GENERAL INTRODUCTION
The risks/prevalence of an unhealthy lifestyle
Insufficient physical activity, smoking, high levels of alcohol consumption, an unhealthy diet and low levels of relaxation characterize an unhealthy lifestyle. Over the past decades we have learned that an unhealthy lifestyle is associated with chronic diseases, like cardiovascular diseases, type-2 diabetes and certain types of cancer [1, 2]. In addition physical inactivity (decreased energy expenditure) and unhealthy nutrition (increased energy intake) lead to a positive energy balance, which leads to overweight and obesity in the long-run [1, 2]. This is unfortunate, since we can prevent those lifestyle-related conditions by adopting and maintaining a healthy lifestyle [1, 2]. Nonetheless, the prevalence of an unhealthy lifestyle among the Dutch population is high. This is also true for overweight and obesity. In 2014, 49% of the Dutch working population (aged 20 to 65 years) was overweight (Body Mass Index [BMI] ≥ 25 kg m⁻²), of which 13% was obese (BMI>30 kg m⁻²)[3]. In 2013, 58% of the Dutch adult population aged 18 years of older met the guideline for moderate intensity physical activity. This guideline states that adults should engage in physical activity of at least moderate intensity (4.5 to 6 MET; MET stands for metabolic equivalent and expresses the intensity of physical activity in terms of oxygen consumption per kg body weight per minute where 1 MET equals 3.5 ml oxygen per kg body weight per minute) for at least 30 minutes a day on at least five days a week. Additionally, 21% of the Dutch adult population met the guideline for high intensity (≥6.5 MET) physical activity, i.e. adults should engage in physical activity of high intensity for at least 20 minutes a day at least three days a week [4]. In 2012, the prevalence of smoking among Dutch adults was 23% and 7% had high levels of alcohol consumption (i.e., for men more than 2 glasses of alcohol a day and for women more than 1 glass of alcohol a day) [5, 6]. An unhealthy diet is also very common: in 2012 30% of the Dutch adult population met the norms for vegetable consumption (i.e., at least 200 grams of vegetables per day, 7 days a week), and 44% met the fruit consumption norm (i.e., at least 2 pieces of fruit per day, 7 days a week) [4].

Benefits of worksite health promotion programs
The WHO states that the workplace directly influences the physical, mental, economic and social well-being of employees and in turn the health of their families, communities and society [7]. Based on this statement, they identified the workplace as one of the priority settings for health promotion in the 21st century [7, 8]. As a consequence, worksite health promotion (WHP) programs have been developed and implemented in research setting (i.e. (randomized) controlled trials) more frequently during the past two decades.
In these studies the coordination of the development and implementation was in the hands of Universities or other research institutes. As employees spend up to 60% of their waking hours at the workplace, a large proportion of the adult population can be reached at once, in groups as well as individually [7, 10-12]. In addition, workplaces allow for the implementation of multi-component interventions that not only influence individual health behaviors, but also could address organizational and environmental factors to maximize impact [11, 13]. Furthermore, they offer an existing infrastructure (i.e., communication channels, social networks and organizational structures) and social support system, making the workplace a convenient setting to stimulate a healthy lifestyle [7, 10]. However, besides these opportunities, the worksite can also be a complicated setting for health promotion activities. First, working adults are in general healthier compared to the general population and compared to non-working adults [14]. Second, ethical issues can play a role, since the worksite is primarily intended for working, not for promoting health and a healthy lifestyle of employees [10, 15]. Related to this, an employee is dependent on an employer. So, privacy and autonomy issues could play a role and the general feeling of employees could be that interference of employers with employee’s health might go beyond their ‘jurisdiction’ [10, 16-18]. However, employees are not legally obliged to engage in worksite health promotion initiatives [9]. Additionally their health status may not at all be disclosed to their employer. It is only allowed to provide results of periodic health checks (including information of lifestyle) to an employer on a group level and not on an individual level, in order to avoid discrimination on the basis of health risks [19-21]. The Dutch Ministry of Public Health, Welfare and Sports (i.e. “Ministerie van Volksgezondheid, Welzijn en Sport”) also stipulates that employers have a duty to take care of the health of their employees [22]. In addition, the European occupational health and safety legislation states that employers are obligated to offer their employees a periodic health check to prevent or limit risks related to employees health caused by their work (environment) [23]. However, this legislation does not mean that employers and employees are legally obliged to engage themselves in a WHP program [9]. Implementing a WHP program is not only beneficial for the individual employee. Organizations may also benefit from these programs, as overweight and unhealthy employees have lower productivity levels, decreased work ability and higher sickness absenteeism rates [24-28]. As research has shown that WHP programs can favorably affect important outcomes from an organizational perspective, such as sickness absence, presenteeism and productivity, organizations could benefit in terms of lowering costs [2, 11, 12, 29, 30]. Although the effectiveness of WHP programs is variable across studies on health
and lifestyle related outcomes on the employee level, indeed positive effects have been reported among participants on behaviors such as physical activity, healthy nutrition and smoking cessation. In addition, studies have reported a significant decrease in the number of employees with obesity [1, 31-36]. Several intervention strategies aimed at improving the health and lifestyle of employees have been investigated over the years. However, multi-component interventions in which several strategies (i.e., environmental, educational and individual) are combined are most effective in improving the lifestyle of employees, provided that they were implemented successfully [37]. However, successful implementation of WHP in daily practice is lacking often [38-42].

Implementation of WHP programs

Literature applies many different terms and definitions for ‘implementation research’. Implementation could best be defined as “an effort specifically designed to get best practice findings and related products into routine and sustained use through appropriate uptake/adoption of interventions” [43]. However, despite the positive effects of WHP programs on both the employee and the organizational level, WHP programs are rarely implemented and used in daily routine or practice. So broad-scale, nationwide implementation of effective WHP programs that promote a healthy lifestyle across a wide range of settings fails [38-42]. An important question is why? Literature has shown that the main focus of researchers in the field of WHP is mostly on determining the effectiveness of these programs in traditional randomized controlled trials (RCT’s). A recent trend is seen in which a more pragmatic design is used. This means that the design could still be a RCT, but that interventions are evaluated under circumstances that resemble routine practice conditions as much as possible [44]. In this type of study the researcher is often merely an observer. Such a pragmatic design makes it possible to evaluate the program under “real world” circumstances. This should facilitate the generalizability of the results (i.e. external validity), but at the same time enhance the internal validity (i.e. the ability to draw true conclusions about causes and effects) of the study, as participants are still randomized [44].

It has also become widely known that higher levels of implementation favorably affect study outcomes [41]. In line with this development, more and more studies evaluate the implementation process of interventions by means of process evaluations. Process evaluations can give valuable insights into the interpretation of the (lack of) effects of an intervention, as it allows researchers to identify successful and unsuccessful program components. Furthermore, a thorough process evaluation allows to map barriers and facilitators affecting
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the implementation of a program on different organizational levels. These are valuable outcomes, which can be used to improve future program implementation in daily practice. However, up till now, no conceptual framework for process evaluations takes all of these aspects into account. As a consequence many aspects remain unknown. How good do these “pragmatic RCT’s” resemble “real-world” circumstances? How applicable are the results of these process evaluations for other settings and for daily routine and practice? It appears that in order to improve the translation from research into practice we need to open the implementation “black box”. In order to do so, there is a need for more observational study designs, such as a formative evaluation that should go alongside pragmatic trials [45, 46]. A formative evaluation is an assessment that focuses on “the internal dynamics and actual operations of a program, in order to understand its strengths and weaknesses and changes that occur in it over time” [46, 47]. So it gives researchers insight into program implementation over time and employs a mix of qualitative and quantitative research techniques and stimulates real-time monitoring. Real-time monitoring can be obtained by an ‘embedded scientist’, meaning that the researchers is part of the implementation process, but does not actively intervene in this process and acts more as a ‘fly on the wall’. This approach should be helpful in opening the ‘black box’ of the implementation process, as it allows researchers to capture the dynamic process of implementation by means of data triangulation. In doing so, detailed information on the implementation of a specific WHP can be obtained, whereby the focus is not solely on the implementation of the specific interventions by using process evaluations, but also on identifying barriers and facilitators that should be taken into account when implementing the program outside a research setting.

7-step implementation strategy

Despite the lack of focus on studying the implementation process of WHP programs and the lack of implementation in practice, researchers do agree that WHP programs should be systematically implemented and should fit the specific context of the worksite in order to enhance success. Additionally, tailoring interventions to the specifics of the target group and the worksite is a successful approach, as each worksite has its own culture and natural social network [48]. In order to successfully implement a WHP program, programs need to go through the four stages of the diffusion of innovations theory: 1) dissemination, 2) adoption, 3) implementation and 4) continuation [49]. The transition from one stage to the next can be influenced by barriers and facilitators on different organizational levels and
can be categorized into five main groups: 1) characteristics of the socio-political context, 2) characteristics of the organization, 3) characteristics of the implementer, 4) characteristics of the program and 5) characteristics of the participant (figure 1) [50, 51]. As research has shown that it is important to take these implementation factors into account when implementing a WHP program, an effective implementation strategy to implement WHP programs within organizations could be a solution [41, 50, 52]. Therefore, Wynne and Clarkin (1992) developed a 7-step strategy of which it is hypothesized that it facilitates a structured and successful implementation of a WHP program that fits the specifics of the worksite. The 7-step strategy is based on the results of a survey among 1500 European companies across seven countries questioning the company’s health policies, worksite health promotion activities and case studies of good practices [53, 54]. The strategy adopts a ‘user-driven’ approach, meaning that employees and managers from different organizational levels are involved and responsible for the development and implementation process. The researchers merely act as observer and do not actively interfere with the process, unless this is specifically asked for by the participating organizations. It is hypothesized that this ‘user-driven’ approach ensures a fit with the wishes and needs of both the employer as well as the employees, thereby enhancing program implementation and maintenance over time. The 7-step strategy mainly aims to systematically develop, implement and maintain health promotion programs at the workplace and consists of the following steps: 1) creating solid support, 2) formation of a project structure, 3) performing a needs assessment, 4) development of interventions, 5) implementation of interventions, 6) evaluation of the implemented interventions, and 7) embedding the interventions in the general occupational health policy of the organization. The 7-step strategy is a general strategy, but it allows a tailored, worksite-specific approach, making it suitable (in theory) for nationwide implementation in different types of organizations.
The 7-step strategy has already been tested in 2007 in daily practice. Stating that a vital, productive and motivated workforce will contribute to maintaining a competitive position in the market, a large national bank implemented an intervention called BRAVO [55]. BRAVO is the Dutch abbreviation for physical activity, smoking, alcohol use, nutrition and relaxation (i.e. ‘Bewegen, Roken, Alcohol, Voeding en Ontspanning’). The 7-step strategy was successfully executed in this national bank and seemed effective in positively changing several lifestyle related variables such as increased physical activity levels of moderate intensity and higher levels of relaxation. Although, the strategy seemed promising, secular trends cannot be ruled out, because there was neither a control group, nor a thorough and real-time evaluation of the implementation process.

**Objectives of this thesis**

Based on the topics discussed in this introduction, this thesis has two main objectives:

1) To identify implementation determinants (i.e. barriers an facilitators) that either hamper or facilitate the implementation of WHP programs focusing on healthy lifestyle changes, and;
2) To assess whether the use of the 7-step strategy contributes to the successful development, implementation and maintenance of a WHP program aimed at stimulating a healthy lifestyle change among employees.

Outline of this thesis
In Chapter 2 a conceptual framework is presented for conducting a formative evaluation, which is also used in this study, including the design of the study and a detailed description of the 7-step strategy. Chapter 3 describes a systematic review that was conducted to further our understanding of the quality of process evaluations alongside effect evaluations for WHP program, to identify implementation determinants in WHP program, and to explore the relationship between program effectiveness and program implementation. Chapter 4 describes the process evaluation that was conducted as part of the formative evaluation by applying a mixed methods approach in order to gain insight into the implementation of the lifestyle interventions that were developed in this study, using the 7-step strategy. Additionally, the effectiveness is described of the implemented lifestyle interventions on lifestyle behaviors (physical activity, fruit intake, vegetable intake, smoking, alcohol use and relaxation), in a quasi-experimental controlled trial conducted alongside the formative evaluation. In chapter 5 the results are presented on the association between measured implementation factors identified in our review and employee participation in and satisfaction with the BRAVO@Work program. The usefulness of the 7-step strategy applied in this study is evaluated in chapter 6. Finally, chapter 7 presents a general discussion of the main findings of chapters 2 to 6, methodological considerations, as well as recommendations for daily practice and research. This thesis is concluded with both an English and a Dutch summary.
Chapter 1

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