difference between self-reported abstinence rates and those verified with biochemical validation is negligible (196-198). In conclusion, when measuring smoking withdrawal in small samples where contact between the researcher and smokers is minimal, the use of self-reporting is usually sufficient; nevertheless, efforts should be made to objectively measure reductions in smoking behavior or changes in motivation to obtain a full overview of the effectiveness of the intervention.

### *2.3.2 Measuring decision making in the PCS*

Inviting smokers to contemplate the optimal or preferred method for quitting smoking rather than (simply) following the advice given in the PCS may in principle lead to increasing uncertainty about the how to quit. To explore the decisional process of choosing a fitting EBSCI option among smokers willing to make a cessation attempt, and also whether the tool facilitated this process, we used the decisional conflict scale (DCS) (334). The DCS measures personal perceptions of uncertainty when choosing options, which includes feelings of being uninformed, being unclear about personal values, and feeling unsupported in the decision-making process. When the decisional conflict measured by the scale is low, there is a higher probability that the decision will be implemented and that the decision maker (i.e., the smoker making a cessation attempt) will be satisfied with their decision. We used the DCS because, in addition to being a validated scale, it takes minimal time and effort to fill in, which agreed with our aim of keeping the study questionnaires as short as possible.

In our main study (Chapter 4), we found no differences between smokers in the experimental and control groups in terms of decisional conflict. Furthermore, both their scores were slightly above the cut-off point, which may indicate some level of conflict associated with decisional delay or uncertainty about implementation (334). In Chapter 7, where we measured decisional conflict among smokers who used the standalone version

of the RA, decisional conflict was even higher, especially among those who rated the RA as moderately average. As we did not measure decisional conflict at the baseline level, we are unable to say what the actual changes of the RA in decisional conflict were. This means that the level of conflict could also be caused by the expanded supply of EBSCIs, or by some forms of EBSCIs, their use, and their availability not being sufficiently conveyed to the patients to enable them to make an unconflicted decision. To explore the decision-making process in more detail, further studies should apply more in-depth measures, such as (1) measuring the level of knowledge that smokers gained on the offer of EBSCIs after discussing the RA and (2) measuring the perceived autonomy support that smokers experience from their PCP and the RA.

As described in Chapter 1, to make an informed decision, individuals (i.e., smoking patients undertaking a quit attempt) are required to gain information about all relevant details of the EBSCIs, such as their cost and effectiveness. To measure whether the individuals succeeded in gaining this information, their knowledge on the subject must be explored. However, no consensus on how to measure knowledge related to decision-making was found in the literature, as there are no cut-off points available for being sufficiently informed (374, 375). The Patient Decision Aids Research Group attempted to create a questionnaire for measuring knowledge, which could be used as a template and needs to be tailored to the relevant subject (334). Although the scale has been used in several clinical applications (376-383), to our knowledge it has not yet been used in a setting similar to that of the research described in this dissertation, but it has potential to be adapted to the relevant context (334). Knowledge regarding EBSCIs can increase smokers' attitude and self-efficacy regarding the use of EBSCIs and might enhance adherence to the chosen form, as they are better informed about how to use EBSCIs and what to expect. Measuring this knowledge could also be used to explore whether PNs explain EBSCIs in the way that was envisioned in the RA and whether the materials of the RA are sufficiently clear for transferring this knowledge. Therefore, measuring if the RA help ensures a sufficiently high level of knowledge on EBSCIs can provide additional information on the operation of the aid.

One of the strengths of the RA, compared with a more traditional DA that is often more focused on standalone use, was the guidance and support that PNs could provide to smokers during the decision-making process. As described in Chapter 1, PNs can take various roles in this process, ranging from more of a guiding role to a role more on the sidelines. The role that PNs might assume depends on the level of autonomy they attribute to their patients or that the patients themselves display. As (perceived) autonomy support has been proven effective in changing health behaviors (such as smoking cessation) (384, 385), the level at which the RA aids the PCP in providing autonomy support can play a role in the overall effectiveness of the RA. During the RCT, we measured the relationship between smoker and PN using the health care climate questionnaire (HCCQ) (386). To further explore the influence of perceived autonomy support and to take the added value of the information

of the RA into account, we recommend using a scale such as the Virtual Care Climate Questionnaire (VCCQ), which was developed for web-based health behavior change interventions (387).

In conclusion, to further explore the process of smokers regarding the decision to choose a well-suited EBSCI, measuring knowledge on EBSCIs and the degree of autonomy support by both PNs and RA could also be useful options in the decision-making process.

## 3. IMPLICATIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH AND PRACTICE

Since our study was not able to demonstrate the effectiveness of the intervention and the use of the program during the RCT was modest, a recommendation to implement the RA described in this thesis in practice would be misplaced. However, we wish to provide some recommendations for the field of health care, for the RA itself, and for the field of smoking cessation care (specifically in general practice) to strengthen the changes of successful and sustainable development, evaluation, adoption, and implementation in the future.

### 3.1 Recommendations for primary care from a PCP perspective

Previous qualitative findings have suggested that patients with low motivation to quit have a negative impact on PNs' level of self-efficacy, as they view the process of motivating smokers as part of their responsibility (61, 114). Although the Dutch smoking cessation guidelines (52) stipulate that all patients be routinely asked if they smoke, this does not always happen (31, 47, 49, 61). Smoking cessation care as part of an intervention or study can be made more efficient by streamlining the actions that PNs are expected to perform and by improving its integration into the PNs' usual routine. Therefore, our recommendations for facilitating research and intervention implementation in primary care are as follows: (1) make better use of co-creation principles during the development and implementation of the intervention and (2) simplify the use of the intervention for PNs to facilitate implementation of the RA. These recommendations are detailed in the following subsections.

#### *3.1.1 Potentially increasing participation and implementation using successful co-creation*

As reported in Chapter 5, we found a low intention to adopt the RA among PNs, even though they reported high appreciation of the materials. This intention was associated with a lower attitude toward the RA (perceiving fewer advantages and more disadvantages), feelings of less social support, and low self-efficacy to use the materials in practice. Other reported barriers were a lack of time and skills. A potential method for motivating PNs to adopt the RA or a related intervention is to attempt to involve them more thoroughly in the process

of intervention development and implementation. Although we involved potential end-users at different stages of the RA's development, for example, in the form of a Delphi Study (Chapter 2), individual interviews (discussed briefly in Chapter 3), at national congresses in the field of primary care and health promotion, and in testing the materials in a pilot (n ≈ 10, convenience sampling, briefly discussed in Chapter 3), the development process began on the basis of scientific research (388). This means that we might not have fully involved all end-users (patients and PNs) and other key stakeholder in the field throughout the process, limiting the effective translation of our research into practice and/or policy (389). This could have been avoided by facilitating more intensive co-creation.

Co-creation focuses on creating value with, and for, multiple stakeholders through regular interactions that can, over time, contribute to the creation of an end product with a high probability of being implemented (390). Research has indicated that implementing co-creation within the development of health-care innovations might (1) decrease the knowledge transition and/or implementation gap (as also described in Chapter 2) (145), (2) enhance involvement in the research, possibly resulting in a higher adherence and recruitment rate (see Chapter 4) (391); and (3) increase the acceptance and intention to adopt a new tool (as discussed in Chapter 5) (392).

However, true co-creation within a time-restricted and regulated sector such as health care is challenging, as PNs often have limited time to partake in tasks that fall outside their daily routine (such as co-creation sessions) (42). To fully incorporate their expertise, the views and experiences of the health-care field need to be adopted as a central starting point. We therefore recommend establishing a fixed group of smoking-cessation experts from both the PCS and research, specifically designed for creating and innovating (smoking cessation) interventions within the PCS. To ensure that a sufficient sense of community is achieved, we suggest involving parties who already have some form of connection or have previously undertaken initiatives together, as was also described in another research study on co-creation in primary care (393).

#### *3.1.2 Simplifying intervention use for PNs to facilitate implementation*

Despite our efforts to ensure the RA materials' ease of use by providing handouts that summarized the materials and making all materials available online, the RA still contained a large amount of textual information and might have still been too complex to be conveyed to patients during the short time frame of a consultation. Implementing online materials provides more options such as only offering information that is relevant to the individual PN (e.g., (183)) or supplementing with video-based materials that explain the aim and use of the RA, a method that has also been proven to be effective among smoking patients (69), and which may also facilitate reaching higher levels of interactivity (394). In our studies, to spare the PNs as much as possible from completing questionnaires and other means of reporting, we chose not to measure the extent to which PNs went through these materials

and understood them, nor did we measure to what extent the materials were applied as intended. The extent to which PNs viewed and understood the prominently paper-based materials within this study therefore remains a black box. It is plausible that poor adherence to and implementation of intervention materials negatively affects a program's impact and possible effectiveness (395). This might not only relate to how the PNs conveyed the materials to their smoking patients during their consultations, but also more importantly to reading and using the materials as they were intended. A possible approach for cracking this black box is to make it easier to measure usage adherence. However, intensively tracking the use of materials, for example, by using triangulated measures (e.g., combining self-reported dose-provided scores of PNs and dose-received measured from a patient perspective) is rather time- and resource-intensive (396). Furthermore, tracking the use of materials can be better facilitated when they are only accessible electronically, for example, by using website tracking technology. Although previous research has reported low adherence when using online materials, another interesting possibility is to examine how, after the COVID-19 pandemic, PNs now view working with online materials, since the pandemic has forced people to be flexible with situations and materials.

As individual interviews with PNs before the development of the RA (briefly reported in Chapter 3) indicated, the PNs often stated that they had little time for peripheral issues not directly related to the delivery of care. Given the relatively high education of the PNs combined with their high workload, when providing the materials for the RA, we had to make a trade-off in terms of providing additional training elements (to elaborate on the use of the RA and to give PNs the option of training their motivational interviewing (MI) techniques; (397)) or explaining the use of the materials as concisely as possible and relying on the knowledge and skills of the users. By applying MI techniques, PNs aim to help patients identify and change unhealthy behaviors through supportive talk therapy based on the principles of cognitive behavioral therapy (216, 398). MI has been proven effective in motivating smokers to quit smoking (257), is included in the general educational program that PNs receive (42), and its use is endorsed by the Dutch Guidelines (52, 53). Previous research included training that entailed making specific plans for how to best counsel smokers and found it to be effective (252). However, based on the aforementioned tight schedules of the PCP, we did not provide them with comprehensive training regarding the use of the materials or provide extensive MI. Instead, we decided to limit the explanation of how to use the materials to a simple manual of approximately 20 pages, which was also available online, as valuable research has reported that PNs prefer e-learning programs over face-to-face training sessions (114, 399). Usually, training courses for this group of people fall under an accreditation program that allows them to complete these hours reimbursement-wise. The design and tight time schedule of this study did not allow us to obtain accreditation. However, previous research has revealed that PNs do not systematically apply these techniques (400-403) and PNs often report

struggling with motivating smokers to participate in the study. Therefore, in retrospect, it might have been more effective to pay more attention to the role that the RA could play in motivating smokers (i.e., to quit and to partake in the study). We attempted to establish this through stage-based tailoring techniques, outlining different scenarios that PNs could deploy while reaching smokers based on their motivation phase (i.e., not motivated to quit, not motivated but willing to think about quitting, or willing to quit at that moment) (404). Thus, smokers who at the time have no quit intention should first be motivated to quit, while smokers who are already quit-motivated could be motivated to be counseled in accordance with the RA to be motivated to use EBSCIs. Therefore, to help PNs motivate smokers who are unwilling to quit, more attention to MI and its techniques could be paid in the RA.

Lastly, providing smoking cessation counseling and referral to EBSCIs, whether as part of research or in daily care, should not feel like a burden. Therefore, instead of opting for more extensive counseling, as is described in the Dutch Guidelines (52, 53) and the similar internationally known 5 As (Ask, Advise, Assess, Assist, and Arrange) method of smoking cessation (55), the feasibility and effectiveness of a more brief version of cessation advice for nonmotivated smokers prior to extensive counseling may be explored as well. Research has concluded that brief cessation advice, for example, based on the Ask–Advise–Refer (AAR or the 3 As) (405) or the similar Very Brief Advice (VBA (62, 405)), can result in effectiveness rates similar to those of intensive counseling (61, 64, 406). Research also found that VBA was also positively received among smokers (407). The AAR strategy focuses less on motivating smokers to quit smoking and more on informing them of the possibilities available to help them when then eventually might be ready to undertake a cessation attempt (407). Because of this setup, this strategy requires less time, knowledge, and skills from the PCP him/herself, but the counseling part is performed by another health-care provider (e.g., a professional smoking cessation counselor) who has more time for it.

Therefore, we suggest that the RA described in this study is implemented in the Refer part of the AAR strategy. This can be done by explaining the available EBSCIs to smokers during the referral phase or as a resource that smokers can refer to themselves after talking to their PCP. By implementing the DA in this way, the PCP can save time in counseling smokers who are ready to make a quit attempt. This will leave more time for counseling smokers who are not ready to quit or who need more counseling. Research showed that the number of referrals to EBSCIs increased significantly after receiving 3.5 hours of training for a similar method (ABC method, ask–brief advice–cessation support; (406)). When smokers seem receptive to the conversation on smoking cessation, this could then be followed up with the more extensive 5A strategy as also described in the Dutch Guidelines (52, 53) or another form of EBSCI.

### 3.2 Recommendations for the RA from a smoker's perspective

In line with our conclusions from Chapter 7, we also wish to propose some adjustments for making the existing RA more suitable for use as a standalone version, an example of which was described in comparable research (343). These recommendations are as follows: (1) make use of content and frame-tailoring to condense the amount of information and (2) include more informed decision-making principles to help smokers in the decision-making process.

Smokers from the usability study described in Chapter 7 indicated that they found the amount of information contained in the RA to be highly extensive. To condense the information presented by the RA and make it more specific to smokers' own preferences and needs, content tailoring (i.e., tailoring the content of the information to the existing knowledge and motivational characteristics of the smoker) can be employed. Content tailoring has already been proven effective in online smoking cessation interventions (341), and adapting the level of counseling to the motivational stage of patients, according to the Stage of Change (110), is recommended by the DGSCC for reaching different groups of smokers (52, 53). However, the guideline does not explain how PCPs should adapt their counseling to deal with the differences between the motivational stages of smokers. Previous research (404) found that smokers in the precontemplation stage benefit more from information about the advantages of quitting smoking and the perception of cessation support, whereas smokers in the contemplation and preparation stages benefit more from self-efficacy-enhancing information regarding a cessation attempt; therefore, further research could examine how this could be implemented in the RA.

In addition, content tailoring can be used to make the aid more usable for lower SES groups, such as those who are less educated, as it will enable the fitting of the aid's information to the preferred language. Furthermore, translating the RA's materials, especially those developed to be handed out to patients and the part of the website accessible to patients, into other languages such as Turkish, Arabic, and English – the most-spoken languages in the Netherlands next to Dutch – could assist in reaching these groups of smokers. Tailoring could also be applied to offer a suitable level of complexity for individual users. Thus, smokers who are interested in more in-depth information can obtain it, while smokers who prefer short and simple information will not be put off by long texts and difficult wording. Another communication strategy to reach more lower-educated smokers may be to include more information on video, as previous studies have demonstrated the benefits of video communication over text (69, 345).

As mentioned in Subsection 2.3.2, where we discussed our practical considerations regarding the measurement of the aid's decision-making process, and based on our findings in Chapter 7, we recommend paying more attention to supporting smokers in actively considering their own preferences before making a decision for an EBSCI that best fits their needs. As the EBSCIs described in this dissertation and in the RA do not differ much in

effectiveness, cost, or other characteristics, decisions regarding the use of EBSCIs can be described as 'preference-sensitive' (127). To structure the preference-sensitive decision-making process, value-clarification methods can be used (129). Although the RA already includes a form of implicit value-clarification methods, by inviting users to take in the information and telling them to think it through, the use of explicit forms of value-clarification methods (such as making use of ranking systems to identify preferences) might be more effective (269). Through integrating these methods into the RA, we suspect that smokers would feel more stimulated to actively think about their own preferences for the use of an EBSCI when they use the intervention on their own.

Naturally, if these adjustments are made to the RA, it will be crucial to pilot test the materials by intensively using a wide range of smoking patients and 'healthy' smokers to ensure an adequate level of usability before testing the intervention by means of a trial.

Lastly, as previously mentioned, if the above-described recommendations were to be included in the DA, exploring the possibility of developing a hybrid variant (blended care; (408)) could be a next step for the RA. Such a variant could be used (1) as a standalone version, (2) to help smokers prepare for a consultation with a PCP, or (3) together with a PCP during counseling sessions. Through this, we would aim to combine the advantages of both face-to-face care and online web-based care (347, 409) as patient support offered over the Internet improves patients' self-management, especially when they are appropriately counseled by a PCP (410, 411). Another advantage of providing blended care is that it allows the combination of personal attention and synchronous communication with the online advantages of high accessibility (347, 412). Given that the PCS prominently reaches smokers who are more motivated to quit (132, 348), a mass media approach might reach a broader absolute number of smokers, and even those who are still in a (pre)contemplation phase (132).

Lastly, in Chapter 7, to reach a larger and broader sample of smokers, intention to quit smoking was not an inclusion criterion for participation. This allowed us to evaluate the RA among smokers who had most likely not yet actively thought about a potential cessation attempt and were possibly less informed about EBSCIs than smokers with an intention to quit. However, this might also explain the large percentage of smokers who rated the materials as only moderately usable. To reach those smokers who are still contemplating quitting, an additional motivational element would need to be included in the RA, aimed at motivating smokers to quit, helping them set a quit date, and motivating them to use EBSCIs during that cessation attempt. Mass media campaigns also make it possible to reach smokers outside of the PCS (89, 132, 413), who can then use the RA in preparation for a consultation with a PCP. This could reduce the workload of the PCP in question (i.e., the time and energy spent informing smokers about EBSCIs). Whether this would also be a solution for this case as well as how best to combine PCP-led and online patient support should be subjects of future research. Such research should focus on the needs and preferences of smokers regarding the information they require about EBSCIs, the talking

points they need when discussing EBSCIs with the PCP, and how they want to be approached – if they want to be approached – if they do not want to quit immediately. This was seen in a study by Gultzöw et al. ((414)), who investigated smoker profiles and their influence on smokers' intention to use a digital standalone DA.

### 3.3 Recommendations for smoking cessation in general

As described in Chapter 1, tobacco use is a major contributor to smoking-related diseases, health-care costs, and the existing inequality between people of different SES. To counter these negative effects and decrease tobacco use, countless studies have been conducted that have examined the possibilities of illicit structural behavior change in the PCS (e.g., (31, 32)) and the field of smoking cessation in general (e.g., (28-30, 33-36)). However, most smokers reached by these interventions already had the intention to quit smoking. This was also seen in our main study (Chapter 4). Therefore, as described in earlier research among COPD patients (367), we suspect it would be advantageous to tailor smoking cessation counseling to two groups – motivated smokers and smokers. This means that as long as smokers are not intrinsically motivated to stop smoking (i.e., motivation comes from within the person and is not controlled by an external reward or punishment), they will not be open to counseling or intervention, such as the RA, that can facilitate the smoking cessation process. We suspect that smokers at this stage may also benefit from extrinsic motivators, such as at the macro level. Since tobacco use is recognized as a policy problem by most countries and their governments, the Framework Convention Alliance (FCTC; www.fctc.org) was established (415, 416). Countries participating in this Convention are legally obliged to take measures that are in line with the obligations of the FCTC. Policies implemented by the Dutch government under this treaty and the National Prevention Agreement (22) include measures such as more nonsmoking zones, lower availability of cigarettes, and higher costs per pack (cost price and taxes). This strongly underscores the message that smoking has more disadvantages than advantages, which may help smokers to make the switch to a more intrinsic form of motivation. Research has demonstrated that PCPs are also positive about these types of measures, such as price increases and smoking bans, but they feel that their government is not doing enough to reduce smoking and is thus failing to facilitate successful smoking cessation efforts and reduce smoking prevalence (417). The meso level of society (e.g., the workplace) can also play a role, such as through providing financial incentives to motivate smokers to quit smoking, which was found to be effective in a study of employees who received a workplace smoking cessation program (25).

When smokers move from a state of nonmotivation to a more motivated state, either through extrinsic or intrinsic motivation, it is critical that they have access to the care they require to maximize the probability of a successful quit attempt. Increasing the affordability and accessibility of EBSCIs will lower the threshold for smokers to make use of them. As

described earlier, this will also require a proactive move on the side of health-care insurers, who will need to provide more means for both PNs (to provide smoking cessation care to their patients) and smokers (to use EBSCIs without financial thresholds). One strategy to consider is increasing attention to policy aspects of smoking cessation care (i.e., reimbursement for providing smoking cessation care to smokers without smoking-related complaints) to ensure a greater chance of successful evaluation, adoption, and implementation of future interventions aimed at increasing the use of EBSCIs or stimulating smoking cessation care within the PCS.

Finally, it is better to prevent people starting to smoke than to cure them after they have become addicted. To endorse this, the Dutch '*Toekomst visie huisartsenzorg 2022' (Future vision of general practitioner care 2022)* (418) advocates the use of indicated and care-related prevention. Indicated prevention means targeting individuals who are not officially diagnosed but are at a higher risk (so called 'healthy smokers') to prevent them actually developing smoking-related diseases (419). Care-related prevention targets individuals who developed a disease but aims to support their self-management and thereby reduce their burden and prevent further complications or progression of the disease (419). The RA described in this dissertation could be used for both forms of prevention and, with minor modifications, could tailor the information provided to both groups. Again, since we are talking about people who have already started smoking, from a prevention point of view the best approach is to engage society in universal prevention; that is, targeting people who may not even have started smoking and preventing them from starting (419). The Dutch campaign for the smoke-free generation is an example of this, and given the rising trend of young people still starting to smoke, it is a good way to prevent long-term addictive behavior that is difficult to resolve among the younger generation.

#### *3.3.1 Availability and accessibility of EBSCIs*

A crucial factor in the usability of the RA is the availability of EBSCIs. During the main study conducted for this dissertation (described in Chapters 3 and 4), a change occurred in the reimbursement system regarding EBSCIs, namely that EBSCIs prescribed by a GP were no longer covered by the deductible. This change in the reimbursement system was initiated by the introduction of the National Prevention Agreement (*Nationaal Preventieakkoord* (22)) and involves evidence-based forms of behavioral support, NRT, and pharmacotherapy. The use of pharmacotherapy does not count toward the deductible if it is combined with behavioral counseling, which makes it a part of a smoking cessation program, as described in the DGSCC (22, 52, 53). This change in policy might lower the financial barriers to the use of EBSCIs among smokers. This was also discovered in previous research conducted when EBSCIs were first available for reimbursement but still counted against the deductible (94). Although this type of care is reimbursed under the compulsory basic insurance, different conditions apply to each health insurer. The most commonly used policy is the reimbursement of a maximum of one form of behavioral counseling (e.g., individual

counseling or group counseling, maximum number of sessions not described in the policy) with the possibility to pair this with a maximum of 3 months use of pharmacotherapy or NRT (as described, for example, on https://www.cz.nl/vergoedingen/stoppen-met-roken). Our recommendation is to further lower the barrier to free smoking cessation by also allowing multiple evidence-based cessation attempts per year, as the cost of EBSCIs could be a barrier to using them for individuals with limited financial resources (420). Doing so is important because the cost of continued smoking is likely to be higher to society and to health insurance than the cost of smoking cessation care.

Although partially forced to by the COVID-19 pandemic, people have started using technology and online services more in their daily lives and work. This has included replacing regular counseling sessions between PNs and smoking patients with (video) calls or email contact. However, the number of effective proven offerings of online smoking cessation care is low and they are often not structurally accessible. For example, although two systematic reviews have been conducted on the effectiveness of eHealth interventions, which identified a total of 121 literature reviews (421, 422), a similar review study on the availability of eHealth interventions in the Netherlands (70) reported only six online cessation interventions tested for their effectiveness in trials, none of which are currently widely available. Furthermore, at the time of writing, we could not find any Dutch mHealth interventions that have been tested for effectiveness. Although previous research from 5 years ago found that mHealth apps were rated as potentially inferior to eHealth versions in terms of usability and appreciation (423), times have changed rapidly. A review on this topic did conclude that mHealth interventions are a potentially useful starting point because of the increase in smartphone users (424). Our participants' need to use eHealth (see Chapter 7) calls for a greater supply of validated (i.e., evidence-based, and effective) eHealth interventions. Since there are also numerous Internet interventions available that are not evidence-based (70), the possible introduction of a certification that allows smokers to recognize validated eHealth interventions may further increase their willingness to use eHealth as it will assist their decision-making process.

Another example to illustrate the nonstructurally implemented offerings of EBSCIs is the offering of behavioral counseling in groups. Of the four agencies mentioned in the RA materials, only one offered group therapy at the time of writing. Smokers can choose between online sessions or meetings at a physical location. Physical meetings are only available in five of the 12 Dutch provinces, indicating low accessibility as a result of a long travel time. To provide smokers with a wider range of options with regard to physical group counseling and to facilitate PNs in their referral process, we recommend wider national coverage, as endorsed by the National Prevention Agreement (22). This can be facilitated by involving PNs from (teaching) hospitals, mental health-care institutions (GGZ), and addiction care services to spread the task of providing smoking cessation care. Other relevant stakeholders for developing and maintaining EBSCIs are organizations that aim to advance smoking cessation care in Dutch general practice (e.g., Trimbos institute, Quit

smoking Quality Register, Stop Smoking Partnership or Professional Association of Nurses [Beroepsvereniging Verzorgenden Verpleegkundigen; V&VN]). Together, they could form a network comparable to the highly effective English network of stop-smoking services (SSSs), which provides both brief cessation counseling and intensive group sessions as well as other forms of behavioral support, possibly supplemented by medication (425). The realization of this transmural cooperation has already been partly set in motion by the renewed version of the care standard for tobacco addiction, which describes how this complex care can be organized within the Dutch care system (426).

## 4. GENERAL CONCLUSIONS

In this dissertation, we aimed to explore the potential of an RA, aiming to increase referral to EBSCIs by educating PCPs about the effectiveness of these interventions and facilitating the referral process.

The studies described in this dissertation show that the RA was well appreciated among PCPs and that its use led to slightly more discussion and referral to EBSCIs. The RA was also appreciated by smokers, especially those who are motivated to quit smoking. Although the RA introduced a wide range of EBSCIs, this did not lead to decisional conflict among its users. However, no effects on smoking abstinence could be reported. This was most probably caused by both conditions receiving evidence-based counseling by their PN and the small study sample. Furthermore, the RA was not intensively used during the RCT, which was probably cased by barriers such as lack of time and a high workload. In this chapter we addressed some considerations regarding facilitating the recruitment of PCPs and smoking patients and their adherence to the RA. We also stated some recommendation for further research related to (1) the PCS (e.g., potentially increasing participation and improving implementation); (2) the RA described in this dissertation (e.g., developing a hybrid variant and supplementing the RA with various forms of motivational techniques, tailoring, video-based materials, and value-clarification exercises); and (3) smoking cessation in general (addressing the health insurance system and policy makers and improving the availability of and access to EBSCIs).

Overall, to increase the use of EBSCIS and implement the RA in the daily routine of PCPs, we can see the potential of the RA as described in this study in the PCs, for example as part of the Ask–Advise–Refer strategy. The available EBSCIs should be explained to smokers during the refer phase, or the RA should be used as a reference that smokers can consult themselves after talking to their PCP, which could decrease active counseling time. In order to stimulate implementation, the RA could therefore be included in national smoking cessation trainings aimed at PCPs. Furthermore, the development of a hybrid variant can support the use of the RA in preparation for a consultation with a PCP or allow the smoker to make their own choice regarding the use of EBSCIs in case the tool is offered online as a self-help tool.

# APPENDICES

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## IMPACT PARAGRAPH

Research is only effective and can have an impact when its results can be used, either in practice or as a springboard, for further research. The aim of the studies described in this dissertation was to increase the referral of smoking patients to EBSCIs. We wanted to achieve this by educating PCPs on the availability, usability, and effectiveness of EBSCIs and by facilitating the referral process to EBSCIs. We therefore developed a referral aid (RA) called the "StopWijzer" (which can be translated as "Stop guide" or "Stop smarter"). The referral aid (RA) did not change smoking cessation rates – which may be due to the fact that in both conditions effective care was provided by the PCPs and to the small sample size in the randomized controlled trial. The results did show that motivated smokers appreciated the RA suggesting that for implementation of such tools may a relevant impact on smokers motivated to quit to aid smoking cessation decision making.

**Research aim**

Our research showed us that PCPs expressed interested in receiving and using an overview of available EBSCIs, becaused they felt that they lacked knowledge on the subject, but also that they had little time in their counseling sessions to provide extensive counseling (Chapter 2). However, PCPs' use of the RA during our randomized controlled trial was low (described in chapter 3), resulting in a low recruitment rate of smoking patients (chapter 4). Therefore, we were unable to identify effects of the RA on smoking abstinence. Despite low adherence and high rate of attrition, the RA was received well by both PCPs and smoking patients and there was a trend toward more referral and use of EBSCIs in the experimental condition. An additional study on the intention to adopt the RA among PCPs, as described in Chapter 5, confirmed this positive appreciation of the RA. However, it also revealed that a large proportion of the PCPs surveyed had no intention of adopting the RA, which was influenced by a more negative attitude toward the advantages of the RA caused by lower self-efficacy and perceived barriers such as a lack of time. Further research suggested that the use of (decision) aids that aim to facilitate the decision-making process underlying the choice between several EBSCIs has the potential to bring about behavior change (i.e., smoking cessation – Chapter 6). Lastly, we tested the usability of an adapted standalone version of the RA among a group larger group of smokers (see Chapter 7). Most participants found the DA only moderately usable, though those who found it more usable often had a higher intention to quit. Based on the results of that study, recommendations to implement the RA for smokers motivated to quit were made. Additionally, recommendations to make the materials more usable and valuable for smokers not motivated to quite were made, such as motivational techniques, tailoring, using video-based information, and including value clarification methods. Furthermore, a hybrid variant was suggested where smokers could use the DA

independently and under the guidance of a PCP, which could aid both groups to choose an appropriate EBSCI option. Further research is needed to explore the possibilities of such a hybrid variant.

**Relevance of the results**

***Practical relevance***

First, as the RA was appreciated by smokers motivated to quit, implementation of such a guide may help this group to aid smoking cessation decision making. Second, the RA may also help PCPs to identify EBSCI's and to attune them smokers' needs. Yet, as its use in our RCT was still low, additional studies are needed on how to improve the RAs use in practice, e.g., by also including the RA in regular smoking cessation training programs. Third, as the RA was not optimally appreciated by smokers not motivated to quit, additional strategies to optimize the RA may be needed, such as including motivational elements tailored to the preferences and needs of this specific group.

***Scientific relevance***

We hoped that use of the RA could improve smoking cessation rates. Yet, we did not find this, potentially also because current care in both conditions of PCPs were sufficient. Testing the efficacy of the RA among those not using EBSCI's might be a next step, as one would hope that usage of the RA would lead to more use of EBSCIs. We also aimed to determine the potential factors facilitating and hindering the effectiveness and possible adoption and implementation of the RA. Although we were only able to provide some preliminary insights into the effects of the RA on smoking abstinence and EBSCI use, we were able to formulate conclusions about factors relevant for the daily practice in the PCS (e.g., the facilitators and barriers for using a DA within the limited timeframe of a counseling session). We also explored the possibilities of further developing the RA to make it possible to use it as a standalone version or as a part of 'blended care' (i.e., a combination of face-to-face counseling and web-based care), which can be used to reach a broader range of smokers willing to quit smoking.

***Societal relevance***

As tobacco use increases the risk of developing cancer and cardiovascular and pulmonary diseases, the burden of smoking in society remains enormous. The RA is of societal relevance, as it may help motivated smokers to find the most effective and preferred method to quit smoking, both among smokers individually as well as among smokers quitting with the aid of professionals. Additionally, it is of relevance as it provides PCPs a concise way to identify EBSCIs. Implementation of such tools in training programs of PCP's is thus recommended in order to facilitate identifying the relevant EBSCI's for smokers in their practice. By also paying special attention to groups with smoking-related complaints (which

accounted for approximately 50% of our sample), we aimed to increase smoking cessation success rates in this group, thus contributing to the decrease of the health divide in society. Yet, in order to optimize societal use, further implementation strategies are needed to target more smokers, also those who are unmotivated to quit yet to quit smoking, to increase societal impact.

**Involving target groups**

We identified three major target groups who can draw lessons from the outcomes of our study: (1) the PCS, as represented by PCPs; (2) the research field of smoking cessation care in the PCS, as represented by scientific researchers; and (3) society, as represented by policy makers in the field of prevention and professionals in the field of health insurance.

***Involving the primary care setting***

The PCS plays an important role in providing smoking cessation care at the individual level. Not only does the PCS have a wide reach but also a unique position, possessing the skills and knowledge to offer smokers the support they need to undertake a successful cessation attempt. Here, the first step is asking each patient whether they smoke (ask), advising smokers to quit (advice), and providing support to smokers who want to undertake a quit attempt (refer) based on the Dutch guidelines for smoking cessation care in the PCS. The RA described in this dissertation played a role in the referral part of this strategy by providing PCPs with an overview of the available EBSCIs. PCPs should also be aware of the vital role they play in engaging smokers with a lower SES or smoking-related complaints, as these group often have lower self-efficacy to ask for help.

To embed the findings of our research project within the PCS in a way that optimizes its impact, the active involvement of potential end-users during all phases of the development and diffusion of an intervention is required to ensure feasibility and effectiveness. Although we tried to include the PCS by using principles of co-creation (i.e., one-on-one interviews briefly mentioned in Chapter 3 and the Delphi study described in Chapter 2), to truly explore PCPs' needs and potential facilitators and barriers relevant for the RA, a more bottom-up approach may be needed. To enable true co-creation in further research, the constitution of a smoking cessation care working group may be considered. This group should include multiple potential end-users from the PCS, such as general practitioners and PNs, practice managers, and policy advisors from a wide array of PCSs, who should be involved in the various research phases whenever possible. Involving end-users from the start of a project would not only help to bridge the gap between daily practice and scientific research but may also facilitate motivation to adopt or to participate in associated research.

***Involving the scientific community***

To increase scientific impact, it is important to reach smoking cessation researchers in general and those in the field of smoking cessation care based in the PCS (i.e., those who develop smoking cessation interventions or guidelines with the aim of improving smoking cessation care in the PCS). At the time of writing, all studies included in this thesis had been submitted to or published in international peer-reviewed journals. Some findings described in this dissertation have also been presented and discussed at (inter)national congresses focused on smoking cessation, primary care, or decision making. Naturally, we will continue to try to involve researchers in the field of smoking cessation by reporting the findings of our studies via peer-reviewed and – when possible – open-access research journals. We recommend the field of research to actively look for solutions for the discovered barriers in this field. In addition to interventions targeting the PCS, we should also aim to increase the amount of evidence-based and structurally available EBSCIs, especially in the form of eHealth and mHealth.

Furthermore, the RA described in this dissertation and the insights provided by our research can perhaps be useful for the developers of the (Dutch) smoking cessation guidelines for the PCS. Although the guidelines currently recommend referring smokers to EBSCIs, they do not specify how this can be done in effectively and efficiently. The RA described in this dissertation can be used to improve the information provided by the guidelines or as a foundation for more specific information dissemination.

***Involving society***

The last important group that needs to be included to make the RA more suitable for widespread implementation in daily practice, is policy makers in the field of prevention and health promotion and professionals in the field of health insurance. As the Dutch proverb goes, prevention is better than cure. Next to preventing the younger generation to start smoking, the measures described in the National Prevention Agreement are mostly aimed at discouraging smoking among existing 'healthy' smokers to prevent them from developing smoking-related complaints. Smokers who seek to quit smoking, including those who are still relatively healthy (i.e., have not yet developed smoking-related complaints), should be able to receive smoking cessation aid, either as counseling or in a different form, as also endorsed by the RA. Policy makers should aim to facilitate smoking cessation counseling in the PCS by, for example, increasing reimbursements for counseling smoking patients, even when they do not have smoking-related complaints. To lower the threshold for a successful quit attempt even further, smokers should be provided with unlimited access to EBSCIs without it having to count towards the yearly deductible set by health insurers. Therefore, we recommend full reimbursement of evidence-based smoking cessation care and interventions to improve access to evidence-based help to quit and increase the use of EBSCIs when undertaking a cessation attempt.

In conclusion, our RA is one of the first attempts to guide both PCPs and smokers in identifying the optimal smoking cessation strategy for the smoker to quit smoking. Whereas the RA (also) targeted smokers who are not highly motivated to quit, it may be more practical and effective to use the RA for smokers who are motivated to quit. Despite indications showing positive evaluations concerning the RA's usability, strategies for identifying factors that facilitate its use by PCPs and smokers are essential to be able to demonstrate the beneficial effects of the use of such RAs on smoking cessation rates.

## ABBREVIATION LIST

| | |
|---|---|
| DA | decision aid |
| DGSCC | Dutch Smoking Cessation Guidelines |
| DRQSCP | Dutch Register for Qualified Smoking Cessation Professionals<br>Kwaliteitsregister Stoppen met Roken |
| EBSCI | evidence-based smoking cessation intervention |
| GP | general practitioner |
| HCPs | health care professionals |
| ICM | integrated change model |
| NRT | nicotine replacement therapy |
| PCPs | primary care professionals |
| PCS | primary care setting |
| PN | practice nurse |
| RA | referral aid |
| RCT | randomized controlled trail |
| SCC | smoking cessation counseling |
| SCI | smoking cessation interventions |
| SES | social economic status |
| TPB | theory of planned behavior |

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## SUMMARY

Smoking is still one of the leading causes of illness and premature death among the general population, but especially among groups with a lower socioeconomic status. It is therefore crucial to improve smoking cessation strategies. The primary care setting (PCS) can play a key role in reaching smokers because of its strategic position in the health-care system and the existence of guidelines aimed at providing evidence based smoking cessation care by practice nurses (PNs) and other primary care professionals (PCPs). These guidelines recommend discussing the use of evidence-based smoking cessation interventions (EBSCIs) such as behavioral counseling (face-to-face counseling, eHealth, group counseling, or counseling over the telephone) and pharmacological supplementations (nicotine replacement therapy or pharmacotherapy in the form of non-nicotine medication). Using EBSCIs can double the chance of success of a smoking cessation attempt, but unfortunately, EBSCIs are still structurally underused. To increase the use of EBSCIs and to support referral by PCPs to EBSCIs during consultations, a referral aid (RA) for smoking cessation interventions for smoking patients within the PCS was developed. The overall aim of the dissertation is to describe the process of the development of this RA and to investigate its potential.

*Chapter 1* provides a general introduction to Chapters 2–7 of this dissertation, including important background information, details on the theoretical groundings, and the research questions of the studies reported on in this dissertation. Chapters 2–5 describe the potential of the RA in the PCS, and Chapters 6 and 7 explore further applications of the RA.

**Part I: The potential of an RA in the PCS**

*Chapter 2* presents a Delphi study that aimed to obtain an overview of the knowledge and viewpoints on the effectiveness and use of EBSCIs among PCPs. A three-round online Delphi study was conducted among researchers and PCPs to gain an overview of (1) the criteria that are important for recommending EBSCIs, (2) the perceptions of both groups on the effectiveness of EBSCIs, (3) the factors to consider when counseling different (high-risk) groups of smokers, and (4) the perceptions of both groups on the use of e-cigarettes as an EBSCI. We found a high level of agreement within the groups on which characteristics of smokers should be considered when recommending an EBSCI. We also found that PCPs displayed a lower consensus on the effectiveness of EBSCIs. Both groups valued the use of special protocols for different (high-risk) groups of patients, but the two groups did not reach a consensus on the use of e-cigarettes as an effective means to quit. This inventory of PCPs' needs regarding EBSCIs, and their usage provided us with clear directions to facilitate a higher uptake of and referral to EBSCIs in the PCS.

*Chapter 3* describes the study protocol of the RA, including the RAs development and study design of the randomized controlled trial (RCT). The RA was named the "StopWijzer," which can be translated as either "Stop guide" or "Stop smarter." The RA aimed to help PNs, and smokers identify an individual patient's preferred method for quitting smoking, and the aim of developing this resource was to increase the use of EBSCIs for smoking cessation. The PNs in the experimental condition received an intervention manual to aid them in discussing smoking cessation with their patients and to help them select an EBSCI that fits patients' needs and preferences. Smoking cessation interventions included in the RA are (1) face-to-face counseling, (2) counseling via the Internet (eHealth), (3) telephone counseling, (4) group counseling, (5) pharmacotherapy, and (6) nicotine replacement therapy. The latter two were preferably combined with a counseling method. Patients who agreed to participate in the study were counseled in accordance with the RA and were stimulated to use an included EBSCI to quit. The principal component was an instruction manual for using the RA, which was also available online. Additional elements were a handout with flowcharts from the manual, a placemat with an overview of all available EBSCIs, and several promotion materials (flyers, posters, business cards, notebook, and pen).

*Chapter 4* presents the results of the process and effect evaluation among smoking patients recruited through PNs in the PCS throughout the Netherlands. The aim of this study was to explore the use, appreciation, and effects of the RA from the perspective of two user groups: (1) PNs (n = 73) and (2) smokers (n = 285). To optimally explore the experiences of both groups, two studies were conducted, namely (1) an RCT among smoking patients recruited by PNs and (2) a process evaluation among a subgroup of these PNs that participated in the trial to investigate the course of the recruitment process. In both groups, the response was low. Overall, PNs found the RA materials to be clear and understandable. Smokers had similar but (slightly) fewer positive opinions. However, the RA was not intensively used, and the experimental groups of smokers did not differ in their rate of smoking abstinence compared with the control group. Since the RA was well-received by both PNs and smokers, the RA is potentially suitable for implementation in the PCS. We concluded that further research should be aimed at determining how to facilitate the adoption of the RA within the PCS as well as how to better involve PNs and smokers when recruiting for an RCT and at how to foster effective counseling and referral to EBSCIs.

*Chapter 5* presents the factors associated with the intention to adopt an RA facilitating the referral to EBSCIs by PCPs in charge of smoking counseling in the PCS (partly from the main study described in Chapter 4 and partly newly gained). Participants (n = 85) were recruited for a cross-sectional study from June to September 2020 and were asked to fill in online questionnaires that were based on the I-Change Model. T-tests were used to compare adopters (n = 37) with nonadopters (n = 48) on predisposing (demographics),

motivational (attitude, social support, and self-efficacy), and post-motivational (perceived skills and barriers) factors. Logistic regression analyses were conducted to explore factors explaining the intention to adopt. Although appreciation was high in both groups, most PCPs did not intend to adopt the RA (>50%). Nonadopters reported an overall more negative attitude toward the RA than adopters by perceiving fewer advantages and more disadvantages, experienced less social support, and had a low level of self-efficacy. They also experienced more barriers such as a lack of time and a lack of skills. These factors were also associated with the intention to adopt. Recommendations for future adoption include improving the tool itself through a second round of co-creation focusing on the adoptability of the RA in practice. A second recommendation pertains to communicating the added value of referring to EBSCIs and integrating the RA's use in smoking cessation training for PCPs. Doing so may help to increase a positive attitude, social support, self-efficacy, and perceived skills toward using the RA among PCPs.

**Part II: Future applications and possibilities**

*Chapter 6* describes the outcomes of a scoping review that explored the literature regarding decision aids (DAs) supporting decision making about diet, physical activity, sleep, and substance use, including smoking cessation. Interventions had to (1) support informed decision making and (2) provide information and assist in choosing between a minimum of two options. Thirty-five scientific articles and four DAs (gray literature) were included, among which 29 (94%) described substance use. All DAs offered users information and possibilities for value and/or preference clarification as well as many other elements, such as goal setting. Few articles used standardized measures, such as decisional conflict (n = 4, 13%). Although the review only found some positive behavioral effects of the use of DAs, this study contributes to charting the existing decision aids and RAs in health promotion, their behavioral effects, and the areas of improvement (e.g., effective intervention elements and development).

*Chapter 7* describes a freestanding usability study conducted in September 2020 on a standalone version of the RA (DA) with smokers (n = 497) recruited through an online research panel using a cross-sectional design. The aim of this study was threefold: (1) to conduct a usability evaluation of a standalone version of the RA; (2) to evaluate the level of appreciation and informed decision making after using the RA; and (3) to determine a possible change in the intention to use EBSCIs before and directly after reviewing the DA. T-tests and Chi-square tests were conducted to test the differences between smokers who differed in perceived usability of the DA in program appreciation and in decisional conflict. Most participants evaluated the usability of the DA as moderate (MU; n = 393, 79.1%) or good (GU; n = 104, 20.9%); by contrast, those who intended to quit found it more usable. Most Participants found the DA only moderately usable, although those who found it more

usable often had a significant higher intention to quit. Participants who found the usability of the DA to be good rated all elements higher concerning the evaluation of the DA (including recommendation to others and overall mark) and experienced less decisional conflict with regard to choosing a potential EBSCI after reviewing the DA. Furthermore, after reviewing the DA, participants on average had a significantly higher intention to use more EBSCIs, particularly in the form of eHealth. We concluded that the RA can be of use to smokers who have an intention to quit smoking. Recommendations for making the DA more usable and well-received among a broader group of smokers include performing tailoring, transforming text-based information into video-based information, and including value-clarification methods. Furthermore, as the DA was only found to be moderately usable in the standalone version, a hybrid variant where smokers can use the DA on their own and with the guidance of a PCP could aid both groups in choosing a fitting EBSCI option.

Finally, *Chapter 8* discusses the results presented in Chapters 2–6 of the dissertation and contains some considerations of the studies described above, including recommendations for future research and practice. The goal of the research was to develop an RA to help PCPs refer to EBSCIs in order to increase the use of EBSCIs among smokers. The studies described in this dissertation show that the RA was well appreciated among PCPs and that its use led to slightly more discussion and referral to EBSCIs. The RA was also appreciated by smokers, especially those who are motivated to quit smoking. Although the RA introduced a wide range of EBSCIs, this did not lead to decisional conflict among its users. However, no effects on smoking abstinence could be reported. This was most probably caused by both conditions receiving evidence-based counseling by their PN and the small study sample. Furthermore, the RA was not intensively used during the RCT, which was probably cased by barriers such as lack of time and a high workload. In this chapter we addressed some considerations regarding facilitating the recruitment of PCPs and smoking patients and their adherence to the RA. We also stated some recommendation for further research related to (1) the PCS (e.g., potentially increasing participation and improving implementation); (2) the RA described in this dissertation (e.g., developing a hybrid variant and supplementing the RA with various forms of motivational techniques, tailoring, video-based materials, and value-clarification exercises); and (3) smoking cessation in general (addressing the health insurance system and policy makers and improving the availability of and access to EBSCIs).

Overall, to increase the use of EBSCIS and implement the RA in the daily routine of PCPs, we can see the potential of the RA as described in this study in the PCs, for example as part of the Ask–Advise–Refer strategy. The available EBSCIs should be explained to smokers during the refer phase, or the RA should be used as a reference that smokers can consult themselves after talking to their PCP, which could decrease active counseling time. In order to stimulate implementation, the RA could therefore be included in national smoking

cessation trainings aimed at PCPs. Furthermore, the development of a hybrid variant can support the use of the RA in preparation for a consultation with a PCP or allow the smoker to make their own choice regarding the use of EBSCIs in case the tool is offered online as a self-help tool.

## SAMENVATTING

Roken is nog steeds een van de belangrijkste oorzaken van ziekte en vroegtijdig overlijden onder de algemene bevolking, maar vooral onder groepen met een lagere sociaaleconomische status (SES). Het is daarom belangrijk om de bestaande stoppen-met-rokenstrategieën te verbeteren. Vanwege de strategische positie in het gezondheidssysteem kan de eerstelijnszorg bijdragen in het bereiken van rokers. Ook beschikt de eerstelijnszorg over duidelijke richtlijnen gericht op het verbeteren van de effectieve stoppen-met-rokenzorg door praktijkondersteuners (POHs) en andere (eerstelijns-)zorgprofessionals (ZPs). In deze richtlijnen wordt ook gesproken over het gebruiken van evidence-based stoppen-met-roken-interventies (EBSMRIs). Deze EBSMRIs bestaan uit vormen van gedragscounseling (face-to-facecounseling, eHealth, groepscounseling of counseling via de telefoon) en uit farmacotherapie (nicotinevervangende middelen of SMR-medicatie). Het gebruik van EBSMRIs kan de kans op succes van een stoppoging verdubbelen, maar helaas worden EBSMRIs structureel onderbenut. Om POHs te ondersteunen bij het bespreken van EBSMRIs en hiermee het gebruik van EBSMRIs te verhogen is een verwijshulp ontwikkeld. Het algemene doel van dit proefschrift is het beschrijven van het ontstaan van deze verwijshulp en het onderzoeken van de mogelijkheden ervan.

*In hoofdstuk 1* wordt een algemene inleiding gegeven op de hoofdstukken 2 – 7 van dit proefschrift, met inbegrip van achtergrondinformatie, de theoretische onderbouwingen en de onderzoeksvragen van de studies in dit proefschrift. In hoofdstukken 2 – 5 wordt vervolgens de potentie van een verwijshulp in de huisartspraktijk beschreven, waarna in hoofdstukken 6 en 7 mogelijke andere toepassingen van de verwijshulp geëxploreerd worden.

**Deel I: Het potentieel van een verwijshulp in de eerstelijnsgezondheidszorg**
*In hoofdstuk 2* wordt een Delphi-studie gepresenteerd waarin de kennis en standpunten van professionals in de eerstelijnsgezondheidszorg met betrekking tot het gebruik en de doeltreffendheid van EBSMRIs wordt beschreven. Een online Delphi-studie van drie ronden is uitgevoerd onder onderzoekers en ZPs om een overzicht te verkrijgen van 1) de criteria die belangrijk zijn voor het aanbevelen van SMR-interventies, 2) de visies van beide groepen op de effectiviteit van SMR-interventies, 3) de factoren waarmee rekening gehouden moet worden bij het begeleiden van verschillende (hoogrisico)groepen rokers en 4) de visies op het gebruik van e-sigaretten als een hulpmiddel om te stoppen. Beide groepen vertoonden een hoge mate van overeenstemming omtrent karakteristieken van rokers die in aanmerking dienen genomen te worden bij het selecteren van een te adviseren EBSMRI. Voorts bleken de ZPs een lagere mate van consensus te vertonen over de doeltreffendheid van EBSMRIs. Daarnaast waardeerden beide groepen het gebruik van speciale protocollen voor

verschillende (hoogrisico)groepen patiënten, maar bereikten geen consensus over het gebruik van e-sigaretten als stophulpmiddel. Deze inventarisatie van de behoeften van ZPs met betrekking tot EBSMRIs gaf ons een beter inzicht in de wijze waarop het gebruik van en verwijzen naar EBSMRIs in de eerstelijnszorg gefaciliteerd kan worden.

*Hoofdstuk 3* beschrijft het onderzoeksprotocol van de verwijshulp (de StopWijzer), inclusief de ontwikkeling en de opzet van het gerandomiseerde onderzoek met zowel een experimentele- als controlegroep om de effectiviteit van de verwijshulp te toetsen. Het doel van de verwijshulp was het ondersteunen van POHs bij het verwijzen van rokende patienten naar EBSMRIs en daardoor het gebruik van EBSMRIs te verhogen. De POHs in de experimentele groep ontvingen een handleiding voor de interventie met het doel om hen te ondersteunen bij het SMR-gesprek met hun patiënten en het selecteren van een EBSMRI die aansluit op de behoeften en voorkeuren van de patiënt. EBSMRIs die in de verwijshulp waren opgenomen zijn 1) face-to-facecounseling, 2) counseling via internet (eHealth), 3) telefonische counseling, 4) groepscounseling, 5) farmacotherapie en 6) nicotinevervangingstherapie. De laatste twee werden bij voorkeur gecombineerd met een gedragsveranderingsmethode. Patiënten die instemden met deelname aan het onderzoek werden conform de verwijshulp begeleid. Naast de eerdergenoemde handleiding, die het belangrijkste onderdeel van de verwijshulp was en ook online te bekijken, ontvingen deelnemende POHs ook aanvullende elementen in de vorm van een hand-out met de in de handleiding weergegeven stroomdiagrammen, een placemat met een overzicht van alle beschikbare EBSMRIs en diverse promotiematerialen (flyers, posters, visitekaartjes, notitieboek en pen).

*Hoofdstuk 4* presenteert de resultaten van de evaluatie van het proces en de effectiviteit van de StopWijzer onder rokende patiënten die door POHs zijn geworven in de eerstelijnszorg in heel Nederland. Het doel van deze studie was om het gebruik, de waardering en de effecten van de verwijshulp te onderzoeken vanuit het perspectief van twee gebruikersgroepen: 1) POHs (n=73) en 2) rokers (n=285). Om de ervaringen van beide groepen optimaal in kaart te brengen zijn twee verschillende onderzoeken uitgevoerd; namelijk 1) een gerandomiseerde gecontroleerde studie onder rokende patiënten die door POHs zijn geworven en 2) een procesevaluatie onder een subgroep van deze POHs om het verloop van het wervingsproces te onderzoeken. In beide groepen was de respons laag. Over het algemeen vonden POHs de StopWijzermaterialen duidelijk en begrijpelijk. Rokers hadden doorgaans een vergelijkbaar maar (iets) minder positief oordeel. De verwijshulp werd echter niet intensief gebruikt, en de rokers in de experimentele groepen verschilden niet in hun mate van rook abstinentie in vergelijking met de rokers in de controlegroep. Aangezien de verwijshulp wel goed werd ontvangen door zowel POHs als rokers en er een hoger aantal EBSMRIs werd gebruikt in de experimentele conditie (vooral in de vorm van

eHealth, groepsconsultatie en nicotinevervangingstherapie, waar deze toename significant was), is de verwijshulp mogelijk geschikt voor implementatie in de eerstelijnszorg. Wij concluderen dat vervolgonderzoek gericht moet zijn op het beoordelen van 1) hoe de adoptie van de verwijshulp binnen de eerstelijnszorg kan worden vergemakkelijkt en 2) hoe POHs en rokers beter kunnen worden betrokken bij de werving voor een RCT en hoe effectieve begeleiding en verwijzing naar EBSMRIs kunnen worden bevorderd.

*Hoofdstuk 5* presenteert factoren die samenhangen met de intentie van ZPs die verantwoordelijk zijn voor SMR-begeleiding in de huisartsenpraktijk om een verwijshulp ter bevordering van het gebruik van EBSMRIs te adopteren. Deelnemers (n=85; deels geworven onder deelnemers aan het hoofdonderzoek beschreven in hoofdstuk 4 en deels nieuw geworven) werden geworven voor een cross-sectioneelonderzoek van juni tot september 2020 en werden gevraagd om online vragenlijsten in te vullen die gebaseerd waren op het I-Change Model. T-tests werden gebruikt om adoptanten (n=37) te vergelijken met niet-adoptanten (n=48) op predisponerende (demografisch), motivationele (attitude, sociale steun en zelfeffectiviteit) en post-motivationele (waargenomen vaardigheden en barrières) factoren. Hoewel de waardering voor de verwijshulp in beide groepen hoog was, waren de meeste ZPs niet van plan om deze te adopteren (>50%). Niet-adoptanten rapporteerden over het algemeen een negatievere houding ten opzichte van de verwijshulp dan adoptanten door minder voordelen en meer nadelen te zien, minder sociale steun te ervaren, en een lagere eigen effectiviteit te ervaren. Verder ervaarden zij meer barrières, zoals gebrek aan tijd en gebrek aan vaardigheden. Deze factoren werden ook geassocieerd met de intentie tot adoptie. Aanbevelingen voor toekomstige adoptie zijn onder andere het verbeteren van het instrument zelf door een aanvullende ronde van co-creatie gericht op het verbeteren van de praktische adopteerbaarheid van de verwijshulp. Verdere aanbevelingen hebben betrekking op het communiceren van de toegevoegde waarde van het gebruik van en het verwijzen naar EBSMRIs en het integreren van het gebruik van de verwijshulp in stoppen-met-rokentraining voor ZPs. Dit kan helpen om onder ZPs de attitude, sociale steun, eigen effectiviteit en waargenomen vaardigheden in relatie tot het gebruik van de verwijshulp te verhogen.

**Deel II: Toekomstige veranderingen en mogelijkheden**

*Hoofdstuk 6* beschrijft de uitkomsten van een scoping-review waarin onderzoek werd gedaan naar literatuur over keuzehulpen die besluitvorming over voeding, lichaamsbeweging, slaap en middelengebruik (waaronder SMR) ondersteunen. De interventies moesten 1) geïnformeerde besluitvorming ondersteunen en 2) informatie verstrekken en helpen om te kunnen kiezen tussen ten minste twee opties. Vijfendertig wetenschappelijke artikelen en vier keuzehulpen werden geïncludeerd, waarvan er 29 (94%) middelengebruik betroffen. Alle keuzehulpen boden gebruikers informatie en mogelijkheden tot waarde- en/of

voorkeursverheldering. Daarnaast werden ook vele andere elementen aangeboden, zoals doelformulering. In slechts weinig van de geïncludeerde artikelen werd gebruik gemaakt van gestandaardiseerde maten, zoals bijvoorbeeld beslissingsconflict (n = 4; 13%). Hoewel uit het onderzoek slechts enkele positieve gedragseffecten van keuzehulpen bleken, heeft deze studie bijgedragen aan het in kaart brengen van de bestaande besluitvormings- en doorverwijzingshulpmiddelen binnen de gezondheidsbevordering, hun positieve gedragseffecten en de verbeterpunten.

*Hoofdstuk 7* beschrijft een vrijstaande *usability* (gebruiksgemak) studie uitgevoerd in september 2020 op basis van een standalone versie van de verwijshulp (beslissingshulp) onder rokers (n=497) gerekruteerd via een onlineonderzoek panel met behulp van een cross-sectioneeldesign. Het doel van dit onderzoek was drieledig: 1) het uitvoeren van een gebruiksgemakevaluatie van een op zichzelf staande versie van de verwijshulp 2) het evalueren van de mate van waardering en geïnformeerde besluitvorming na gebruik van de verwijshulp en 3) het bepalen van een mogelijke verandering in de intentie om EBSMRIs te gebruiken vóór en direct na het beoordelen van de beslissingshulp. De mogelijke veranderingen in de intentie om EBSMRIs te gebruiken tijdens een stoppoging vóór en na het beoordelen van de DA werden getest met t-tests en McNemar. Deelnemers beoordeelden de bruikbaarheid van de beslissingshulp als matig (MU; N=393, 79,1%) of goed (GU; N=104, 20,9%). De meeste deelnemers vonden de beslissingshulp slechts matig bruikbaar, deelnemers die de beslissingshulp meer bruikbaar vonden hadden ook vaak een hogere intentie om te stoppen. Deelnemers die de beslissingshulp wel goed bruikbaar vonden, beoordeelden alle elementen betreffende de evaluatie van de beslissingshulp (inclusief de aanbeveling aan anderen en het algemene rapportcijfer) beter en ervaarden minder beslissingsconflicten ten opzien van het kiezen van een potentiele EBSMRIs nadat zij de materialen hadden bekeken. Daarnaast hadden de deelnemers na het doornemen van de beslissingshulp gemiddeld een significant hogere intentie om EBSMRIs te gebruiken, met name in de vorm van eHealth. Aanbevelingen om de beslissingshulp bruikbaarder te maken, waardoor deze beter zal worden ontvangen door een bredere groep rokers, zouden kunnen bestaan uit tailoring op de voorkennis van de gebruikers, het omzetten van op tekst gebaseerde informatie in op video gebaseerde informatie en het opnemen van methoden voor het verhelderen van de waarde. Omdat de beslissingshulp slechts matig bruikbaar bleek in de standalone versie, zou een hybride variant waarbij rokers de beslissingshulp zowel zelfstandig als met begeleiding van een ZP kunnen gebruiken, beide groepen mogelijk kunnen helpen bij het kiezen van een passende EBSMRI.

Ten slotte bespreekt *hoofdstuk 8* de resultaten gepresenteerd in de hoofdstukken 2-7 van dit proefschrift. Ook bevat dit hoofdstuk een aantal overwegingen van de hierboven beschreven studies inclusief aanbevelingen voor toekomstig onderzoek en de

uitvoeringspraktijk. Het doel van het onderzoek was om een RA (referral aid, verwijshulp) te ontwikkelen om ZPs te helpen bij het verwijzen naar EBSMRIs om zo het gebruik van EBSMRIs onder rokers te verhogen. De studies beschreven in dit proefschrift laten zien dat de RA goed werd gewaardeerd door ZPs en dat het gebruik ervan leidde tot iets meer discussie en doorverwijzing naar EBSMRIs. De RA werd ook gewaardeerd door rokers, vooral door degenen die gemotiveerd zijn om te stoppen met roken. Hoewel de verwijshulp een breed scala aan EBSMRIs introduceerde, leidde dit niet tot beslissingsconflicten onder de gebruikers. Er konden echter geen effecten op rookabstinentie worden gemeld. Dit werd hoogstwaarschijnlijk veroorzaakt door het feit dat beide condities evidence-based counseling ontvingen van hun POH en door de kleine studiesteekproef. Verder werd de verwijshulp niet intensief gebruikt tijdens de RCT, wat waarschijnlijk werd veroorzaakt door barrières zoals gebrek aan tijd en een hoge werkdruk. In dit hoofdstuk hebben we een aantal overwegingen besproken met betrekking tot het vergemakkelijken van de werving van ZPs en rokende patiënten en hun therapietrouw aan de verwijshulp. We hebben ook enkele aanbevelingen gedaan voor verder onderzoek met betrekking tot (1) de ZPs (bijv. mogelijk verhogen van deelname en verbeteren van implementatie); (2) de verwijshulp beschreven in dit proefschrift (bijv. ontwikkelen van een hybride variant en aanvullen van de verwijshulp met verschillende vormen van motiverende technieken, tailoring, video-gebaseerde materialen, en waarde-verklaringsoefeningen); en (3) stoppen met roken in het algemeen (aanspreken van het zorgverzekeringssysteem en beleidsmakers en het verbeteren van de beschikbaarheid van EBSMRIs).

Om het aantal gegeven stopadviezen in de eerstelijnszorg te verhogen en de verwijshulp in de dagelijkse routine van de ZPs (voornamelijk POHs) te implementeren, zien we mogelijkheden om de verwijshulp te implementeren in de praktijk, bijvoorbeeld binnen het verwijsonderdeel van de strategie Ask-Advize-Refer (AAR: vraag, adviseer, verwijs). Op deze manier kan de verwijshulp dienen om de beschikbare EBSMRIs aan rokers uit te leggen tijdens de verwijsfase, maar ook als een referentie die rokers zelf kunnen raadplegen na het gesprek met de ZP, wat de actieve begeleidingstijd kan verminderen. Om de implementatie te stimuleren, zou de RA daarom kunnen worden opgenomen in nationale stoppen met roken trainingen gericht op POHs. Verder kan de ontwikkeling van een hybride variant het gebruik van de RA ondersteunen ter voorbereiding op een consult met een ZP of de roker in staat stellen een eigen keuze te maken met betrekking tot het gebruik van EBSMRIs in het geval de tool online wordt aangeboden als een zelfhulp tool.

## CURRICULUM VITAE

Daniëlle Nicole Zijlstra was born on the 23rd of October 1993 in Hoogeveen, the Netherlands. After graduating high school (Pre-University Education; Culture and Society) at the Roelof van Echten College in 2012, she studied Psychology (Bachelor) at the University of Twente, from which she graduated in 2015. She subsequently studied Positive Psychology and Technology (Master) until July 2016.

In January 2017, Daniëlle started working as a PhD-student at the Department of Health Promotion at Maastricht University. For four and a half years she worked on several studies regarding the StopWijzer-project that are described in this dissertation. Besides her work on the StopWijzer-project, she has also been actively involved in teaching activities in the Bachelor of Health Sciences and the Master of Health Education and Promotion. These teaching experiences led her to receive the Basic Teaching Qualification Certificate.

Daniëlle currently continues to work as a full-time teacher in various educational roles (tutor, mentor, trainer, course planning member) at the Department of Health Promotion at Maastricht University. She aspires to further develop her teaching and mentoring skills as well as to focus on educational research and development.

## PUBLICATION LIST

### Publications in this thesis

Zijlstra, D. N., Hoving, C., Bolman, C. A. W., Muris, J. W. M. & De Vries, H. (2021). Do professional perspectives on evidence-based smoking cessation methods align? A Delphi study among researchers and healthcare professionals. *Health Education Research.* https://doi.org/10.1093/her/cyab022

Zijlstra, D. N., Muris, J. W. M., Bolman, C. A. W., Elling, J. M., Knapen, V. E. R. A. & De Vries, H. (2021). A referral aid for smoking cessation interventions in primary care: Study protocol for a randomized controlled trial. *Primary Health Care Research & Development,* 22, E22. https://doi.org/10.1017/S1463423621000244

Zijlstra, D. N., Muris, J. W. M., Bolman, C. A. W. & De Vries, H. (2021). What went wrong? A randomized controlled trial of a process and effect evaluation of a referral aid for smoking cessation counseling in primary care. *Manuscript submitted for publication.*

Zijlstra, D. N., Bolman, C. A. W., Muris, J. W. M. & De Vries, H. (2021). How to convince more primary care professionals to adopt a valued smoking cessation tool: Facilitators and barriers. *Manuscript submitted for publication.*

Gültzow, T., Zijlstra, D. N., Bolman, C. A. W., de Vries, H., Dirksen, C. D., Muris, J. W. M., Smit, E. S., & Hoving, C. (2021). Decision aids to facilitate decision making around behavior change in the field of health promotion: A scoping review. *Patient Education and Counseling*. https://doi.org/10.1016/j.pec.2021.01.015

Zijlstra, D. N., Bolman, C. A., Muris, J. W., & de Vries, H. (2021). The Usability of an Online Tool to Promote the Use of Evidence-Based Smoking Cessation Interventions. *International Journal of Environmental Research and Public Health*, 18(20), 10836. https://doi.org/10.3390/ijerph182010836

### Presentations at (inter)national congresses

**Care and Public Health Research Institute (CAPHRI) Research Day, 2017, Maastricht, Nederland**
**Poster:** Making your own choice – A study on smoking cessation among smokers with smoking related complains.

**16th International Conference on Communication in Healthcare (ICCH), 2018, Porto, Portugal**
**Presentatie:** General Practice Professional needs and expectations regarding a patient smoking cessation support
**Poster:** An integral Pro-Active Multicomponent Approach (PAMA) to optimize and tailor smoking cessation strategies for the primary health care (PHC) setting

**Nederlands Netwerk voor Tabaksonderzoek (NNvT) congres, 2018, Utrecht, Nederland**
**Presentatie:** Delphi studie naar consensus tussen onderzoekers en zorgprofessionals over evidence-based stoppen met roken interventies in de huisartspraktijk

**ZonMW Werkconferentie, 2018, Utrecht, Nederland**
**Presentatie:** An integral Pro Active Multicomponent Approach (PAMA) to optimize and tailor smoking cessation strategies for the primary health care (PHC) setting

**COPD & Astma Huisartsen Advies Groep (CAHAG) conferentie, 2019, Zeist, Nederland**
**Presentatie:** StopWijzer - De stoppen-met-roken keuzetool voor in de Huisartspraktijk

**Nederlands Netwerk voor Tabaksonderzoek (NNvT) congres, 2019, Utrecht, Nederland**
**Presentatie:** Het stimuleren van verwijzingen naar effectieve counseling door de huisartspraktijk (onderdeel van symposium: *Never change a winning team? Of blijft het belangrijk om nieuwe manieren te zoeken om tabaksgebruik aan te pakken?*)

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