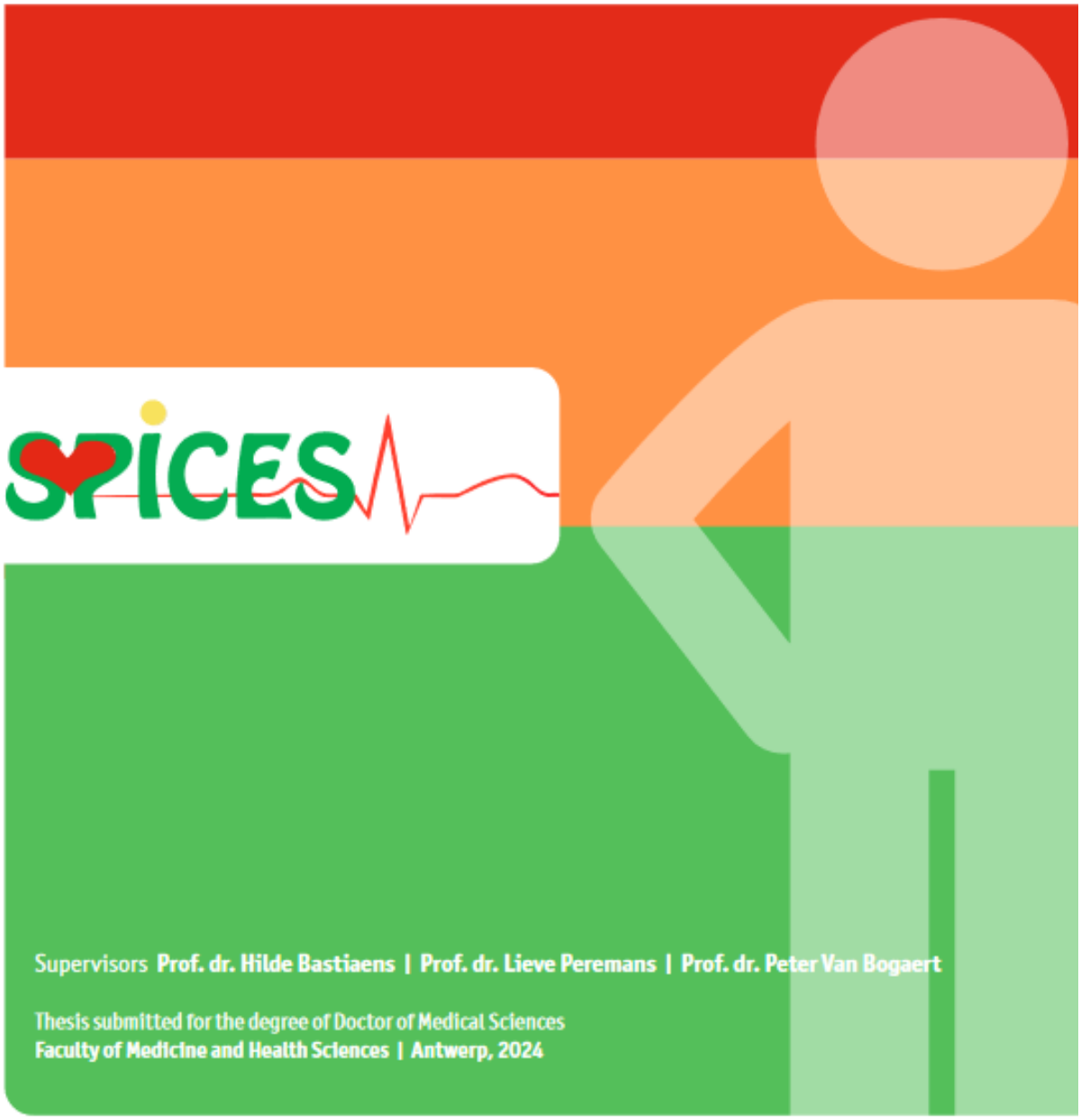
Primary prevention of cardiovascular diseases in Belgian primary health care

Development and implementation of a comprehensive intervention program in general practice and community settings in Antwerp

Naomi Aerts



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Primaire preventie van hart- en vaatziekten in de Belgische eerstelijnszorg.

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Table of contents

Acronyms and abbreviations

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ABCD	Attitudes and Beliefs about Cardiovascular Disease
BA	Brief Advice
BCC	Behavior Change Counselling
BMI	Body Mass Index
BOV	Bewegen op verwijzing
BP	Blood Pressure
CFIR	Consolidated Framework for Implementation Research
CHW	Community Health Worker
COREQ	Consolidated criteria for Reporting Qualitative research
COVID-19	Coronavirus disease 2019
CP	Community Partner
CPG	Clinical Practice Guideline
CVD	Cardiovascular Disease
DALYs	Disability Adjusted Life Years
DASH	Dietary Approaches to Stop Hypertension
EBSP	Evidence-Based SPICES Program
F	Female
FR	France
GP	General Practitioner
GUIDED	Guidance for reporting Intervention Development studies in health research
HCP	Health Care Provider
HVZ	Hart- en Vaatziekten
ICCC	Innovative Care for Chronic Conditions framework
IPAQ	International Physical Activity Questionnaire
LCh	Blood lipids
LDL	Low-Density Lipoprotein
LSt	Lifestyle behaviour
M	Male
N/A	Not Applicable
NCD	Noncommunicable Diseases
NL-IHRS	Non-Laboratory INTERHEART Risk Score
OW	Over Weight
PA	Physical Activity

PAR	Participatory Action Research
PDSA	Plan-Do-Study-Act
PHC	Primary Health Care
PN	Practice Nurse
QIF	Quality Implementation Framework
RAM	RAND/UCLA Appropriateness Method
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
RE-AIM QuEST	RE-AIM Qualitative Evaluation for Systematic Translation
SES	Socioeconomic Status
SPICES	Scaling-up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and Sub-Saharan Africa: An implementation research
StaRI	Standards for Reporting Implementation studies
T2DM	Type 2 Diabetes Mellitus
TIDieR	Template for Intervention Description and Replication
UG	Uganda
UK	United Kingdom
WHO	World Health Organization
ZA	South Africa

Summary

Summary

Cardiovascular disease (CVD) is the world's leading cause of morbidity and mortality, placing a disproportionately higher burden in populations with a low socio-economic status. Nearly 75% of premature deaths from CVD are believed to be preventable. Healthy lifestyle behaviour, including smoking cessation, healthy diets, physical activity and alcohol reduction, are important in the prevention of CVD and its modifiable risk factors, such as hypertension, (pre-) diabetes, dys- and hyperlipidaemia, overweight and obesity. Although numerous strategies to reduce the risk of CVD exist, a critical research-practice gap remains on the actual implementation of structured preventive interventions, resulting in poor achievement of guideline-recommended CVD prevention targets. Moreover, people with a low socio-economic status generally benefit less from preventive care. Hence, there is an urgent need to further develop and implement interventions for detection and management of CVD risk factors, in the general population as well as in vulnerable subpopulations. In Belgium, prevention is mainly carried out in primary health care, yet interventions for CVD prevention should be systematically integrated across a variety of settings to address socio-economic health differences. Horizon 2020 funded 'Scaling-up Packages of Interventions for cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa' (SPICES) project aimed to implement an evidence-based intervention program for the primary prevention of CVD in individuals, including vulnerable people, in low-, middle-, and high-income countries. This PhD outlines part of the activities carried out in the context of the SPICES project at the Belgian study site. The general objective of this thesis was to develop and implement a comprehensive intervention program for the primary prevention of CVD, comprising of risk profiling and a multicomponent behaviour change intervention, in primary health care and community settings.

We explored the views and experiences of general practitioners, practice nurses and individuals living with chronic illness in relation to the shift to an interprofessional approach in general practice in **Chapter 3**. We learned that interprofessional collaboration within general practice improves responsiveness to patient needs, and that the evolution of the role of practice nurses to autonomous decision-making can be facilitated by a clear vision and mission, team communication, complementarity of responsibilities and trust-based professional relationships. A clear vision and mission statement amongst team members, supported from a shared understanding of the concept of care and transparency towards patients thereof, are crucial in implementing an interprofessional model of care in general practice. Clearly defined roles and responsibilities are necessary in the transition from instrumental collaboration towards a more integrated collaboration within interprofessional teams in general practice. Traditional role concepts, current legal frameworks and reimbursement schemes were identified as barriers to a more integrated interprofessional

collaboration. We could conclude that Belgian general practice is urging for well-defined task descriptions for interprofessional collaboration and systematic guidance and support for the sustainable integration of practice nurses.

Chapter 4 systematically reviewed and synthesized evidence on best practice recommendations regarding the design and implementation of interventions to promote physical activity in the adult general population for the primary prevention of CVD at primary health care and community level. We found strong evidence on the benefit of regular moderate-intensity aerobic exercise to reduce individual CVD risk. Engaging in at least 30 minutes of moderate-intensity aerobic physical activity on at least five days a week was recommended by international clinical practice guidelines. Although recommended strategies to achieve and maintain behaviour change varied, we could conclude that multi-component interventions, consisting of education, counselling and self-management support, are important to include in CVD prevention programs. In addition, we learned that person-centred care and behaviour change techniques need to have a central role in the design of such interventions. We identified a gap in the evidence on the implementation of these recommendations into practice, especially in vulnerable subpopulations. To reach vulnerable populations for prevention and to maximize the intervention's effectivity, intervention programs should be delivered by multi- or interdisciplinary teams in primary health care and community settings.

Using the Consolidated Framework for Implementation Research, we analysed the Belgian context and explored macro-, meso-, and microlevel stakeholders' views on potential implementation determinants of a comprehensive intervention program for the primary prevention of CVD through interviews and focus groups in **Chapter 5**. We identified key stakeholders and learned that the SPICES project was valued as an opportunity to improve risk awareness and health behaviour in the target population, in particular among vulnerable communities. Our research highlighted contextual dimensions that needed to be considered and tailored to primary health care and community needs and capacities when planning the implementation of a CVD prevention program in real life settings. We identified its relative advantage, evidence-based design, adaptability to the needs and resources of target communities, and the alignment with policy evolutions and local mission and vision, as important facilitators. The main barriers included legal and structural characteristics and intervention complexity.

In **Chapter 6**, we described the process of developing a comprehensive intervention program for the primary prevention of CVD, consisting of generic core intervention components and implementation strategies for the SPICES consortium, and its contextualization to the Belgian study site. In addition, we documented the adjustments to the program during implementation based on implementer and participant feedback. We incorporated multiple methods and techniques during the four phases of our

iterative, cyclic approach: Identification of core components (Phase 1); Contextual translation (Phase 2); Design of content, materials and protocols (Phase 3); and Implementation, evaluation and refinement (Phase 4). We described the program's components in detail using the Template for Intervention Description and Replication. The intervention program consisted of two main components: 1) a profiling component including CVD risk profiling using the Non-Laboratory INTERHEART risk scoring tool and risk communication, and 2) a coaching component including behaviour change and motivational interviewing techniques.

The implementation of our CVD prevention program across various primary health care and community settings in selected vulnerable regions in Antwerp was evaluated and discussed in **Chapters 7 and 8**, guided by the RE-AIM and Consolidated Framework for Implementation Research. We evaluated the implementation process in general practice, described influencing factors and facilitators and provided lessons learned on how to overcome barriers. We also assessed the implementation across the included settings and captured pros and cons, and the variation in reach, adoption, implementation, and maintenance of general practices compared to community settings. Overall, our evaluation demonstrated the high potential of primary CVD prevention implementation in general practice and existing community organizations. We learned that general practice has a relatively better adoption rate, and participants are more likely to be enrolled and stay engaged in prevention programs. Community settings seemed to be preferable for reaching vulnerable populations for prevention, although there are many barriers to the sustainable integration of prevention programs in such settings. Actions to address barriers should be tailored to each unique situation and structurally linked to implementation strategies. Prioritization of prevention, ownership and shared responsibility of all team members, compatibility with existing work processes and systems, expanding practice nurses' roles and upskilling competence profiles, supportive financial and regulatory frameworks, and a strong primary health care - community link were identified as crucial factors to increase implementation success and long-term maintenance of prevention programs.

Our findings urge healthcare systems to move towards a highly integrated community health model integrating health and well-being through health promotion and disease prevention. This requires aligning policy, legislative and financial systems with the current and future challenges of primary health care. Furthermore, collective efforts are needed across all sectors to improve health in all communities, including vulnerable populations.

Samenvatting

Samenvatting

Hart- en vaatziekten (HVZ) zijn 's werelds belangrijkste doodsoorzaak, en de ziektelast is zwaarder binnen populaties met een lage socio-economische status. Geschat wordt dat bijna 75% van de vroegtijdige sterfgevallen ten gevolge van HVZ kunnen worden voorkomen. Gezonde levensstijl, waaronder rookstop, gezonde voeding, beweging en beperking van alcoholgebruik, zijn belangrijk in de preventie van HVZ en hun beïnvloedbare risicofactoren, zoals hoge bloeddruk, (pre-)diabetes, dys- en hyperlipidemie, overgewicht en obesitas. Hoewel onderzoekers talloze strategieën ter vermindering van het risico op HVZ aanbevelen, blijft de daadwerkelijke implementatie van gestructureerde interventies in de praktijk vaak uit, waardoor de aanbevolen preventiedoelstellingen voor HVZ niet of onvoldoende behaald worden. Bovendien worden net mensen met een lage socio-economische status doorgaans minder bereikt door preventieve acties. Dit noopt tot verdere ontwikkeling en implementatie van interventies voor de detectie en management van risicofactoren voor HVZ, zowel in de algemene bevolking als in kwetsbare subpopulaties. Interventies voor de preventie van HVZ moeten meer systematisch in verschillende contexten worden ingebed, zodat socio-economische ongelijkheden op vlak van gezondheid kunnen worden aangepakt. Het 'SPICES' project, gefinancierd door Horizon 2020, was gericht op het implementeren van een evidence-based interventieprogramma voor de primaire preventie van HVZ bij individuen, inclusief kwetsbare mensen, in lage-, midden- en hoge-inkomenslanden. Dit proefschrift omhelst een deel van de activiteiten die werden uitgevoerd in de context van het SPICES project in België. De algemene doelstelling was het ontwikkelen en implementeren van een interventieprogramma voor de primaire preventie van HVZ, bestaande uit risicobepaling en een gedragsveranderingsinterventie, in de huisartspraktijk en welzijnsorganisaties.

In **Hoofdstuk 3** exploreerden we de visie en ervaring van huisartsen, praktijkverpleegkundigen en mensen met een chronische ziekte met betrekking tot interprofessionele samenwerking in de huisartspraktijk. Dit leerde ons dat interprofessionele samenwerking in de huisartsenpraktijk leidt tot het beter inspelen op de behoeften van de patiënt. De evolutie van de rol van praktijkverpleegkundigen kan worden gefaciliteerd door een heldere visie en missie, optimale communicatie binnen het team, complementariteit van verantwoordelijkheden, en samenwerking die gebaseerd is op wederzijds vertrouwen. Bij het implementeren van een interprofessioneel zorgmodel in de huisartspraktijk is een gedeelde visie op zorg tussen de teamleden cruciaal, evenals de transparantie ervan naar patiënten toe. Binnen de transitie van een instrumentele naar een meer geïntegreerde samenwerking binnen interprofessionele teams is er tevens nood aan duidelijk gedefinieerde rollen en verantwoordelijkheden. Traditionele rolconcepten en de huidige wettelijke kaders en financieringssystemen werden geïdentificeerd als voornaamste barrières.

Hoofdstuk 4 geeft een overzicht van best practice aanbevelingen voor het ontwikkelen en implementeren van interventies ter bevordering van fysieke activiteit in de volwassen bevolking ter preventie van HVZ in de gemeenschap en eerstelijnsgezondheidszorg. Het regelmatig beoefenen van aerobe fysieke activiteit met een matige intensiteit gedurende ten minste 30 minuten minimum vijf dagen per week, werd aanbevolen door internationale richtlijnen om het individuele risico op HVZ te verminderen. Hoewel de aanbevelingen met betrekking tot strategieën om gedragsverandering te bekomen sterk varieerden, konden we concluderen dat programma's ter preventie van HVZ interventies moeten bestaan uit meerdere componenten, waaronder educatie, begeleiding en zelfmanagementondersteuning. Daarnaast leerden we dat persoonsgerichte zorg en technieken voor gedragsverandering moeten worden geïntegreerd in dergelijke interventies. De richtlijnen konden echter onvoldoende sluitend bewijs leveren over hoe bovenstaande aanbevelingen moeten worden geïmplementeerd in de praktijk. Teneinde kwetsbare populaties te bereiken voor preventie en de effectiviteit van interventies te maximaliseren, dienen interventieprogramma's te worden geïmplementeerd door multi- of interdisciplinaire teams in de gemeenschap en eerstelijnsgezondheidszorg.

Met behulp van het Consolidated Framework for Implementation Research (CFIR) analyseerden we in **Hoofdstuk 5** de Belgische context en onderzochten de visie van belanghebbenden op macro-, meso- en microniveau op mogelijke factoren die de implementatie van een preventieprogramma voor HVZ zouden kunnen beïnvloeden. Het SPICES project werd gezien als een kans ter verbetering van het bewustzijn van het individuele risico op HVZ en het gezondheidsgedrag in de doelpopulatie, met name bij kwetsbare doelgroepen. In dit hoofdstuk werd benadrukt dat men rekening dient te houden met contextuele dimensies bij het plannen van de implementatie van een preventieprogramma voor HVZ in de praktijk. De belangrijkste facilitatoren van SPICES waren het relatieve voordeel ten opzichte van de reguliere praktijkvoering, het evidence-based ontwerp, het aanpassingsvermogen aan de behoeften en beschikbare middelen van de context, en de compatibiliteit met de huidige beleidsevoluties. De voornaamste barrières waren onder meer het ontbreken van een ondersteunend beleid, structurele kenmerken en de complexiteit van de interventie.

In **Hoofdstuk 6** beschreven we het ontwikkelingsproces van een interventieprogramma voor de primaire preventie van HVZ, bestaande uit generieke kerncomponenten en implementatiestrategieën als gemeenschappelijke basis voor het SPICES onderzoeksproject, en de adaptatie ervan aan de Belgische context. Daarnaast documenteerden we de aanpassingen die in het programma werden doorgevoerd op basis van feedback van implementeerders en deelnemers tijdens de implementatie. We integreerden verschillende methoden en technieken tijdens de vier fasen van onze iteratieve, cyclische aanpak: Identificatie van kerncomponenten (Fase 1); Contextuele vertaling (Fase 2); Ontwerp

van inhoud, materialen en protocollen (Fase 3); en Implementatie, evaluatie en verfijning (Fase 4). Alle componenten werden gedetailleerd beschreven met behulp van de Template for Intervention Description and Replication. Het interventieprogramma bestond uit twee hoofdcomponenten: 1) een HVZ risicobepaling met behulp van het NL-IHRS instrument en risicocommunicatie, en 2) een coachingtraject inclusief technieken voor gedragsverandering en motiverende gespreksvoering.

De implementatie van het hierboven beschreven interventieprogramma in verschillende settings in kwetsbare regio's in Antwerpen werd met behulp van RE-AIM en CFIR geëvalueerd en besproken in de **Hoofdstukken 7 en 8**. We evalueerden het implementatieproces in huisartspraktijken, identificeerden beïnvloedende factoren voor succesvolle en duurzame implementatie, en beschreven hoe we met bepaalde barrières zijn omgegaan. Bovendien evalueerden we de implementatie in de verschillende settings en beschreven hierbij de voor- en nadelen, evenals de variatie in bereik, adoptie, implementatie en inbedding. Deze evaluatie toonde het grote potentieel van zowel huisartspraktijken als bestaande welzijnsorganisaties voor primaire preventie van HVZ. Huisartspraktijken toonden een hogere adoptiegraad, en hun doelpopulatie was sneller bereid om deel te nemen aan het interventieprogramma en dit te voltooien zoals voorzien. Welzijnsorganisaties leken dan weer het meest geschikt om kwetsbare groepen te bereiken voor preventie, maar ondervonden veel barrières die de duurzame inbedding van preventieprogramma's zouden kunnen belemmeren. Acties om met barrières om te gaan dienen aangepast te worden aan elke unieke situatie en structureel gekoppeld te zijn aan implementatiestrategieën. Prioritering van preventie, eigenaarschap en gedeelde verantwoordelijkheid van alle teamleden, compatibiliteit met bestaande werkprocessen en systemen, uitbreiding van de rol van praktijkverpleegkundigen en versterken van hun competentieprofielen, ondersteunende financiële en regelgevende kaders, en een sterke band tussen de eerstelijnsgezondheidszorg en de gemeenschap werden gedefinieerd als cruciale factoren voor implementatie succes en behoud.

Onze bevindingen moedigen gezondheidszorgsystemen aan om te evolueren naar een sterk geïntegreerd gezondheidszorgmodel, met integratie van gezondheid en welzijn vanuit gezondheidsbevordering en ziektepreventie als uitgangspunt. Dit vereist de afstemming van beleids-, wetgevende en financiële systemen op de huidige en toekomstige uitdagingen van de eerstelijnsgezondheidszorg. Bovendien zijn er collectieve inspanningen nodig over alle sectoren heen om de gezondheid in alle gemeenschappen te verbeteren, inclusief in kwetsbare populaties.

Chapter 1

General introduction

Cardiovascular disease burden

Cardiovascular diseases (CVD) are the leading cause of death worldwide and a major contributor to disability. Over the past 30 years, the calculated prevalence rate of all CVD nearly doubled to 523 million in 2019. The number of CVD deaths increased by over half, to an estimated 18.6 million deaths each year (1); representing 32% of global mortality (2, 3). All CVD together are responsible for 393 million Disability Adjusted Life Years (DALYs) (4, 5), affecting people in low-, middle and high-income countries. In developing countries, CVD even account for three-quarters of all deaths, and by the year 2030, CVD will be responsible for more deaths than all infectious, nutritional, maternal and perinatal diseases put together in developing countries. Not only CVD, but non-communicable diseases as a whole account for more than three-quarters of deaths worldwide. In 2019, out of 17 million premature deaths (under the age of 70) due to noncommunicable diseases (NCD) 38% were caused by CVD (3).

In Europe, mortality rates vary across regions, as a higher rate is observed in Central and Eastern Europe compared to Northern and Western Europe (6). With around 3.9 million deaths each year, CVD accounts for almost half of all deaths in Europe and every year there are currently more than 11 million new cases of CVD. Despite sustained declines in CVD mortality in several countries across Europe, CVD have remained one of the leading causes of death together with cancers. Therewith, CVD still is the leading cause of mortality in the population under 65 years in Europe (7); continuingly placing a heavy burden on health care systems.

CVD are a group of disorders of the heart and blood vessels; including coronary heart disease (e.g. heart attack); cerebrovascular disease (e.g. stroke); peripheral arterial disease; rheumatic heart disease; congenital heart disease; and deep vein thrombosis and pulmonary embolism. Among CVD, ischaemic heart disease and strokes are responsible for more than four out of five deaths related to CVD; and one third of these occur prematurely in people under the age of 70 (3). In 2019, ischaemic heart disease and stroke were the top-ranked causes of DALYs in the global population above 50 years of age (8). The total number of DALYs due to ischaemic heart disease reached 182 million DALYs, 9.14 million deaths, and 197 million prevalent cases in 2019. Likewise, the total number of DALYs due to stroke has increased over the years, reaching 143 million DALYs, 6.55 million deaths, and 101 million prevalent cases by the year 2019 (1). In Europe, the incidence of CVD's major components, ischaemic heart disease and stroke, have both shown a downward trend, however changes in prevalence remain limited. Ischaemic heart disease and stroke still account for 82% of DALYs due to CVD in European countries. DALYs due to CVD were almost twice as high in males compared with females and three times as high in middle-income compared with high-income European countries (7).

Not only is CVD a severe health issue, it also contributes to a major economic burden on health care systems worldwide including excess health system costs. The financial burden of CVD and its risk factors on society and the healthcare system is indeed substantial (9). In terms of costs on a global level, CVD represent between 7.6% and 21.0% of national health expenditures, mainly due to ischaemic heart disease and stroke. Hospital inpatient care and pharmacological treatment usually take up the largest share of expenditures (10). The cost to European countries' economies is as high as €210 billion each year. Around 53% (111€ billion) is allocated to health care costs, 26% (€54 billion) to productivity losses, and 21% (€45 billion) to informal care of people living with CVD (7). These numbers show that the burden of CVD is not only a critical health issue, but also an economic challenge to healthcare systems worldwide which is expected to grow exponentially in near future (7).

In Belgium, 26,289 people died from CVD in 2020, i.e. 20.7% of all deaths (5). Similar to European trends there is a limited decrease of CVD compared to 2019, with 27,297 deaths (-3.7%). Neoplasms have become the first cause of death in the Belgian population since 2019. However, for women and in people aged 65 and older, CVD remain the main cause of mortality (11). In Belgium, heart failure, stroke and ischemic heart disease are the leading causes of CVD-related mortality. CVD are responsible for 20% and 25% of premature deaths in women and men, respectively, with ischemic heart disease (11.6%) and cerebrovascular disease (8.1%) being some of the main causes of disease burden and premature death (years of life lost YLL). Ischemic heart disease is therewithal also one of the main specific causes for DALYs with 6.8%. Stroke and ischemic heart disease are in addition some of the main causes of preventable death (12). Overall, CVD is estimated to take up around 6% of the total health care expenditure in Belgium (7).

Determinants of cardiovascular health

Various risk factors for CVD and underlying determinants can influence cardiovascular health. CVD are generally caused by a complex interplay of hereditary, metabolic, behavioural, socioeconomic and psychosocial factors. Lalonde's Health Field Concept summarizes these into four categories: biological factors, health care facilities, lifestyle and environment (13, 14), as shown in Figure 1.

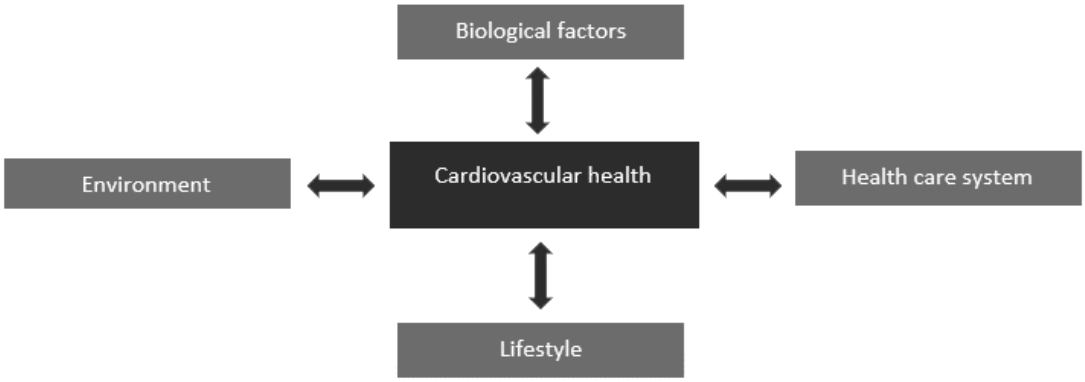

Figure 1 Lalonde's Health Field Concept, adapted from Vlaams Instituut Gezond Leven (15) and Public Health Ontario (14)

Lifestyle and biological risk factors for cardiovascular disease

Lifestyle refers to a combination of behaviours that are related to health. Several lifestyle-related behavioural determinants exert a strong influence on the individual risk of developing CVD. The most important behavioural risk factors of heart disease and stroke include smoking, unhealthy diet, physical inactivity and harmful alcohol intake (3). These unhealthy behaviours may lead to acquired biological determinants, including metabolic risk factors for CVD. Metabolic risk factors are raised blood glucose or diabetes, high blood pressure or hypertension, dyslipidaemia (low high-density lipoprotein cholesterol or high triglyceride levels), hypercholesterolemia (high total or low-density lipoprotein cholesterol), and overweight or obesity (16, 17). Presence of one or more of these intermediate risk factors indicate an increased risk of heart attack, stroke, heart failure and other complications related to CVD (3). In 2019, behavioural and metabolic risks were among the top-10 mortality risks (18), responsible for >90% of the population attributable risk of acute myocardial infarction (7). The average adult world population has at least one metabolic risk factor or risk behavior for CVD and is unaware of it (18). Particularly in Europe, more than half of adults older than 50 years have at least two behavioural risk factors (19).

According to the World Health Organization (WHO), **tobacco use** is an important public health issue and the single most preventable cause of illness and death. Europe has the highest prevalence of tobacco smoking among adults but also one of the highest among adolescents (7, 24). In 2019, 18.4% of the EU population aged 15 years or more were daily cigarette smokers (25). Although the prevalence of daily smoking has decreased by 40% between 1997 and 2018, still 15% of the Belgian population smokes daily, which is slightly lower than the European average (26). Europe had the highest proportion of people (excessively) **consuming alcohol** and the highest intake of alcohol, and of total morbidity and premature death due to alcohol worldwide. One fifth of the European population aged

15 years and older reports heavy episodic drinking (five or more drinks on an occasion, or 60g alcohol) at least once a week (27). The average consumption of pure alcohol in Belgium is 12 litres per capita per year, which is indeed above the mean European consumption. Therefore, Belgium is one of the countries with the highest disease burden related to excessive alcohol consumption. In 2018, 7.4% of men and 4.3% of women aged 15 years and older reported a hazardous consumption of alcohol (28). According to WHO, the burden of disease associated with **poor nutritional habits** is still increasing in European countries. Unhealthy diets, strongly related to overweight and obesity, contribute to a large proportion of NCD, including CVD (29). Across European countries, just over half of all adults consumed at least one portion of both vegetables and fruit (7). In line with other European countries, Belgian nutritional habits are characterized by excessive consumption of red and processed meat, sugar sweetened beverages, and by insufficient consumption of fruits, vegetables, nuts and seeds, milk, eggs and fish. For example, in 2018, only 12.7% of the population aged 6 years and over consumed the daily recommended amount of fruit and vegetables (at least 5 portions) and 20.4% of the population drank sugary drinks on a daily basis (21, 30). The WHO states that **physical inactivity** causes around 6% of the burden of disease from coronary heart disease and 7% of type 2 diabetes. Moreover, premature deaths (9.0%), all-cause mortality (7.2%) and CVD deaths (7.6%) are attributable to physical inactivity. The latest statistics show that at least one in three people in Europe are not active enough (31) and rates of inactivity are somewhat higher in high-income countries such as Belgium. Only few adults in European countries participate in adequate levels of physical activity (7). The Belgian national health survey showed that in 2018, less than one third (30%) of the adult population (18 years and older) met the WHO recommendations for physical activity (at least 150 minutes of moderate-intensity aerobic physical activity throughout the week) (7, 32).

Across European countries, at least one in four people have **elevated blood pressure** (≥140/90 mmHg), accounting for about half of all heart disease- and stroke-related deaths (7). According to the Belgian Cardiology League, hypertension affects one in four people in Belgium. Of the almost 2,500,000 people with high blood pressure, only 1,250,000 are diagnosed and only 625,000 are treated for hypertension (20). **Raised cholesterol levels**, particularly of LDL cholesterol, are a major determinant of CVD risk which increases linearly as blood concentrations increase. Globally, a third of ischaemic heart disease is attributable to high cholesterol. The prevalence of elevated total cholesterol exceeds 50% in high-income countries including Western-European countries (7). Almost half of the Belgian adult population (47%) has a cholesterol value exceeding the threshold value of 190mg/dl). In 10% of these cases, this constitutes an important health risk (21). As many as 15% of CVD deaths in Europe are due to high blood sugar. Prevalence of **diabetes** is increasing in Europe, reaching rates of 10-12% of the population in some of the European countries (22) and prevalence has increased three-fold over the

last 25 years (7). In Belgium, prevalence is increasing over time and in 2021 at least 1 in 10 people had diabetes (21). **Overweight and obesity** have reached epidemic proportions in Europe, affecting almost 60% of adults and alarmingly, the prevalence of overweight and obesity is still increasing in this region (23). As in most industrialized countries, weight excess is an important problem in Belgium. The 2018 Belgian health interview survey showed that 55% of the population has overweight (Body Mass Index (BMI) ≥ 25), 21% is obese (BMI ≥ 30) and 39% has an excessive waist circumference (21).

Due to their latent onset and largely asymptomatic course in the short- and mid-term stages, many people with increased risk of developing CVD are unaware of the presence of any modifiable risk factors such as diabetes, hypertension, and elevated cholesterol levels, leading to severe consequences on the long-term. Nearly half of adults (46%) are unaware that they have hypertension and less than half of adults (42%) with hypertension are diagnosed and treated (33). Not even half of the people with hypertension perceive themselves at risk (21). Overweighted or obese people also underestimate their weight and the associated health risks. The Belgian national health survey in 2018 showed that more than one in three people with diabetes (37%) was unaware of their diabetes status (21). Likewise, only one in three people with excessive cholesterol serum levels and/or who are treated with cholesterol-lowering medication, reported being at risk (21). Poor health literacy and the discrepancy between perceived individual risk of CVD and actual CVD risk are important barriers to lifestyle change and improvement of health outcomes. In fact, being knowledgeable about family history, and CVD and its risk factors, is a necessary condition for high-risk populations to change health-related behavior (34).

Environmental determinants and disparities in cardiovascular disease burden

The occurrence of behavioural and metabolic risk factors for CVD in individuals is highly dependent on the physical, socio-cultural, economic and political environment in which an individual lives and the extent to which interlinked adverse social determinants of health regarding e.g. economic context and commercial influences, education, media, neighbourhood infrastructure and community, are associated with it (35, 36). Adverse social determinants play a significant role in the development of CVD risk factors and CVD-related morbidity and mortality (37); whereas a favourable environment has protective effects on CVD (35). Social determinants are believed to be major drivers of sociodemographic disparities in CVD, with a disproportionate impact on socially disadvantaged populations (35). The burden of CVD is highest among individuals in the lower socioeconomic status (SES) quintile (38, 39) as a strong relationship exists between cardiovascular health and education level, occupation, and income (40, 41). CVD morbidity, mortality, metabolic and behavioural CVD risk factors are highly related to low SES (42, 43). People in vulnerable social situations often live in unhealthier

environments and tend to experience more barriers to developing a healthy lifestyle, thus having a higher chance of certain biological factors that increase the risk of cardiovascular health problems. For example, the raising problem of diabetes is strongly associated with increasing trends towards overweight and obesity, unhealthy diets, physical inactivity and socioeconomic disadvantages; and the prevalence of diabetes is higher for individuals with a lower income (22). Furthermore, overweight and obesity are strongly related to SES, with a much higher prevalence among people with a lower educational level (21). Likewise, socio-economic disparities are significant regarding smoking behaviour, with the proportion of daily smokers and electronic cigarette users being 2.4 times lower in the higher versus the lower educated people (26). A significant proportion of the population has insufficient CVD knowledge and awareness, especially among low SES populations in Europe (44)(45). In addition, certain aspects of healthcare are still less tailored and accessible to people in vulnerable social situations. In Europe, low SES populations are less likely to access preventive interventions or specialist care (46) and where improvements in CVD-related outcome have occurred, there is an inequity in benefits with a lesser impact in socio-economically deprived populations (47, 48).

The city of Antwerp, our study site, has a metropolitan population of 521.946 inhabitants spread across 9 districts. More than half of the inhabitants are singles, with or without children (49). Of the Antwerp inhabitants, 52% are natives and 48% have a migration background (50). Various city neighbourhoods are highly vulnerable in terms of socio-economic deprivation of their inhabitants. Indicators for vulnerability are the rate of long-term unemployed jobseekers in the occupational age population, the share of occupational age population receiving social and financial support and the number of taxpayers with net taxable income of less than 10.000 euro per year (51). Of the taxpaying population in Antwerp, 34.8% has a net year income under 10.000 euro. Of the total Antwerp population, 26.5% has the right to an increased financial support compensation and 5.5% of the Antwerp inhabitant families has the right to additional social and financial support (52). Moreover, the degree of employment in the professional environment, which indicates the extent to which people between 18 and 64 years are actively working, is relatively low in Antwerp compared to Flanders. About 57.5% of the Antwerp inhabitants is actively working compared to 66% in Flanders. Of the total occupational age population, the general unemployment ratio is twice as high in Antwerp (11.3%) as in Flanders (6.5%) when the job seeking unemployed are compared to the total population of 18-64 years (53). Finally, as for the level of education of job seekers, 50.6% has a lower degree (primary or lower secondary education), 34.3% has medium level education (higher secondary education) and 15.1% has a high degree of education (higher education or university degree). 53.1% of job seekers have been unemployed for longer than a year (53, 54).

Call to preventive action

The WHO estimates that nearly three quarters of premature CVD deaths are preventable (55). Preventive strategies have been shown to be more effective to reduce the burden of CVD and reducing disease burden rather than focusing on treatment. Although most CVD are preventable by targeting modifiable metabolic and behavioural risk factors (56-60), global and local health policies only give little attention to prevention and spend only a small fraction of healthcare budgets at preventive action (61). In the European Union, only 2.8% of the total healthcare expenditure is allocated to prevention, and in Belgium this is only 2% (62). Primary prevention should be made a priority for future health policy development (63).

Recommendations at the European level emphasize the need for coordinated application of preventive policies and health promotion (7). Proactive public health approaches focused on population-wide policies are increasingly valued as potentially powerful, rapid, equitable and cost-effective (64). For example, health policies designing conducive environments for making healthy choices affordable and available are essential for motivating people to adopt and sustain healthy behaviours. Lalonde's Health Field Concept calls for multi-level action; and advocates to invest resources beyond health services to improve the health of a population (13, 14). Hence, national strategies should target both cost-effective population-wide and individual interventions (55). Important areas of action are building a healthy public policy; creating supportive environments; strengthening community action; developing personal skills; and reorienting health services (65). Prevention can play an essential role in reducing both prevalence and socioeconomic impact of CVD. Nevertheless, current policies fail to consistently propose structured protocols to guide practitioners, and evidence gaps are reported especially regarding strategies targeting vulnerable populations (66, 67). Consequently, people with low SES tend to benefit less from preventive care including lifestyle interventions (68, 69), and sometimes preventive actions thus widen the health inequality in favour of people with a higher level of education and higher incomes (70, 71). Efforts to achieve health equity should therefore take into account the structural, institutional, and environmental barriers to optimum cardiovascular health in marginalized populations (35).

Intermediate and modifiable CVD risk factors account for around 90% of the risk of acute ischaemic events (72). The growing understanding of CVD mortality highlights the crucial role of tobacco, diet, alcohol and inactivity as key determinants (64). Cessation of tobacco use, reduction of salt in the diet, eating more fruit and vegetables, regular physical activity and avoiding harmful use of alcohol have been shown to reduce the risk of CVD. Addressing behavioural risk factors of heart disease and stroke can prevent disability and death due to CVD and improve quality of life (73, 74). Thus, the most

effective and feasible way to prevent CVD is through the promotion of a healthy lifestyle at all stages in life of the whole population (71). However, next to environmental factors and aging of the population, lack of adherence to a healthy lifestyle remains the major challenge towards CVD prevention. Therefore, primary prevention including early individual interventions is key to avoid preventable deaths. Identifying people at increased risk of developing CVD and ensuring they receive appropriate follow-up treatment, including behavioural counselling and drug treatment of hypertension, diabetes and high blood lipids, is key to reduce CVD risk and prevent events (3). A strong consensus exists on the importance of raising awareness of CVD risk factors and their asymptomatic course CVD, and on the impact of health behaviour and lifestyle on health outcomes (75-77). Studies showed that knowledge of behavioural risk factors is crucial in behaviour change and individuals who perceive themselves to be at increased risk of developing CVD, are more likely to adopt healthy behaviours (34, 78, 79). Active profiling of individuals' CVD risk level, raising awareness and communicating risk in relation to risk behaviours, are crucial to potentially trigger behavior change (80, 81). Despite the widespread dissemination of guidelines and recommendations on the primary prevention of CVD, their incoorporation in routine practice remains limited; leading to a prevention gap that calls for the implementation and evaluation of effective and feasible strategies (82-85).

The central role of the primary health care system

As shown in Lalonde's conceptual model, both quality and organization of health care are important determinants of cardiovascular health. To combat CVD, health systems must focus on health promotion, defined as 'the process of enabling people to increase control over, and to improve their health' (86), and disease prevention. Primary health care (PHC) plays a critical role in this. In Belgium, as in other high-income countries, prevention is primarily performed in PHC. Access to NCD medication and basic health technologies in all PHC facilities is essential to ensure that those in need receive treatment and counselling. The challenges of CVD however contribute to an increase in service capacity that is needed to cover the rising demand; to overcome a shortage of physicians in certain settings; to improve the quality of care; and to reduce healthcare costs by employing the 'lowest cost provider' (87). As such, health systems fail to provide systematic support for all aspects of prevention. Thus, in order to increase quality and accessibility of care (88-91), new models of PHC are needed (92, 93).

The conceptualization and implementation of PHC is highly variable in different settings. Belgium has a strong overall PHC system in comparison to other European countries, based on indicators like structure, process of care delivery and health outcomes (94, 95). General practice in particular plays an increasingly critical role in primary prevention and in addressing socio-economic health differences,

due to frequent contact with a large and often diverse target population (96, 97). According to national data, nearly the entire population (94%) is registered with a regular general practitioner (GP) and patients have, on average, four contacts with their GP each year (98). However, prevention-orientated services are not systematically provided in Belgian general practice due to many challenges related to the expanding role of the GP (99). Belgian GPs were traditionally organized in independent, one-handed practices, although today the majority have reorganized into small monodisciplinary teams and a smaller number into multidisciplinary practices with integration of nurses. Moreover, national workforce studies report differences in GP density causing an impending shortage in certain regions. GP demographics, with 75% being aged 45 and older, feminization of the medical profession and young GPs pursuing better work-life balance through part-time employment make the need for change more urgent. Certain Belgian regions will not be able to overcome the impending GP deficit during the next few years (100, 101).

Current literature reports various interprofessional collaboration models, including role expansion and task delegation in PHC (67). Integrated care delivered by physicians and nurses in general practice indeed entails opportunities to increase quality and accessibility of preventive care (89-91, 102, 103). Moreover, nurses play a critical role in expanding, connecting, and coordinating primary and community care (104) and have the ability to make a difference in areas such as patient advocacy and education, and people-centred care (105). Many countries have sought to shift tasks within PHC from physicians to nurses to meet current and future challenges as efficiently as possible. Nevertheless, a better understanding of the potential contribution of nurses working in general practice is needed (106). Research has demonstrated that this task shift generates similar or better health outcomes for a broad range of patient conditions, relieves the GP's workload, decreases health care costs, improves satisfaction of both patient and health care provider and provides equivalent or improved quality of care (107-113). Collaboration between physicians and nurses has been demonstrated to have a positive impact on a range of patient outcomes and on a variety of pathologies when embedded within integrated interprofessional collaboration care models with adequately trained nurses (102). Although the benefits of a nurse-coordinated approach on morbidity, mortality, and lifestyle-related risk factors in both primary (114-116) and secondary (117-120) prevention of CVD have been demonstrated, it is only established to a limited extent in some contexts (121). In contrast to other countries, experiences in Belgium with an interprofessional approach in general practice are scarce. A cross-sectional study showed that 30% of the 271 included general practices are supported by a practice nurse (PN), only an estimated 5% of which have implemented an interprofessional collaboration model (122). At the same time, the job profile and legal-deontological framework remain insufficiently defined (121).

Next to PHC, community-based preventive interventions and active engagement of the community are essential to combat CVD (123). International and national policies and directives on primary prevention of CVD are evolving from fragmented care towards an integrative approach (124). In the context of these reorganizations, interventions for CVD prevention should be actively and systematically integrated in both PHC and community settings (67). Health care systems need to be integrated with existing social organizations (61). This approach for patient-centred care is even more important in disadvantaged communities, to address the many economic and socio-cultural barriers (125). Moreover, evidence shows intervention models that have successfully used non-healthcare professionals, such as peers and community partners, as facilitators to enhance cardiovascular health (126, 127), and that they can be trained for CVD prevention and management in a cost-effective manner (128). A reform of the health system is needed to establish the basis for strong integrated care and strengthen well-being initiatives, social care and health care and their interaction (129). However, the link between PHC and the community is unclear in the Belgian context.

Implementation project SPICES: background and rationale

This thesis was carried out in the context of a larger implementation project 'SPICES' ('Scaling-up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa'). Passive dissemination of prevention guidelines alone is not effective and only results in subtle changes CVD and its risk factors (130, 131). Despite a large evidence base on validated interventions to reduce the risk of CVD, studies show poor achievement of guideline-recommended CVD prevention targets as a critical research-practice gap remains on the implementation of efficacious interventions into real-life contexts, particularly in vulnerable populations (67, 83, 132-134). As such, there is an urgent need to further develop and implement interventions and strategies for detection and management of CVD risk factors, in the general population as well as in vulnerable subpopulations (135). Little is known about how to implement validated preventive interventions in specific PHC and community settings, and to which extent new interdisciplinary, collaborative forms can enhance their uptake. This knowledge gap was aimed to be addressed through implementation research project SPICES; funded by the European Commission through Horizon 2020 research and innovation action. The aim was to evaluate the implementation of evidence-based interventions for the primary prevention of CVD, with a focus on CVD risk assessment and supporting people to change their lifestyle. SPICES ran from 2017 until 2022 and was rolled out across five settings including a rural & semi-urban community in a low-income country (Uganda), middle income (South Africa) and vulnerable groups in three high-income countries (Belgium, France and United Kingdom).

Research aims

The general objective of this thesis was to develop and implement a comprehensive intervention program for the primary prevention of CVD, comprising of risk profiling and a multicomponent behaviour change intervention, in PHC and community settings in Belgium.

The specific research aims for the different chapters of this PhD were:

1) To explore the views and experiences of GPs, PNs and patients living with chronic illness regarding interprofessional collaboration between physicians and nurses in general practice.

2) To review and synthesize evidence on clinical practice guidelines' recommendations to improve physical activity levels in PHC and at community level, for the primary prevention of CVD.

3) To enhance the understanding of the potential contextual determinants of the implementation of a comprehensive intervention program for the primary prevention of CVD, from macro-, meso-, and micro-level stakeholders' perspectives.

4) To design a multi-component intervention program for the primary prevention of CVD and to adapt the program to the local context of Belgian PHC and community settings.

5) To evaluate the implementation process of a comprehensive intervention program for the primary prevention of CVD in general practice and to gain insight into implementers' experiences with integrating the program in their daily practice.

6) To assess different avenues to mitigate the risks and burden of CVD in vulnerable communities by evaluating the implementation of a comprehensive intervention program for the primary prevention of CVD in various PHC and community settings.

Outline of the thesis

This dissertation is aligned with the research questions and structured into nine main chapters outlining the process of the research activities that have been carried out, the findings, and implications for practice, policy and research. Chapters 3 to 7 form the core of this thesis and are all either published in or (to be) submitted to international, peer reviewed journals. They are preceded by a general introduction and methodological chapter; and concluded by a general discussion.

Chapter 1 General introduction

In chapter 1, we provide the global and national problems related to CVD and its risk factors and disparities in CVD burden, framed within the determinants of cardiovascular health. We highlight the urgent need for preventive action and the role of PHC and community settings. We also define

opportunities, challenges, rationale and research aims of this thesis, in the context of implementation project SPICES.

Chapter 2 Overview of research methodology and approaches

Chapter 2 outlines the philosophical underpinnings of this research, and describes and justifies the specific methodological choices that were made during the course of this thesis. This chapter also provides some general information on the methodologies, designs and sampling strategies that were employed, which are explained more in depth in each of the following chapters.

Chapter 3 Integration of nurses in general practice

In Chapter 3, we explore the views and experiences of GP, PN and patients living with chronic illness in relation to the shift to an interprofessional approach in general practice; and to understand to what extent this new partnership between a PN and the GP meets the individual and joint needs and expectations of each of the three stakeholder groups. This chapter reflects the thematic synthesis of four studies conducted before the establishment of the SPICES project.

Aerts N, Van Bogaert P, Bastiaens H, Peremans L. Integration of nurses in general practice: A thematic synthesis of the perspectives of general practitioners, practice nurses and patients living with chronic illness. Journal of clinical nursing. 2020;29(1-2):251-64.

Chapter 4 Recommendations on promoting physical activity for primary prevention of cardiovascular disease

Chapter 4 reports on the systematic review of international clinical practice guidelines to identify best practice recommendations regarding the design and implementation of interventions to promote physical activity in the adult general population, for the primary prevention of CVD in PHC and on community level across all Horizon 2020 project SPICES sites.

Aerts N, Le Goff D, Odorico M, Le Reste JY, Van Bogaert P, Peremans L, et al. Systematic review of international clinical guidelines for the promotion of physical activity for the primary prevention of cardiovascular diseases. BMC Family Practice. 2021;22(1):97.

Chapter 5 Pre-implementation contextual analysis

Chapter 5 explores macro-, meso-, and microlevel stakeholders' views on implementation determinants of a comprehensive intervention for the primary prevention of CVD prior to its implementation in general practice and community settings. In addition, it summarizes key

recommendations for planning successful and sustainable implementation of related health programs in similar contexts.

Aerts N, Anthierens S, Van Bogaert P, Peremans L, Bastiaens H. Prevention of Cardiovascular Diseases in Community Settings and Primary Health Care: A Pre-Implementation Contextual Analysis Using the Consolidated Framework for Implementation Research. International Journal of Environmental Research and Public Health. 2022;19(14):8467.

Chapter 6 Development and contextualization of a cardiovascular disease prevention program

In Chapter 6, we describe the process of developing an intervention program, consisting of generic core intervention components and implementation strategies for the SPICES consortium, and the contextualization of that program to the Belgian study context of this thesis. In addition, this chapter documents the adjustments to the program during actual implementation based on implementers' and participants' appreciation.

Aerts N, Van Royen K, Van Bogaert P, Peremans L, Bastiaens H. Development and contextualization of a comprehensive intervention program targeting cardiovascular disease prevention in primary health care and community settings in Belgium: a multimethod study. [Manuscript ready to be submitted]

Chapter 7 Process evaluation of the implementation of a cardiovascular disease prevention program in general practice

In Chapter 7, we evaluate the implementation process of a comprehensive CVD prevention program in general practice in a high-income country as Belgium. We describe the influencing factors and facilitators for a successful implementation and sustainability, and provide lessons learned on how to overcome barriers, guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) and Consolidated Framework for Implementation Research (CFIR) implementation frameworks.

Aerts N, Van Royen K, Van Bogaert P, Peremans L, Bastiaens H. Understanding factors affecting implementation success and sustainability of a comprehensive prevention program for cardiovascular disease in primary health care: a qualitative process evaluation study combining RE-AIM and CFIR. Primary health care research & development. 2023;24:e17.

Chapter 8 Lessons learned from implementing preventive interventions across various primary health care and community settings to reach vulnerable communities

In Chapter 8, we compare the implementation of primary prevention of CVD in primary care and community settings, and evaluate the role of the newly emerged Health kiosk in reaching vulnerable groups in lifestyle interventions. We describe pros and cons, and the variation in reach, adoption, implementation, and maintenance across the different implementation settings.

Hassen HY & Aerts N, Van Royen K, Peremans L, Abrams, S, Bastiaens H. Implementing an intervention for primary prevention of cardiovascular diseases in vulnerable communities in primary care and community settings in Belgium: A mixed method evaluation. [Manuscript ready to be submitted]

Chapter 9 General discussion and conclusion

In Chapter 9, we summarize the key discussion points of our findings in the context of international literature and wider research community; this thesis' implications for practice, policy and research; and the final concluding statements.

Other contents of this dissertation include a table of contents, a list of acronyms and abbreviations, a summary, supplementary materials for each chapter, a curriculum vitae of the candidate, and an acknowledgements section.

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Chapter 2

Overview of research methodology and approaches

Theoretical lenses of the research

Transformative paradigm

A transformative paradigm provided the overarching, philosophical assumptions behind the construct of this research. The paradigm served as an entry-point to guide the development of responsive research decisions during this PhD research, encouraging transformative change throughout the entire implementation process (1). Its advocacy and participatory worldview was translated into the empowerment, collaborative and change-oriented PhD concept (2, 3). This paradigm emphasises the importance of establishing a strong relation with researched groups (5) and the triangulation between various stakeholders (6), which was reflected in this research by the involvement of relevant local stakeholders, including implementers and the target population. An empowering learning community was established through strong interaction and dialogue between researchers and all those directly or indirectly involved. Moreover, the paradigm's mechanism for changing a social reality by addressing inequity in health systems supported our goal to reach underserved populations for prevention (7), by applying transformative mixed methods to link research findings to actions intended to mitigate health disparities (8).

Innovative Care for Chronic Conditions Framework

The Innovative Care for Chronic Conditions (ICCC) framework, developed by the World Health Organization (WHO), supported the initial conceptualization and design of the overall research activities of this thesis. It presents a structure for organizing and optimizing health care to meet the needs regarding chronic care (9, 10). The framework has proven to be useful in informing a wide range of actions within diverse healthcare systems and socioeconomic contexts (11). In case of optimal integration of all essential components, the ICCC recognises that patients and their social networks may be empowered to actively prevent and manage chronic conditions with the support of their health care teams and communities (12). Therefore, it provides strong capacity serving as a road map for transforming and reorienting health systems towards better prevention and management of chronic conditions; as also emphasized in the mission statement of the overarching SPICES project. The ICCC framework was the cornerstone for conceptualizing, planning and designing the research activities within this thesis focused on the prevention of cardiovascular diseases (CVD) in the high income country Belgium. It supported us to approach and clarify the problem from a theoretical perspective including the ICCC's essential elements relevant to taking action on chronic disease prevention and health promotion in both primary health care (PHC) and the community.

The framework guided our initial conceptualization of the problem of CVD and vulnerability in the Belgian context, and our mapping of any immediate or underlying influences and causal pathways. Within the SPICES consortium, the concept vulnerability was defined as: *"People with low-medium-high cardiovascular risk and no or limited access to care"*. This consensus definition was translated to the Belgian study site, where vulnerability can be determined by three major determinants: risk of CVD, socioeconomic status (SES) and PHC characteristics. Figure 1 visualises the factors that contribute to vulnerability on different levels in the Belgian context, using a combination of the ICCC and a theoretical model of vulnerability (13-16). In addition, it reflects our focus on the essential health care triad that represents a partnership between patients and their families, community partners, and PHC teams; but also in interaction with health care, society and policy systems in which these are embedded.

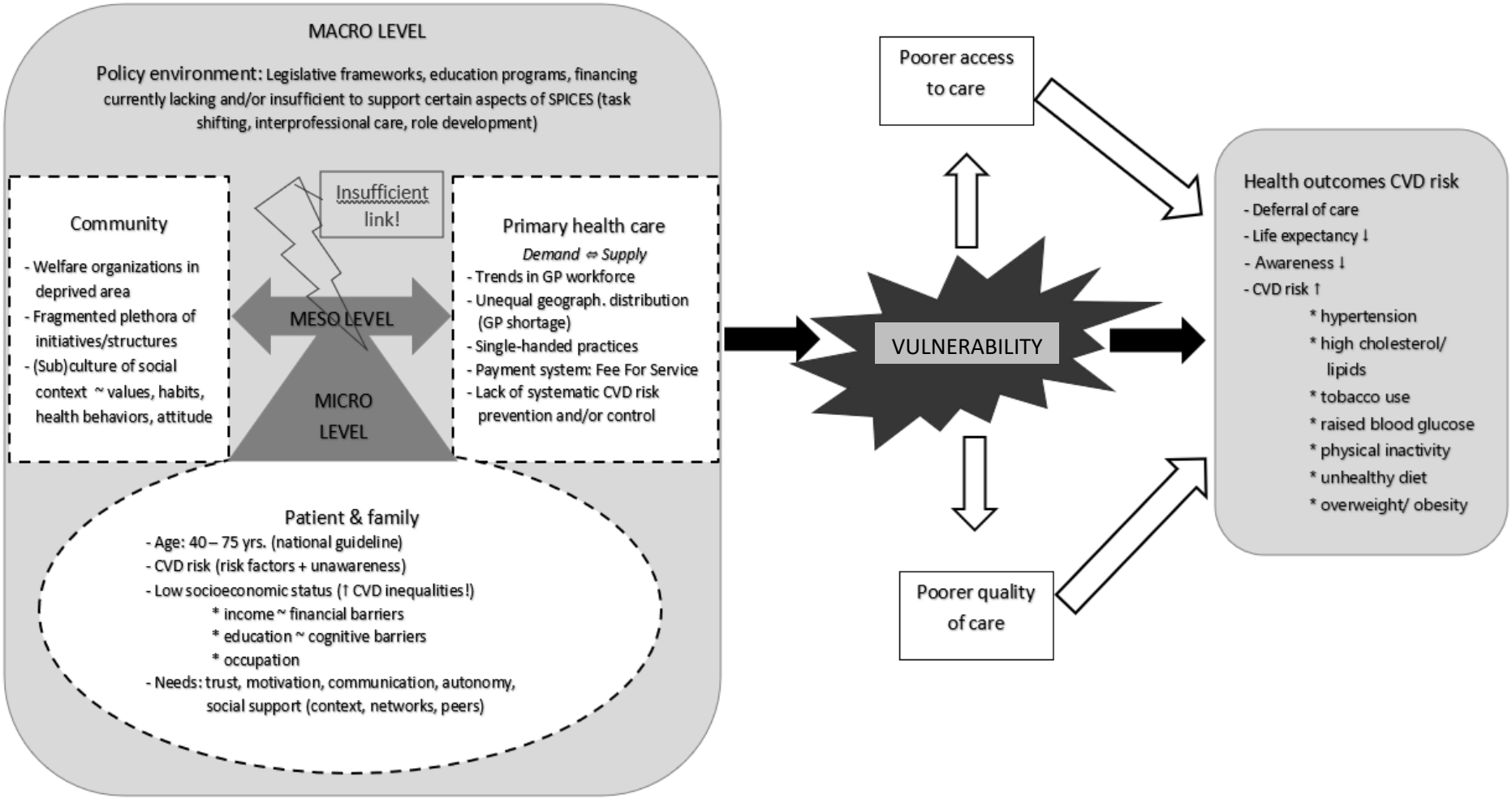

Figure 1 Multi-level factors contributing to the definition of the concept of vulnerability in the Belgian study context of this thesis

Research methodologies and approaches

Implementation research

This thesis was conducted within the field of implementation research. It is well known that a theory-practice gap impedes the uptake of well-researched, evidence–based programs, practices, interventions and policies into routine practice (17); which is also the case for evidence-based interventions on CVD prevention in particular. Implementation research is set to close the gap through understanding and increasing the sustainable integration of evidence-based innovations into everyday practice settings to improve health (18). Implementation is described by Greenhalgh et al. as *'The carrying out of planned, intentional activities that aim to turn evidence and ideas into policies and practices that work for people in the real world. It is about putting a plan into action, the 'how' as well as the 'what'."* (19). Bauer et al. define implementation science as *"The scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services and care."* (20). Implementation research translates evidence-based practice into real life settings using favourable implementation strategies in order to overcome implementation barriers and to make optimal use of facilitators; identified and modified trough the understanding of the context in which the implementation takes place (21). Outcomes may be evaluated at different levels including implementation outcomes (e.g. acceptability, appropriateness, feasibility, reach, adoption, maintenance); service outcomes (e.g. effectiveness); and patient outcomes (e.g. health status) (22).

This PhD work was carried out in the context of the overarching implementation project SPICES. We have applied the fundamental aspects of implementation research as described above, to a conceptual model for this thesis, as shown in Figure 2. The model was built on Proctor's conceptual model for implementation research (22) and Pearson's example of components of an implementation logic model (23). It integrates the different components that were developed and refined during the implementation research activities within this thesis; and it highlights how selected evidence-based practices were implemented using targeted strategies in correspondence to contextual factors influencing adoption, implementation and sustainability of the evidence-based practice. In addition, the model presents both proximal (24) and distal (patient) outcomes on which our implementation research mainly focused, as well as the formative process evaluation which was the primary focus of this PhD study.

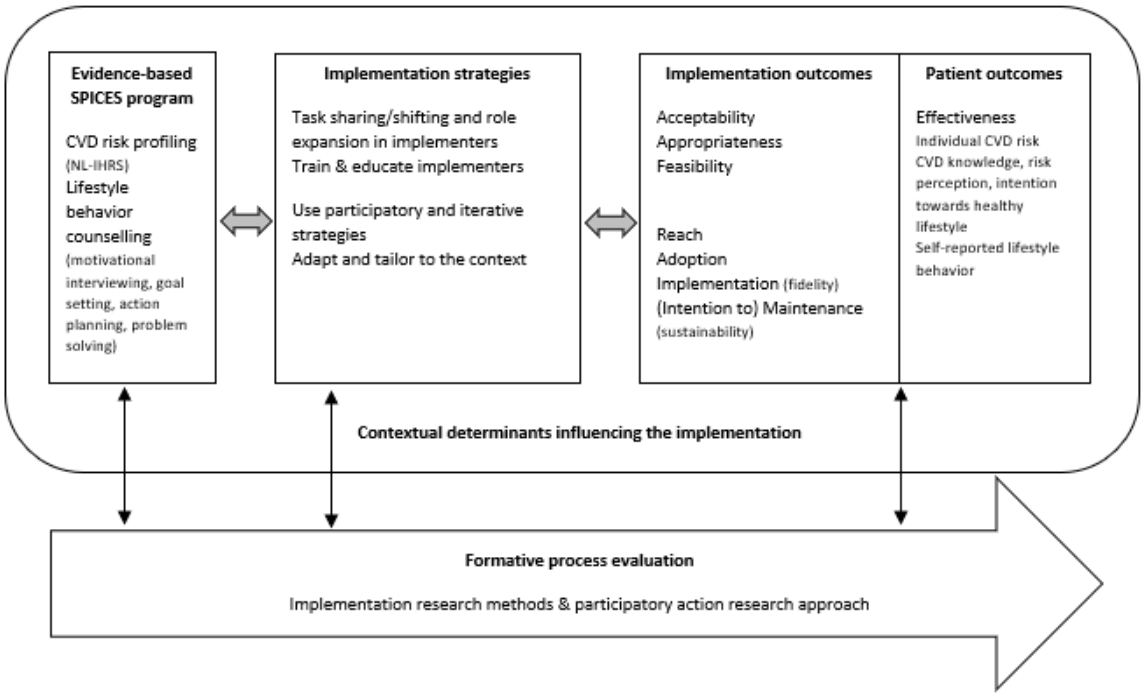

Figure 2 Conceptual model of the implementation research; adapted from Proctor et al. (22) and Pearson et al. (23)

Drawing upon other research fields, implementation science uses theories, models and frameworks to conceptualize implementation setting, process or mechanisms; to plan, guide and monitor the implementation process; and to evaluate the implementation of innovations, practices and policies. Moreover, they can assist in highlighting avoidable pitfalls; understanding the implementation context; identifying implementation barriers and facilitators across multiple levels; guiding the selection of implementation strategies; specifying implementation outcomes; informing data collection; and clarifying terminology (25). In this thesis, we made use of both a determinant and evaluation framework, which are briefly outlined in the following paragraphs.

Determinant framework: Consolidated Framework for Implementation Research

Determinant frameworks describe general types of determinants, each typically comprising a number of barriers and/or enablers that are hypothesized or have been found to influence implementation outcomes. Determinant frameworks do not address how changes take place or any causal mechanisms. Their overarching aim is to explain influences on implementation activities, by predicting or interpreting implementation outcomes (21). In this thesis, we applied the Consolidated Framework for Implementation Research (CFIR) in each step of our implementation research. Grounded in relevant theories such as Rogers' Diffusion of Innovations Theory and analysis of the 19 theories, frameworks and models used in implementation science literature, the CFIR considered the spectrum of construct terminology and definitions and compiled them into one comprehensive framework (26). The CFIR offers a pragmatic and comprehensive taxonomy of constructs on multiple levels that have been

associated with effective implementation (27). CFIR constructs are organized into five domains, here applied to this study: characteristics of the intervention program (e.g. adaptability to the local context); outer setting (e.g. vulnerable populations, PHC and community), inner setting (e.g. compatibility of the intervention program with previous or existing practices, characteristics of eligible partner organizations), characteristics of individuals (e.g. attitude, knowledge, self-efficacy) and implementation process (insight on steps to implement the intervention program). The CFIR recognizes relationships between these determinants, thus acknowledging that implementation is a multidimensional phenomenon, with multiple interacting influences (21). The CFIR was originally published in 2009, and was recently updated in 2022 based on user feedback; including revisions to existing domains and constructs as well as the addition, removal, or relocation of constructs. Despite the many updates, constructs can be mapped back to the original CFIR to ensure longitudinal consistency (28). Since our research activities took place before the updated version was published, this PhD was framed within the original CFIR. Its key domains and constructs are shown in Figure Figure 3.

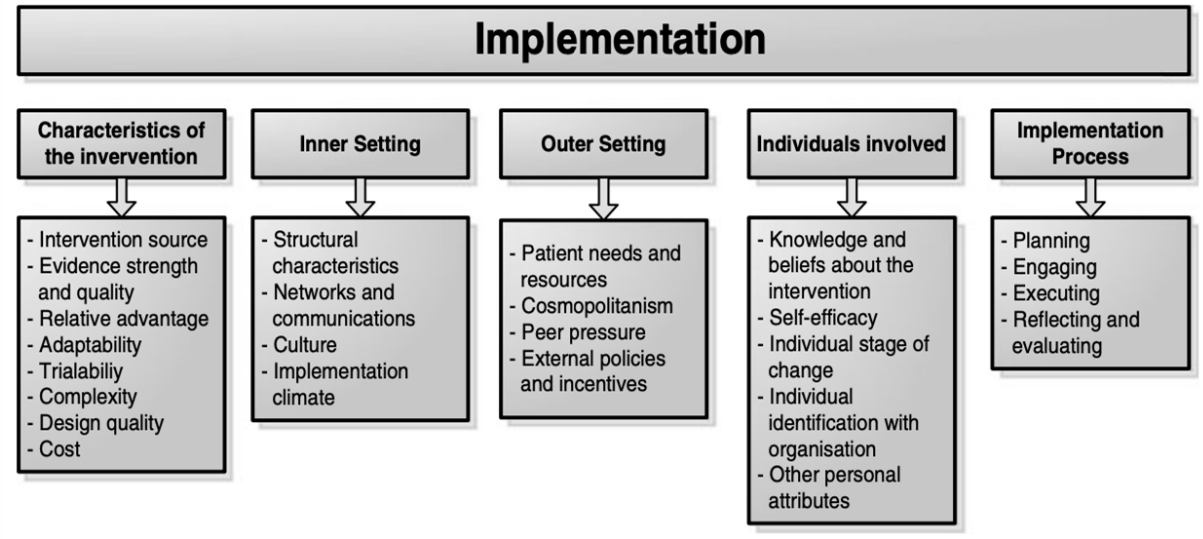

Figure 3 The Consolidated Framework for Implementation Research; reproduced from Damschroder et al., before its update in 2022 as this version was used in this thesis (27)

The CFIR has helped us to understand the complexity of the context in which we aimed to implement our intervention program; to inform the design and execution of the intervention components as well as the implementation strategies we used to overcome barriers and make optimal use of identified enablers. Later, it guided the systematic, formative evaluations during and after the implementation, explained our implementation outcomes, and built our implementation knowledge base across all 'SPICES' implementation settings. The CFIR was applied extensively in Chapters 5 and 7 of this thesis.

Evaluation framework: RE-AIM

Evaluation frameworks provide a structure for evaluating implementation efforts by specifying those determinants, that could estimate implementation success (21). Glasgow's RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework consists of five fundamental dimensions with individual and/or setting level impact in translating research into practice; i.e. (29) **Reach** is defined as the absolute number, proportion, and representativeness of eligible individuals who are willing to participate in a given initiative, intervention, or program; (2) **Effectiveness** refers to the impact of an intervention on important targeted outcomes, including potential negative effects, quality of life, and economic outcomes; (3) **Adoption** is defined as the absolute number, proportion, and representativeness of settings and providers who are willing to initiate a program; (4) **Implementation** refers to the implementers' fidelity to the various elements of an intervention's protocol, including consistency of delivery (at setting level), and to clients' use of the intervention strategies (at individual level); and finally (5) **Maintenance** is described as the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies, while maintaining its effectiveness (30, 31).

Forman et al. (29) added a qualitative component to the RE-AIM, in the expanded RE-AIM Qualitative Evaluation for Systematic Translation (RE-AIM QuEST) framework. This mixed-method framework guided both our formative and summative evaluative activities. It supported the identification of real-time implementation barriers and facilitators, informed rapid-cycle adaptations and modifications, and helped us explain how context influences implementation success and sustainability, as well as scale-up to other implementation settings (30, 32). As proposed by Holtrop et al., the complexity of the implementation context required the use of qualitative methods as these methods provided insight into 'why and how' the implementation process led to certain results, and additionally encouraged collaborative stakeholder engagement (33); which enabled us to understand the translational potential of our research activities for wider implementation in similar contexts. The RE-AIM QuEST was applied in Chapters 7 and 8 of this thesis.

Participatory action research approach

"Research that produces nothing but books will not suffice – the case for action research." (Lewin, 1948) (34). The increased and sustainable uptake of evidence-based practices for the primary prevention of CVD in PHC is necessary; and action research has the potential to strengthen implementation-related efforts. Koshy et. al. (35) define action research as an approach which can be applied for improving practice; involving action, evaluation, and critical reflection throughout the change process. Action research is participative and collaborative, and requires context-specific

tailoring founded on a partnership between researchers and all those involved in the change process (36, 37). It involves a dynamic, non-linear, process-driven approach comprising of dynamic, iterative 'plan do study act' cycles to adapt to the local context, practices and those involved (38, 39). Figure 4 shows how reflexive cycles are repeated to allow for incremental changes to a program throughout the implementation process. The increasing size of the cycles reflects the dynamics of the extended power, focus, and impact of implementation efforts over time (40).

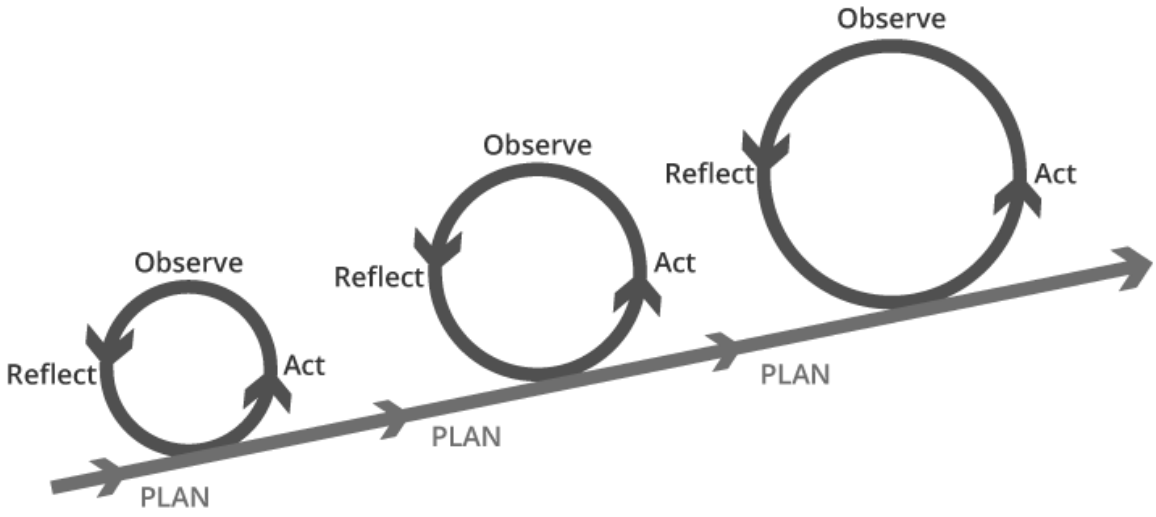

Figure 4 Reflexive cycles in participatory action research (40)

In this thesis, we employed a 'participatory action research' (PAR) approach to bolster our implementation efforts within the transformative paradigm. PAR has an added value to implementation research efforts due to their complementarity (41). The use of PAR within implementation science can reduce the research-practice time lag, and additionally it can reinforce further reflection on the complex nature of health care organizations (42). Furthermore, PAR brings about a broader focus on what is researched and for whom (43). PAR and implementation science intersect by the increasing imperative of better accounting for context, in order to gain understanding under what conditions an implementation is successful and to explain variations in its process and outcomes (41). Moreover, PAR approaches have been proven to serve as a strategy to reduce health inequities, with the potential of increasing social capital and cohesion (44). They can also inform how an intervention program interacts with context, how and why adaptations took place, and which sub-populations are affected disproportionately by social and health inequities potentially arising from its implementation (45). This PhD research intended to strongly involve local stakeholders, including health care providers, but also professionals and volunteers from community settings focused on vulnerable populations. This means that they were involved in the reflexive PAR cycles from the very beginning and in further steps of the project. These self-reflective research spirals allowed us to

continuously monitor the dynamic process of implementation in co-creation with our local stakeholders, as extensively illustrated in Chapter 7 of this thesis.

Mixed methods in data collection and data analysis

Our research aims and questions; the state of existing knowledge; the intention to obtain local and transferable knowledge; the context; resources and available opportunities to conduct the research, helped to determine our research design methods (46-48). As literature suggests, a wide variety of qualitative, quantitative, and mixed methods can be used in implementation research and PAR. Implementation and PAR studies typically employ mixed qualitative and quantitative methods to monitor and evaluate factors that impact uptake across multiple levels, including patient, provider, clinic, facility, organization, and often the broader community and policy environment (2, 20); which implicates the need for careful consideration of how such data are collected, analysed and combined.

The evaluation of the overall SPICES project is fitted within a convergent parallel mixed method design, where complementary quantitative and qualitative data were collected and analysed in parallel. In a subsequent phase, we corroborated, compared and related the data in order to enable interpretation of the mixed data in the search of answers to related research questions (2), as described in **Chapter 8** of this thesis. However, in this thesis we have focused extensively on the formative and qualitative component, applying different qualitative research techniques during the collection and analysis of primary data throughout the research process. During data collection, we conducted individual in-depth interviews, focus groups and stakeholder meetings, using semi-structured topic guides and data extraction forms. In analysing the data, we applied thematic analysis, thematic synthesis, adaptive framework analysis and document analysis. The rationale for using these techniques and a comprehensive description of their application in the relevant sub-studies, will be discussed in detail in the following chapters of this thesis.

Implementation process

In order to increase the probability of successful implementation, we have considered and accomplished several activities which can be clustered into the critical phases of the dynamic implementation process. Process models can assist in describing and guiding the cyclic implementation process as such (21). In this thesis, we therefore applied and modified the Quality Implementation Framework (QIF) (4); an action model which was developed based on literature review of theories, models, frameworks and individual studies to identify key features of successful implementation activities. The QIF provided practical guidance in the planning and execution of implementation research activities related to this thesis, by specifying the different critical phases and steps that

needed to be followed throughout the implementation process. We have selected this particular process model because of its cyclic, iterative approach. Moreover, the QIF incorporates dynamic interplay among its different phases, which corresponds to the non-sequential or -linear reality we have experienced in conducting our implementation research. This allowed us to build up, prioritize, revisit and tailor our activities according to contextual needs and determinants throughout the implementation process; a critical aspect reinforcing our adaptive PAR approach.

Figure 5 outlines the core research activities we have carried out, clustered and classified into the four critical phases of the implementation process according to the QIF, yet adapted to the conceptual model of this thesis. The figure's description below also refers to the relevant chapters of this thesis, as described in **Chapter 1**, and the mainly applied sampling strategies.

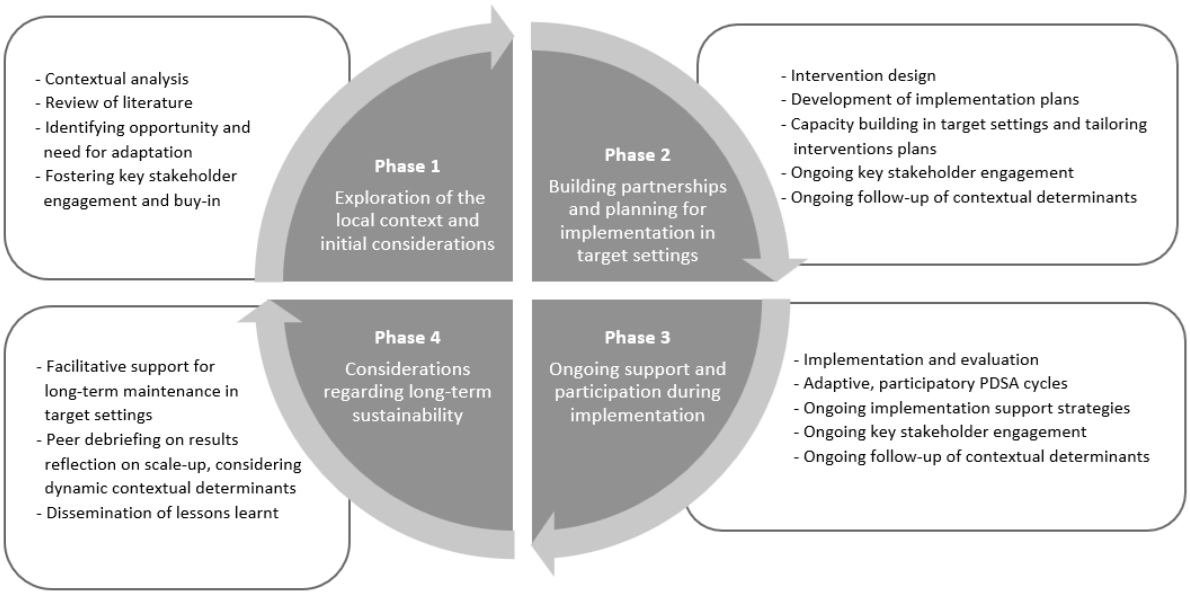

Figure 5 Critical phases of the Quality Implementation Framework (QIF) containing the implementation research activities related to this thesis; adapted from Meyers et al. (4)

During phase one (pre-implementation), we mainly focused on careful, deliberate planning especially in the early stages of our implementation study. Research activities were focused on the exploration of the context in which our study would take place. First, we explored the integration of practice nurse roles in general practice from the perspectives of general practitioners, nurses and patients living with chronic disease **(Chapter 3)**. This was realized through the thematic synthesis of four studies that were conducted before the establishment of the SPICES implementation project. In this phase, we took a broad approach by which eligible general practices were selected within the province of Antwerp. This was done on the basis of the general practices' websites, and through registration data of a symposium on integration of nurses in PHC, organized at the university. A total of 46 general practices were contacted, 26 of which were included. Second, we identified evidence-based interventions for the primary prevention of cardiovascular diseases regarding physical activity **(Chapter 4)**, diet (49), and

smoking behavior (50) through the systematic review of international clinical guidelines. Finally, we undertook a comprehensive contextual analysis within which we reviewed national data on the burden of cardiovascular diseases, guidelines and policy frameworks guiding primary prevention interventions and programs. Next to this review, we also explored micro-, meso- and macrolevel key stakeholders' perspectives; including the assessment of characteristics, needs, fit, capacity, readiness, acceptability, appropriateness, feasibility and the opportunities and need for adaptation of the intended interventions **(Chapter 5)**. Key stakeholder identification was done through brainstorming sessions with our local advisory board and snowballing. Next, we took a purposeful approach, targeted at the vulnerable city district of Antwerp-East, to select a heterogeneous sample of eligible organizations at PHC and community level. This was realized through consultation of key stakeholders from local networking organizations, but also professional networks and associations. Five welfare organizations were contacted, four of which participated. A total of 30 general practices were contacted, 12 of which were included. During this first intensive exploratory phase, we simultaneously fostered key stakeholder engagement and buy-in. Throughout all further implementation phases, ongoing stakeholder engagement and monitoring of contextual dimensions was bolstered through periodical stakeholder feedback and reflection sessions (resonance group).

Phase two (pre-implementation) was dedicated to practical preparation of the implementation, including three main aims being intervention program design, partnership development, and planning of the implementation. The intervention program, consisting of multiple intervention components, materials and implementation strategies, was designed and contextualized based on our activities from phase one and in co-creation with the input of the implementation teams in the target settings and our key stakeholders resonance group. Supportive training materials to train the implementation teams were also developed, along with training scripts for the various implementers' roles, including information on target populations, learning objectives, format and content **(Chapter 6)**. Implementation plans were developed, including the research team's strategy for communicating study aims and planned activities in order to reach relevant multi-level stakeholder networks, thus creating a supportive network in the relevant context. In addition, we developed contact and engagement scripts for eligible partner organisations, and participant (target population) recruitment strategies. We also outlined implementation and evaluation roadmaps to guide the actual implementation. Furthermore, this phase strongly focused on developing partnerships within eligible settings targeted for actual implementation. Several organisations at PHC and community level were contacted and informed about the study aim and scope, after which they were given the opportunity to commit to participation in our implementation study. Subsequently, we progressed with the practical planning of the implementation in all partner organisations once they decided to participate.

Planning activities included contextualizing implementation plans and building capacity by training implementation teams in each setting.

Phase three (per-implementation) was dedicated to the implementation and evaluation of the intervention program. At this stage, we primarily aimed to engage participating general practices from the contextual analysis (Chapter 5) targeted at the Antwerp-East region. Because of low response rates, we additionally organised a training and networking event on the topic of CVD prevention in PHC, in collaboration with the university's postgraduate training for nurses in general practice. In total, 20 general practices were invited, five of which agreed to participate in the implementation project (one from the contextual analysis, four from the university's postgraduate training network). However, two of them dropped out after the pre-implementation phase. Out of 29 organizations invited within the community settings, six agreed to participate (three of which were also included in the contextual analysis, Chapter 5), but one dropped out before the implementation phase. We conducted formative process evaluation; a method for evaluation which was specified a priori in the core research questions of this PhD and fitted within our participatory design, whilst monitoring patient outcomes. The findings were continuously fed-back to the team of implementers in each study setting, allowing us to adapt and improve the process of implementation, intervention components and implementation strategies in close collaboration with the implementation teams (20). These research activities and findings were thoroughly described in **Chapters 7 and 8** of this thesis. In addition, we gathered experiences from participants who received some or all components of the intervention program. During this phase, the research team provided ongoing supervision, coaching and technical support to the implementation teams in each participating setting.

Finally, phase four (post-implementation) mainly involved activities aiming at facilitating long-term sustainability of components of the intervention program in the participating settings if the implementation teams had expressed their intension to maintain the program. Furthermore, we focused on dissemination activities intended to actively spread the lessons we learnt about implementing our intervention program in the given context. Strategies consisted of designing policy brief and infographics, and organizing a symposium in order to reach relevant multi-level stakeholders.

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Chapter 3

Integration of nurses in general practice

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Aerts N, Van Bogaert P, Bastiaens H, Peremans L. Integration of nurses in general practice: A thematic synthesis of the perspectives of general practitioners, practice nurses and patients living with chronic illness. Journal of clinical nursing. 2020;29(1-2):251-64. https://doi.org/10.1111/jocn.15092

Abstract

Aims and objectives

The aim of this study was to explore the views of general practitioners, practice nurses and patients on interprofessional collaboration in general practice, and to understand to what extent the nurse – doctor relationship meets their needs and expectations.

Background

In order to address future challenges of primary health care, there is a need for integrated interprofessional collaboration care systems with a patient-centered focus. Worldwide, there is an integration of nurses in general practice. However, in a transitioning Belgian context little is known about the perspectives of three key stakeholder groups.

Design

The results of four qualitative descriptive primary studies were triangulated and a secondary analysis resulted in a thematic synthesis within a pragmatic research paradigm.

Methods

Primary data were collected through individual, semi-structured interviews with 7 general practitioners, 19 practice nurses and 21 patients living with chronic illness in 26 primary care centers with different nurse integration levels. We conducted a secondary analysis for the thematic synthesis of the different stakeholders' perspectives. This study was reported in accordance with the COREQ checklist.

Results

Four overarching themes were found: vision and mission at general practice level, patient centered care, practice nurse role development, and interprofessional collaboration. Interprofessional collaboration within general practice ensures better response to patient needs. Evolution of the practice nurse role to autonomous decision-making can be facilitated by clear vision and mission, team communication, complementarity of responsibilities and trust-based professional relationships.

Conclusions

The key for patient-centered care in a well-organized practice is a clear vision and mission and well-defined task description for interprofessional collaboration. General practice is urging for systematic guidance for the sustainable integration of a practice nurse.

Relevance to clinical practice

Our study highlights opportunities and challenges to nurse integration in general practice from key stakeholders' perspectives, which can inform other transitioning contexts.

Introduction

The context of health care worldwide, influenced by demographic, social and policy evolutions, places overwhelming demands on health care systems (1). An ageing population and the increasing prevalence of non-communicable diseases and multimorbidity lead to a high burden on health care systems (2, 3). By the year 2050, 39% of the Belgian population will be aged 67 years or older and 10% will be even more than 80 years old. An estimated 55% of the population is diagnosed with at least one chronic disease. Complex chronic diseases and multimorbidity represent up to 80% of the demands for care (4), reinforcing the need for building and maintaining a strong primary health care (PHC) to deliver both preventive health care and ongoing chronic disease management (5). Countries worldwide are encouraged to develop new models of PHC delivery with patient-centered care as one of the main objectives (6). Interprofessional, collaborative practice occurs when multiple health workers from different professional backgrounds work together with patients, families, caregivers and communities to deliver the highest quality of care (7).

Background

The conceptualization and implementation of PHC is highly variable in different settings. The study of Kringos and colleagues (2013) concluded that Belgium has a strong overall PHC system in comparison to other European countries, based on indicators like structure and delivery process (8). Despite the negative factor of higher costs, there are better health outcomes in general population (9). The growing importance of general practice in the context of current developments in Belgian PHC is illustrated by data from the National Health Survey and health insurances' registration data. Nearly the entire population (94%) is registered with a regular general practitioner (GP) and, on average, patients have four contacts with their GP each year. Essential components of the GP's mission include elderly care, addressing health inequalities, preventive care, quality assurance and protocol-based care for defined populations living with chronic illness (10). Challenges of the expanded role for GPs are an increased workload and the need for acquiring or improving competencies for interprofessional collaboration (1). This model conflicts with the current organization of general practice in Belgium, where GPs are traditionally self-employed in single-handed practices or small monodisciplinary teams. Moreover, national workforce studies report differences in GP density causing an impending shortage in certain regions. GP demographics, with 75% being aged 45 and older, feminization of the medical profession and young GPs pursuing better work-life balance through part-time employment make the need for change more urgent. Certain Belgian regions will not be able to overcome the impending GP deficit during the next few years (11, 12).

These challenges contribute to an increase in service capacity that is needed to cover a rising demand, overcome a shortage of physicians in certain settings, improve the quality of care, and reduce healthcare costs by employing the 'lowest cost provider' (13). Many countries have sought to shift tasks within PHC from physicians to nurses in order to meet these challenges as efficiently as possible in the future. Nevertheless, a better understanding of the potential contribution of nurses working in general practice is needed (14). Research has demonstrated that this task shift generates similar or better health outcomes for a broad range of patient conditions, relieves the GP's workload, decreases health care costs, improves satisfaction of both patient and health care provider (HCP) and provides equivalent or improved quality of care (15-21). A recent overview of systematic reviews by Matthys et al. (2018) demonstrated that collaboration between physicians and nurses may have a positive impact on a range of patient outcomes and on a variety of pathologies when embedded within integrated interprofessional collaboration care models with adequately educated nurses (22). In contrast to other countries, experiences in Belgium with an interprofessional approach in general practice are scarce. A recent cross-sectional study showed that 30% of the 271 included general practices are supported by a practice nurse (PN), only an estimated 5% of which have implemented a interprofessional collaboration model (23). Nevertheless, reorganization of general practice is needed in the context of Belgian PHC, with policy currently evolving from fragmented care towards an integrative approach (24).

The direct relationship between GP, PN and patient is substantially affected by this current transition. However, little recent research has been done on a comprehensive approach taking these three essential perspectives into careful consideration. Therefore, the aim of this study was to explore the views and experiences of GPs, PNs and patients living with chronic illness in relation to the shift to an interprofessional approach in general practice and to understand to what extent this new partnership between a PN and the GP meets the individual and joint needs and expectations of each of the three stakeholder groups.

Methods

Design

In this study, we conducted a thematic synthesis of four unpublished primary studies, all of which had a qualitative descriptive research design and used an exploratory approach within a pragmatic paradigm (25). The aim of each study was to gain understanding in this innovative transition in PHC from different stakeholders' perspectives. The primary studies were carried out as master theses by junior researchers, who were supervised by the author team: three female master's students in nursing and midwifery and one male master's student in medicine. All four studies had good coherence and

were methodologically sound. Their findings were triangulated and synthesized in one comprehensive report on different key stakeholders' perspectives. The body of data from the primary studies supporting the findings of this synthesis is applicable to the context of our research question (26).

Sampling and recruitment

The researchers of the four primary studies recruited respondents from various general practices, with a planned or existing formal collaboration with a PN at the time of the study. Their aim was to include general practices varying in geographical location, practice capacity and level of partnership between the GPs and other HCPs within their clinical setting. Single-handed practices were excluded, because of their lack of experience with team-based care. Invitation letters were sent to eligible general practices, inviting GPs and PNs to participate as respondents or to assist in the recruitment process of the patient sample. The four researchers sought a purposive sample, each within their specific target population. One researcher focused on registered nurses who had been employed in a general practice for at least six months. A second one recruited GPs who had been active in general practice for at least three years. The third and fourth researchers each included patients living with at least one chronic illness during a minimum of one year and with a need for a regular follow-up within primary care. Within all three target populations, a heterogeneous sample was intended to reflect maximum variation with regard to personal (e.g., sex, age, place of residence, socio-economic class, family situation) and professional (e.g., education degree, full/part-time regime, seniority, additional training) or medical (e.g., type and number of chronic disease(s), comorbidity, care process, follow-up period) characteristics. Individuals were excluded when they were underage or pregnant, had insufficient knowledge of the Dutch language, or were exclusively managed for acute illness or diagnosed with chronic illness less than one year ago.

Overall, 26 general practices agreed to participate in the four primary studies, 20 of which reported a formal collaboration with a PN. The level of PN integration in patient care management varied from instrumental, meaning that nurses' activities were mainly on a technical level described by task delegation, to full integration of nurse-led components, including autonomous decision-making. In 16 general practices at least one PN (n=19) participated, and in another five general practices seven GPs took part. One of these practices took part in the recruitment of patients as well. In addition, four general practices and one community health center[1] agreed to recruit patients. A HCP (GP or PN) in

[1] In Belgium, a 'community health center' is a multidisciplinary PHC team which is embedded in a third payer financial system, thus making PHC accessible for vulnerable populations

each of these participating practices nominated patients that met the inclusion criteria (n=21). Table 1 outlines the characteristics of participants and their PHC setting respectively.

Table 1 Study population and setting characteristics

Practice nurse (PN) characteristics (N = 19)					
Gender	Male	1	Additional training	Management & leadership	1
	Female	18		Additional baccalaureate degree	4
Age (years)	< 30	4		Practice nursing (Netherlands)	1
	30-40	5		Diabetes specialist	7
	41-50	6		Wound care	5
	> 50	4		Spirometry	3
Full/part time status (%)	< 75	8		Medical pedicure	3
	≥ 75	11		Radiology	2
Tenure in current practice (years)	< 5	11		Palliative specialist	2
	≥ 5	8		Pain management	1
Employment status	Employed	18		Other	5
	Self-employed	1			
Educational qualifications in nursing	Higher professional education	3			
	Baccalaureate degree	14			
	Master's degree	2			

General practitioner (GP) (N = 7) characteristics					
Gender	Male	2	Employment status	Self-employed	7
	Female	5	Family status	Partner	1
Age (mean ± SD)		43,1 ± 7,6		Partner & kids	6
Age (years)	30-40	3	Tenure in current practice (years)	< 5	1
	41-50	2		5-10	3
	> 50	2		> 10	3
Full/part time status (%)	< 75	1			
	≥ 75	6			

Patient characteristics (N=21)					
Gender	Male	11	Chronic illness	Type 2 diabetes	14
	Female	10		Cardiovascular disease	11
Age (mean ± SD)		63,1 ± 14,6		Respiratory disease	3
Age (years)	< 50	4		Stroke	3
	50-65	7		Mental health disorder	3
	66-80	8		Other	7
	> 80	2	Chronic illness comorbidity	1	7
Area of residence	Urban	10		2-3	10
	Rural	11		> 3	4
Follow-up period in years (mean ± SD)	By current GP †	14,5 ± 6,3			
	By current PN ‡	4,8 ± 3,7			

Primary health care (PHC) setting characteristics (N=26)					
Type of center	Community health center	1	Disciplines present, other than GP/PN	< 3	10
	General practice	25		≥ 3	16
Location §	Urban	4	PN present	N = 20	
	Rural	6	Level of PN involvement	Instrumental	19
				Integrated	1
Level of partnership between GPs	Duo	7			
	Group	16			
	Other	3			

† N=13 because of missing data regarding other patients

‡ N=11 because the other 10 patients had no experience with a PN in their primary care setting

§ N = 10 because of missing data regarding other general practices

Data collection

Primary data were collected through an individual in-depth interviewing technique appropriate to the descriptive and exploratory approach. Each researcher independently developed a flexible, semi-structured data collection tool to guide the interviews with key topics related to the research question, tailored to the subpopulation targeted in each of the primary studies (Table 2Table 2). The interview scripts included: the interviewer's educational background, rationale of the research, research topic and data collection method, and a short questionnaire to gather demographic characteristics. All interviews were face-to-face at the participant's home or at the general practice and were audio recorded. The interviewers provided a robust and detailed account of their experiences during data collection in thick description. It is hoped that this contributes to a richer and fuller understanding of the research setting, enabling the reader to determine the level of transferability to other primary care settings. Along with compiling detailed field notes during each interview, these methods contributed to the trustworthiness of the data collection. Data were collected until data sufficiency was reached on the research topic for each stakeholder group. Interviews were conducted between December 2015 and March 2016. This data collection method generated four separate primary data sets.

Table 2 Description of topics used to guide interview sets

Topic	***Description and aim***
All samples	
Integration of PN	Explore participant's recognition of nursing competences and skills. Is participant open to acknowledge role expansion of nurses (or other disciplines within the general practice) and in what circumstances would stakeholders benefit most? Describe attitude towards this innovation taking into account transforming patient-GP relationship. What scope is there to engage the PN in collaboration, possibilities for improvement?
PHC in general practice	Describe current follow up and guidance of patients living with chronic illness in PHC and more specific the general practice. Which are the complex care needs and to which extent are expectations consistent with the care offered? Outline participant's experience with the tense circumstances under which PHC is performed.
HCP samples specific (PN & GP)	
PHC setting	Learn about different aspects of the context. Describe the shared vision and mission by which team members are bound, practice layout, organization of work process, existing care partnerships and disciplines present. Take notes on financial structure and practice capacity. Which are/were the incentives to consider/adopt PN integration in practice?

Organization of current or future PN competences & skills	Describe integration level of the PN in practice activity. How are the PN's activities embedded in organization and structure of the practice? Categorize responsibilities/tasks and further development. Explain link between the PN and other team members (e.g., communication strategies, relating roles). Under which necessary conditions?
Patient sample specific	
Illness perception & course	Explain the timeline of the chronic disease from diagnosis to present stage. How are following aspects perceived: identity, consequences, extent to which the disease is embedded in everyday life and in their environment. What are the individual care needs and future goals depending on the severity (including comorbidity) and illness duration?
Disease management	What is the patient's view on treatment and expectations about treatment, scope for ownership? Describe level of involvement in disease management. Insight in cause, consequence, cure-control. Share opinion relating to motivation and adherence, challenges, possibilities, quality of life.

Data analysis

Primary analysis

The four researchers each analyzed their data set iteratively using an inductive, thematic approach. They familiarized themselves with the interview data and transcribed them verbatim within 48 hours. First, the researchers assigned descriptive codes to relevant narratives, and in a second step these codes were interpreted in relation to the research topic, resulting in interpretative codes. Recurrent, distinctive aspects of the data were considered relevant subthemes and aggregated to themes. Employing a spiral coding-recoding strategy, this iterative and reflexive analysis process was characterized by constant recurrence of these different steps. The four researchers independently analyzed one transcript of another data set, and in case of inconsistency they discussed until coding consensus was met. This qualitative thematic data analysis generated four separate codebooks and preliminary reports of results for each primary data set. The methodological quality of each of the original reports was confirmed by a master thesis assessment procedure.

Secondary analysis

During the secondary analysis, the author team of this study (first author NA and senior researchers PVB, HB, LP), triangulated the four preliminary reports by comparing, contrasting and corroborating the perspectives from different stakeholder populations. The used methodology contributed to a more

in-depth understanding of the research topic (27). We applied the principles of thematic synthesis (28) in merging and modifying the data as presented in the preliminary reports. In a first step, we independently developed preliminary overarching themes based on the preliminary results and underlying codebooks. All themes were coherent over the four studies and relevant to answering the research question. Next, we used the new overarching themes as a frame and engaged in an inductive, iterative, cyclic secondary analysis process, with constant feedback loops to the primary studies' codebooks to make sure the original messages were captured. Confirmability is further demonstrated by the use of verbatim quotes, translated - back-translated, to provide the participants' voice rather than exclusively the researchers' data interpretations. The author team discussed and reflected on this process, following a peer debriefing procedure to support credibility. Team analysis assisted in identifying personal or professional bias of the researchers through self-reflection, which is important to establish dependability. To meet the overall quality standards, we followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) reporting guidelines (See Supplementary File 1) (29).

Ethical considerations

The appropriate local ethics committee formally granted ethical approval for the four primary studies. Participation was voluntary, signed informed consent was obtained from all participants prior to the interview, and they all had the right to withdraw consent at any time. Pseudonymization of the qualitative data was ensured so that the identity of clinical settings and respondents can no longer be retrieved, and confidentiality of all collected data is guaranteed.

Results

After the secondary analysis, four overarching themes could be derived from the data: vision and mission at general practice level, patient centered care, practice nurse role development, and interprofessional collaboration. Table 3 summarizes the main findings within each of these themes by stakeholder group.

Table 3 Summary of main findings within the four themes by stakeholder group

	1. Vision and mission at general practice level	2. Patient-centered care	3. Practice nurse role development	4. Interprofessional collaboration
General practitioners	Comprehensive, holistic approach - Patient centered care Patient safety Quality of care Fit between personality & practice profile Team approach - Team cohesion vs. hierarchy - Incongruence between GPs Trust-based relationships - Building trust through familiarization, competence, professional & personal attitude & values, structured communication	Interprofessional collaboration Trust –based relationships - High value of doctor-patient relationship - Maintaining personal contact with patient - Protective of doctor-patient relationship vs. threat of new nurse- patient relationship	GP focus on core medical business Role & responsibility - Setting-dependent - Administration & logistics - Medical – technicalities - Prevention - Chronic disease - Innovation & quality improvement Professionalism - Role-specific competence development: previous work experience & specific education tailored to general practice needs - Difficult balance between supervising GP role vs . nurse autonomy	Overburdened primary health care - High workload: ageing of population & multimorbidity - Work-life balance Practice organization - Supervising role of GP - Responsibility conflicts Facilitators/barriers - Tailored guidance for practical implementation - Financial restraints - Governmental support - Time & resources - Learning community - Information on meso & micro level

Practice nurses	Shared ideology - Social commitment Team approach - Equal partnership - Shared decision-making - Mutual respect for different perspectives - Acknowledgment of input & opinion Trust- based relationships - Building trust through familiarization, competence, professional & personal attitude & values, open communication	Trust-based relationships - Investing in new nurse – patient relationship - Building trust through familiarization, phased transition - High accessibility	Professionalism - Expanding field of nursing - Gaining responsibility - Working autonomously - Job satisfaction - Within legislative framework Role & responsibility - Dynamic development - Setting-dependent - Administration & logistics - Medical – technicalities - Prevention - Chronic disease - Innovation & quality improvement	Overburdened primary health care - Reorganization general practice - Multidisciplinary practice Practice organization - Task delegation vs. autonomous decision making - Protocol-based care - Interprofessional consult Facilitators/barriers - Role-specific competence development - Within-team trust - Guidance from GPs -Clear work organization with team input

People living with chronic illness	**Trust-based relationships** - Mutual trust between team members **Team approach** - Close collaboration **Shared goals & core values** - Transparency to patient - Incongruence between HCP	**Individualized care** - Needs oriented - Goal oriented - Tailored to preferences & expectations - Context matters - Patient empowerment in disease management **Health advocacy** - Theory-practice gap - Navigating health care system **Trust-based relationships** - Traditional doctor-patient relationship - Open communication - Facilitates disease management - Building trust through familiarization, competence, professional & personal attitude & values	**Social skills** - Communication - Motivational interviewing - Personality **Professionalism** - Working autonomously - Confidence in own competences - Referral to other HCP - Role-specific competence development: previous work experience & education	**Overburdened primary health care** - Reorganization general practice - Waiting times - Consultation times **Practice organization** - Familiar contact person - Shared follow-up of chronic disease - Complementary roles - Continuity of care - Close interaction **Facilitators/barriers** - Role clarity - Transparent communication - Structure, organization & information on macro, meso, micro level - Building trust

Theme 1. Vision and mission at general practice level

Both GPs and PNs indicated that a shared understanding of the concept of care is important for interprofessional collaborative practice. A clear vision and mission statement, supported by all members of the general practice team, is essential in overcoming the challenges in PHC and in strengthening the trust-based professional relationship between the team members. Respondents indicated that lack of consensus and transparency hinders their daily practice activities due to insufficient trust in each other. Some GPs indicated that this is also the reason why they remain cautious about sharing responsibilities with a PN.

"In our general practice, I think we strive to really keep primary health care at that primary care level. That is the vision that we think is translated into our mission and strategy."
(GP, F, 36 yrs.)

"What I always think is that it should click. What kind of person fits in well with the team and the practice profile? The personality of the nurse must click with our patients as well as with us, the GP team, because we need to work together closely. "
(GP, F, 36 yrs.)

"I now have more responsibility than I had a few years ago. It's a mutual trust issue which has grown gradually. The doctors and I, we find each other *in competence. Making clear agreements and being able to discuss everything, that's important to build and sustain our relationship."*
(PN, F, 42 yrs.)

Respondents reported patient safety, quality of care, patient-centered care and interprofessional care as the leading concepts in defining a general practice's vision and mission. Several GPs and PNs worked together to reach common targets with their interdisciplinary team facilitating goal-oriented patient care. In these practices, there is a stronger cohesion between team members with different backgrounds due to complementary competence, mutual respect, open communication and equal partnership in the decision-making process, in contrast with the hierarchical structures which continue to exist in other settings.

"I think I would be afraid to overlook something. We are all going to have to monitor that everything is going well, so we don't miss anything and patients feel safe. "
(GP, F, 54 yrs.)

"The nurse should be an equal partner, I think. We should drop the notion that maintaining the hierarchical levels is the solution, as it still is in hospitals. The team as a whole should be the core care-providing unit, and not just the doctor."
(GP, F, 54 yrs.)

Respondents living with chronic illness recognized the importance of all HCPs collaborating closely and promoting and communicating the same core values for the patient's well-being. Too often, however, patients encounter incongruent attitudes of HCPs towards team-based care.

"When the nurse first started it didn't go all that smoothly to be honest. But gradually it has improved… the way of thinking in the practice."
(Patient, F, 63 yrs.)

Theme 2. Patient-centered care

A patient-centered integrated care was a key element for all respondents in the study. GPs and PNs emphasized the value of patient-centered care in their daily practice, together with core values such as integrity, respect for privacy and diversity.

"We try to conserve a close personal contact with our patients so that they wouldn't get the feeling that they are being treated like a number."
(GP, F, 36 yrs.)

Nevertheless, patients living with chronic illness generally experience care as being delivered rather routinely and without consciously considering the major impact of their condition on their lives. They pointed out their need for appreciation and recognition of the key role they play in the entire care process. Besides competence and a professional attitude, HCPs need to offer guidance in coping with loss or change in their daily practice. Affective aspects are also deemed imperative for patients to build trust - for example, investing time to listen and showing genuine concern, empathy, involvement and interest.

"Sometimes it lacks the human aspect of care, the connection with people, although the nurse treats me somewhat differently; more like I am a real human being, without a label or a number."
(Patient, M, 71 yrs.)

"I need someone that really makes time for me, who isn't preoccupied with anything else, … you know… the feeling of truly being listened to and that we were going to solve my problem together."
(Patient, M, 53 yrs.)

Patients expressed a strong need for the HCP to invest in health advocacy and individualizing care, two important aspects that they feel are often lacking due to time restraints, mostly reported in settings with limited levels of interprofessional collaboration.

"What is important to me is having someone familiar I can turn to and who will navigate me through the complex health care system, pointing me in the right direction."
(Patient, F, 83 yrs.)

"Every human being is different, right? And yet my treatment is not adapted to me as an individual. It's standardized, based on how they see it, not on how I want it to be. Actually, I feel like I don't have a say in anything as a patient."
(Patient, F, 57 yrs.)

The professional relationship of patients with their HCPs is based on trust as well. Trust in the GP or PN facilitates open communication about confidential matters and creates a solid support base for disease management. The traditional doctor-patient relationship was given much emphasis during the interviews, illustrating its great significance for all three included stakeholder groups. A specific PN-patient relationship could assist in taking down certain barriers people may encounter when they seek care. Patients expressed their need for time to adapt to the new situation by gradually introducing the PN role and encouraged by the already established trust-relationship with their GP.

"I'm kind of an 'intermediary' between the doctor and the patient. It lowers some thresholds, I think. Some patients would rather share something personal with me than with the GP."
(PN, F, 33 yrs.)

"It is nice if you know the people. It creates a relationship of trust, in fact. Because they know your medical history, your medical conditions… and often your personal situation as well."
(Patient, M, 64 yrs.)

"Our GP team has been planning the integration of a nurse for quite some time now, so we are used to the idea, but of course it will be new for our patients. So we're going to have to re-educate them on this matter."
(GP, M, 41 yrs.)

"At first, I was a bit hesitant because all of this was new to me, and I prefer turning to someone I am familiar with. The first time, the doctor did consultations together with the nurse and he introduced us. And that's how she was integrated, gradually. From the beginning, I noticed my doctor was really supportive of her, and I trust my doctor to choose the 'right' person for the job, someone with the same values."
(Patient, M, 53 yrs.)

Theme 3. Practice nurse role development

The respondents perceived that the dynamic PN role is continuously developing at different speeds and levels, dependent on contextual factors and the clinical setting in which they were working. This asynchronous transition is driven by explicit needs and expectations of general practices and patients, and an increasing trust-based relationship between the PN and the GP and patients. A changing PHC climate and increasing workload are the main reasons for GPs to consider working together with a PN.

"Nowadays, patients don't present themselves with only one problem; they often come with several problems they want to see solved. This evolution in health care use puts a lot of pressure on the GP."
(GP, M, 38 yrs.)

"There are several tasks I can think of that we could delegate to a nurse. In that way, yes, there is a certain need. A nurse in our practice would certainly provide added value, but also ease our workload as GPs."
(GP, M, 41 yrs.)

"The waiting room is always overcrowded and I always have the feeling that the GP needs to work faster to get all the work done, whereas the nurse takes the time to really listen. And meanwhile the doctor is less bothered by time-consuming trivia and can invest more in people who really need it."
(Patient, F, 70 yrs.)

"I must admit that my diabetes consultation is rather technical. So yes, there's probably other ways to do that. A nurse would also have more time to address the patient's perception of an illness."
(GP, F, 53 yrs.)

Both GPs and PNs were positive about future opportunities arising with interprofessional development. As the nursing profession is evolving rapidly, physicians may potentially gain more time to focus on their fundamental, medical responsibilities. Respondents in all three stakeholder groups reported diverse PN role responsibilities. The range of nursing competences that were reported during the interviews with the three stakeholder groups could be grouped into five leading categories: administration and logistics, medical-technicalities, prevention, chronic disease management and innovation and quality improvement.

"As physicians, we would prefer to focus more on the patient's medical problems, our core business, during consultation. "
(GP, F, 53 yrs.)

"After working in nursing for 15 years, I wasn't really satisfied with my job anymore. It felt like I was just executing orders all the time. Instead, I wanted to be part of the decision-making in the care process and consult with the doctor. That is why I seized the opportunity to become a PN. "
(PN, F, 53 yrs.)

In some settings, the PN role is growing further, whilst getting more integrated in the work structure of the PHC team. Therefore, the PN should acquire specific competences so they can feel confident about their new role. This competency-based development allows them to further refine proficiency within their own professional domain, framed by legislative frameworks. Respondents described expertise as being able to work autonomously on the one hand and, on the other, being able to correctly recognize their own boundaries and thus consulting other disciplines if needed.

"I need to be attentive to the extent of my domain of expertise. I am a nurse, not a doctor. So I think it is important to recognize my limits."
(PN, F, 24 yrs.)

"And the way the nurses work, that's something like... 'professionalism'. Knowledge and skills. You can tell by their self-confidence that they are not doubting every decision. And, of course, that they call in the doctor when necessary!"
(Patient, M, 71 yrs.)

Respondents indicated the importance of a high-quality, practically-oriented and theoretically substantiated study program, aimed at a reorienting specialization for nurses with a thorough pre-existent knowledge of basic competences and relevant, previous work experience, combined with context-specific coaching.

"A one-size-fits-all nurse is not delivered, you can't just drop them in a practice and say: 'do it, make it work'. This mentorship is a responsibility of the GP team."
(GP, F, 36 yrs.)

"If you do this kind of work, you have to be very independent and not be afraid of taking decisions. It is a big responsibility. I often get to follow refresher trainings to update my skills and knowledge, in order to guarantee our patients the best care."
(PN, F, 53°yrs.)

"People are afraid to share confidential things with others. In order to do so, they really have to be convinced that those people have the right level of competence for their job."
(Patient, F, 51 yrs.)

Theme 4. Interprofessional collaboration

The participants experience the formalization and operationalization of the collaboration between GP and PN considerably differently in the various settings. Clearly defined, complementary job roles and responsibilities and transparency thereof enhance professional relationships between all three stakeholder groups. Many practices are still trying to find their way in this transitional stage. In the interviews, the PN role description was oriented towards coordination, organization and follow-up of low complexity aspects of patients living with chronic illness. The role of the GP was referred to as supervising and being responsible for complex cases. A protocol-based work organization facilitates formalizing these developing professional relationships and incorporating roles and responsibilities into practice. Moreover, it contributes to the transparency between both PHC team members and patients, and to promoting competence, autonomy and job satisfaction.

"My work is protocol-based. If something occurs that goes beyond my area of responsibility, I consult with the GP first. Yes, both nurse and GPs adhere to the protocol which we agreed upon. Current work agreements are reassessed during each interprofessional consultation and both parties give the pros and cons and then we change it if expedient. Always in consultation with each other."
(PN, F, 40 yrs.)

Interprofessional care in general practice entails shared-decision making. Reaching team consensus by dialoguing and discussing issues with all team members on an equal level and from their own perspective is highly valued by the three stakeholder groups.

"We always take decisions in consultation with one another."
(GP, F, 54 yrs.)

"I feel that we are all on the same level, doctors and nurses, each of us contemplating from our own perspective. So we complement each other."
(PN, M, 38 yrs.)

According to all included stakeholder groups, interprofessional teamwork translates into more continuity and quality of care due to the centralization of HCPs. Effective, interprofessional communication on medical data exchange and coordinating and reporting care processes was thought to be crucial in strengthening this new collaboration between GP and PN.

"They have their weekly meetings to discuss their patients. This way, when my doctor is on holiday, the others are also informed. And also about things that have nothing to do with medical stuff, for example a personal story I was telling. Then they also ask me: 'Tell me, how did that end?' And that's important to me. I never have to tell the same thing twice and they really work together for me, the patient."
(Patient, M, 71 yrs.)

Patients appear to be receptive to the development of a close collaboration between their GP and PN or other disciplines in the general practice. They regarded this transition as beneficial to their experiences in PHC and recognized several practical advantages: a larger amount of time spent with the HCP affects their perception of quality of care; greater availability is perceived as better access to care.

"In primary health care, health care providers often work very independently, whereas patients could really benefit more from them working together."
(Patient, F, 35 yrs.)

HCPs seem to come across several organizational challenges in sustainably implementing this transition in their existing practice structure. GPs expressed their concerns about the barriers of the conventional 'fee for service' financial system, whereas a capitation payment system creates more financial resilience, although the GP population seems rather reluctant to switch. Respondents pointed out the urgent need for revised financial and legislative frameworks that support this transition in the general practice. The investment of time and resources required for the integration of nursing competences into practice was mentioned as another barrier. GPs and PNs indicated the need for practical guidance during this transition that is tailored to their setting, for example by sharing good practices within a GP community and coaching from expert educational institutions.

"The financial obstacle is substantial. If we were to shift patient consultations to a nurse, the government should at least offer some kind of compensation. We lose income because we have to pay a nurse, and a nurse may not charge anything herself, due to current legislative structures. So that's actually a double loss.
(GP, M, 41 yrs.)

"But they should create the right conditions for that nurse, thus allowing her to work independently. Because currently she can only execute the doctor's 'orders'. She is restricted, that is the main problem. They will have to change the basis first."
(Patient, M, 49 yrs.)

"I was thrown in at the deep end, although the three GPs supported me. They told me a little about how the GP practice worked, but there was little structure and organization at the time. And so I just … started. Step by step, and in collaboration with the doctors, we got everything up and running."
(PN, F, 42 yrs.)

"Since we lack experience in working with a nurse in our practice, the practical organization of implementing something like this seems challenging. How about the training and coaching of the nurse? How do we inform our patients? You know… the practical side, the organization within our practice, how are we going to tackle that?"
(GP, F, 36 yrs.)

Discussion

This study provides salient insight into the perspectives of GPs, PNs and patients living with chronic illnesses, who are substantially affected by the context of Belgian PHC transitioning towards an integration of nurses in general practice.

The importance of a clear mission and vision statement about interprofessional teamwork and patient-centered care in general practice was voiced by both HCPs and patients. Our findings on the importance of a shared understanding of the concept of care, which facilitates team work and affects patients' experience with PHC, are echoed by previous research. **Shared mental models** can help describe, explain and predict the behavior of a team, allowing members to coordinate their actions and adapt their behavior to common expectations (30). They are accepted as a meaningful driving force for ongoing systematic practice development and provides orientation for teams (31), especially if endorsed by the individual values and beliefs of team members (32). Moreover, different actors' common interest in collaborating, improving quality of care and developing new professional fields is known to facilitate interprofessional collaboration (33). Despite valued advantages, however, nurses and physicians might have differing views on the essentials of collaboration and autonomous PN practice (34), and team work remains inadequately translated into practice (35).

As this study demonstrates, both the context of PHC and patients' needs lay the basis for actively moving towards the integration of nursing competences in general practice. In congruence with international data, the nurse's role in this setting has diversified in response to a shortage of clinicians in general practice and an increasing burden of chronic diseases and multi-morbidity (36). This transition fits within a **patient-centered model of PHC** and leads to health benefits in patients living with chronic illness (37), provided that PNs expand their role in chronic disease management (38).

Collaborative care leads to a shift from subordination to complementarity and from cost containment to meeting patients' previously unmet needs within a broader concept of health (33).

Despite congruent views on several benefits of including a PN in a primary care practice, nurses, physicians and patients in our study expressed concerns around responsibility, trust and accountability, hampering interprofessional teamwork. The considerable **heterogeneity of the scope of nursing practice and unclear responsibilities in collaboration with physicians**, and subsequent elaboration of nursing roles, can be attributed to the ad hoc development which has occurred in many countries because of the urgency for differentiating and expanding tasks concerning complex care (22, 39). Research shows that poorly defined roles are a potential source of conflict, may reduce effectiveness of care, and cause lack of confidence in, and resistance to, the integration of new roles (40, 41). Conversely, clear definitions of each team-member's role may facilitate optimally shared responsibility for patient care within primary care teams (42). The extent to which the legitimacy of practice nursing is established and maintained in general practice, may explain the divers ways the PN-GP collaboration was described during the interviews: instrumental **-**meaning that the PN performs delegated tasks based on the GP's orders- or rather integrated, including the PNs' autonomous decision-making competence based on structured agreements.

This study has identified **medical liability** for nursing practice and the lack of formal **governmental support and long term secure funding** for GPs to employ a nurse, as barriers to interprofessional GP-PN care in Belgian PHC.

A defined scope of practice and suitable legislation can facilitate interprofessional collaboration (33). Enabling nurses to work to the full extent of their scope is expected to mitigate future workforce shortages and improve patient access to care (43). However, in Belgium, the level of clinical practice is restricted to perform only a limited set of advanced clinical activities, under physician supervision, thus limiting the PN's ability to strengthen primary health care (42). Although introducing protocol-based care may facilitate instrumental PN-GP collaboration in this context (42), it also may diminish opportunities for the shift from task delegation to integrated team care with shared responsibilities (44).

Fee-for-service schemes, which are widely used in Belgian general practices, hamper role expansion of nurses as only services delivered by physicians are reimbursed, whereas capitation-based reimbursement schemes are supportive of role expansion of PNs (42). Policy initiatives have led to a significant increase in the number of practice nurses working in a general practice in other countries (45). Moreover, when governmental support is linked to a number of requirements that create the

conditions to work within their area of clinical expertise, it can support further evolvement of the PN discipline (23).

A timely and thorough planning of the dynamic and complex integration process of the nurse in general practice is indispensable to inform and prepare PHC teams (46). Such initiatives are expected to reinforce confidence and trust of all included stakeholder groups in the new PN role, besides the gradual adaptation this transition requires to overcome organizational constraints (47). Broadening collaboration towards an interprofessional approach creates the need for **training and evaluation at a team level** (33). The development of **national professional practice standards** for PNs working in Belgian general practice, as proposed by Halcomb et al. (48), might support the ongoing transition in PHC. Such standards could contribute to defining the role and scope of the PN and transparency thereof for both HCP and patient and, in addition, guide curriculum development, the practical implementation of nursing skills in specific settings and measurement of performance; all of which are actions that have been put forth as much needed during our interviews. Specialized interprofessional clinical **education** for PHC may consolidate further PN role expansion (49). Responding to the importance of education of nurses, a post-graduate education program was delivered in Antwerp in 2016. A collaboration between the university and university colleges of the province was set, supported by a strong involvement of both GPs and nurses in the development and follow-up of the program, as learning process to integrate nurse competencies in general practice. During their training program, student PNs do internships in GP practices, which increases sustainability in settings that don't have experience with interprofessional collaboration. Moreover, the program is guided by a research initiative to study the effect on patients as well as GPs and nurses in order to provide evidence for practices and policy making.

We recognize that some **limitations** have to be considered when interpreting our findings. First, the study was performed in a specific PHC setting so transferability to other settings is not evident. However, we described the specific characteristics of Belgian PHC thoroughly, to enable a clear understanding of the context and the potential use of the results in other contexts . Therefore, further research might be needed to confirm the identified themes in other settings. Second, because of our focus on patients living with chronic illness, perceptions about the potential PN role in preventive initiatives and care for acute minor illnesses, as proposed in previous research (50), are still open to further exploration. Next, the recruitment strategy of patient respondents was organized with involvement of their HCP in general practice, which could have led to selection bias. Finally, we acknowledge the difficulties in triangulating the results of four primary studies that were conducted independently and without preceding methodological proposal to reinforce consistency. Nevertheless, minor heterogeneity in primary data collection and analysis of incorporated studies was diluted, due

to the similarly narrow range of epistemological assumptions and qualitative methodologies all four primary studies were informed by. Thematic synthesis contributed to a fresh interpretation of the researched phenomenon, rather than merely describing and summarizing primary data.

Conclusion

This study used a qualitative design that incorporated semi-structured interviews to better understand the PN's, GP's and patient's perceptions and experiences about integration of nurses in Belgian general practice. Interprofessional collaboration and accurate integration of clinical and organizational nursing skills and knowledge are needed in a patient-centered model in general practice. However, many contextual and organizational barriers remain, hindering further role development and long-term sustainability, whereas clear vision and mission and trust-based professional relationships facilitate the transition.

Relevance to clinical practice

Our study highlights contextual opportunities and challenges to consider in implementing the interprofessional model of care that has been demonstrated to improve health outcomes. This transition in international PHC contexts involves a critical learning process for researchers, policymakers, HCPs and a population with a potential need for care. Current and future challenges in PHC require a more integrated interprofessional collaboration with shared responsibilities instead of task delegation between GPs and PNs. Shifting from 'task delegation' to 'team care' is a global trend, yet limited by traditional role concepts, legal frameworks and reimbursement schemes (22, 42). We strongly recommend that future research is dedicated to systematically document, plan, monitor and assess further transition of PHC in Belgium and other contexts, which will provide the systematic guidance general practices are urging for and lay the groundwork for sustainable change that is much needed. Moreover, future research would be an investment in building solid arguments for policy makers to reevaluate legislative and financial frameworks, currently defined by hierarchically structured health care professions and lacking resilience to this urgent transition.

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Chapter 4

Recommendations on promoting physical activity for primary prevention of cardiovascular disease

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Abstract

Background

Cardiovascular diseases are the world's leading cause of morbidity and mortality. An active lifestyle is one of the cornerstones in the primary prevention of cardiovascular disease. An initial step in guiding primary prevention programs is to refer to clinical guidelines. We aimed to systematically review clinical practice guidelines on primary prevention of cardiovascular disease and their recommendations regarding physical activity.

Methods

We systematically searched Trip Medical Database, PubMed and Guidelines International Network from January 2012 up to December 2020 using the following search strings: 'cardiovascular disease', 'prevention', combined with specific cardiovascular disease risk factors. The identified records were screened for relevance and content. We methodologically assessed the selected guidelines using the AGREE II tool. Recommendations were summarized using a consensus-developed extraction form.

Results

After screening, 27 clinical practice guidelines were included, all of which were developed in Western countries and showed consistent rigor of development. Guidelines were consistent about the benefit of regular, moderate-intensity, aerobic physical activity. However, recommendations on strategies to achieve and sustain behavior change varied. Multicomponent interventions, comprising education, counseling and self-management support, are recommended to be delivered by various providers in primary health care or community settings. Guidelines advise to embed patient-centered care and behavioral change techniques in prevention programs.

Conclusions

Current clinical practice guidelines recommend similar PA lifestyle advice and propose various delivery models to be considered in the design of such interventions. Guidelines identify a gap in evidence on the implementation of these recommendations into practice.

Background

Cardiovascular diseases (CVDs) are the number one cause of death worldwide; more people die annually from CVDs than from any other cause. In 2016 alone, an estimated 17.9 million people died from CVDs, accounting for 31% of global mortality. According to estimates of the World Health Organization, nearly 75% of vascular events may be prevented when a combination of cost-effective population-wide and individual interventions are implemented appropriately (1). Addressing modifiable CVD risk factors can prevent disability and death, and improve quality of life. The most important behavioral risk factors of heart disease and stroke are physical inactivity, unhealthy diet, tobacco use and harmful use of alcohol (2, 3).

Current literature demonstrates numerous methods to reduce CVD risk profile with strong consensus regarding lifestyle behavior. Primary prevention is an important priority for all developers of health policy (4). Physical activity (PA) is one of the main targeted areas in CVD primary prevention, nested within a broader lifestyle approach and besides medical treatment (5). Although countries are facing an overall pandemic of physical inactivity similar to that of smoking, the response to the public health challenge of inactivity has not been as strong as needed (6). Worldwide, one in four adults and three in four adolescents currently do not meet the global recommendations for PA set by the World Health Organization. In some countries, levels of attainment of PA guidelines can be as low as 30% and inactivity accounts for 1–3% of national health care costs (7). Evidence shows that adults stand to gain substantial longevity benefits by becoming more physically active, irrespective of established CVD risk factors. Increasing and maintaining PA levels to meet the minimum public health recommendations can prevent nearly one in two deaths associated with physical inactivity (8).

Despite high evidence on the importance of lifestyle behavior change interventions, implementation in practice remains limited (9). Horizon 2020 project SPICES[2] aims to implement a program, containing PA behavior interventions, for the primary prevention of CVD in primary health care and community settings in various high (Belgium, France, United Kingdom), middle (South Africa) and low (Uganda) income contexts. As improving the efficiency of disseminating the evidence-based practices to practitioners is often seen as a solution for bridging the science-to-practice gap (10), a first step for us was to explore the guidelines in order to inform the SPICES program, before evaluating further implementation thereof. Clinical practice guidelines (CPGs) organize and provide the best available evidence to support clinical decision making (11). Systematically reviewing existing CPGs is an

[2] Scaling-up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and Sub-Saharan Africa: An implementation research – European Commission

approach that has been used before, however, to our knowledge, no recent study exists that systematically reviewed international CPGs with a focus on PA in the primary prevention of CVD. Our aim is to review guidelines in order to identify best practice recommendations in terms of the design and implementation of interventions, e.g. setting; intervention deliverers; intervention content, for the implementation and evaluation in the Horizon 2020 project SPICES sites.

This systematic review aims to answer the following research question: What recommendations are made in CPGs to guide the design and the implementation of PA interventions in primary health care and at community level, for the primary prevention of CVD?

Methods

We applied standard systematic review methodology as outlined by the Cochrane Collaboration (12) and we used the PRISMA[3] checklist (13) ***[Supplementary material 1]*** for self-evaluation of the overall standards and quality requirements for reporting a systematic literature review. All authors contributed to the development of the research protocol prior to the study.

Data sources and search strategy

Between September 2017 and January 2018, NA, PVR and HB carried out a systematic search on Trip Medical Database and International Guidelines Library of the Guidelines International Network (G-I-N) to reach a broad scope of CPGs. An additional systematic search was subsequently carried out on G-I-N and PubMed in December 2020, with the aim of updating the results of this review with the most recently published guidelines. Suitable search strategies were developed for each database, using multiple combinations of free text, MeSH terms, word variants, Boolean operators and truncation for: 'cardiovascular disease', 'prevention', 'risk', 'lifestyle', 'physical activity'. Publication type was restricted to 'guidelines', the status was specified to be published or under review and language was restricted to English, Dutch and French.

Selection of guidelines and inclusion criteria

All records were submitted to a selection procedure on relevance and content, by means of pre-defined in- and exclusion criteria. Publication types other than CPGs and those published before January 2012 were excluded from this review. In case of different versions of the same CPG, we included the most recent one. Titles and abstracts were independently screened by NA, DLG and MO.

[3] Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Records were excluded if both reviewers agreed they were not eligible; discrepancies between reviewers were resolved by discussion until consensus (NA, DLG, MO, JYLR, HB).

CPGs were included if the recommendations described PA interventions for primary prevention of CVD, in comparison to other (lifestyle) intervention or no intervention, targeting the general, adult population. Guidelines needed to report on at least one relevant patient outcome measure commonly used for CVD risk assessment, such as CVD mortality and morbidity, or modifiable risk factors in relation to the primary prevention of CVD (e.g. overweight and obesity, hyperlipidemia, hypertension, lifestyle behavior, dysglycemia). Interventions had to be implemented in primary health care or community settings.

CPGs were excluded if they focused exclusively on CVD risk assessment, pharmacological interventions or lifestyle interventions other than exercise (diet, smoking, alcohol), or if they were explicitly targeting children, adolescents or a geriatric population. Guidelines addressing secondary prevention of CVD, specific conditions related to CVD (e.g. familial hypercholesterolemia, chronic kidney disease, type I diabetes mellitus) and the management of CVD risk factors beyond primary prevention, were excluded from this review as well.

Guideline quality assessment

At least two researchers (NA, MO, DLG, JYLR, PVR, PVB, HB) independently performed a quality appraisal of full text records with the AGREE[4] II instrument. The tool comprises 23 items, organized into six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability and editorial independence (14). The reviewers' overall assessment (scores from 0 to 7, with a consensus-based cut off at a minimum score of 5/7 for inclusion) in combination with a positive advice on use of the guideline ('yes' for inclusion), determined the in- or exclusion of each CPG. Records with scores below 5 or around cut-off (one score 4 and one score 5), were excluded. Discrepant scores (more than 1-point difference and one score above 4) and reviewers' recommendations regarding use of the guideline were discussed until we reached a consensual decision by pooling the data.

Data extraction and synthesis

In order to ensure accuracy of data extraction for this literature review, an author-team consensus-based data extraction form was determined, comprising of three phases. NA extracted the data, regularly conferring with the senior research team (PVR, LP, PVB, GM, HB). Firstly, we listed all included

[4] Appraisal of Guidelines for Research and Evaluation

CPGs and extracted publication year (or year of latest update), country, developing organization, language and title. Secondly, we made an inventory of all PA recommendations, stand alone or as a component of a broader lifestyle recommendation, in order to get an overview of the relevant content of each included CPG with regards to our research questions. If reported, the following characteristics were extracted from each recommendation and its scientific underpinning: strength of recommendation and level of evidence, intervention description and outcomes, implementation strategies, evidence gaps.

Thirdly, two core recommendation matrices ***[Supplementary materials 2 and 3, to read together with Supplementary material 4 – Grading]*** were produced: with a listing of relevant recommendations for each CPG; entailing detailed information on clinical relevance and level of evidence grades, primary study intervention characteristics and reported outcomes. Taking into consideration cross-guideline recurrence, results were summarized in Table and Table .

Results

Our systematic searches retrieved a total of 826 records. After rejection of 757 records based on title and 6 duplicates, 63 CPGs were eligible for full text screening. Finally, 47 CPGs could be withheld, 20 of which did not meet the minimum quality appraisal criteria according to AGREE II. A summary of the full search and review process is presented in a PRISMA flow chart (13) in Figure 1.

Table 1 summarizes the basic characteristics of the 27 included CPGs, all of which were developed in Western countries. CPGs were categorized according to their main focus. Seven were dedicated entirely to the global prevention of CVD and a further three to lifestyle behavior (LSt), whereas the other CPGs addressed prevention at the level of specific CVD risk factors: seven records on weight management (OW), four on blood lipids (LCh), three on blood pressure control (BP) and three on blood glucose (DM). All included CPGs met the pre-defined minimum quality according to AGREE II criteria. The domain scores showed some variability. Lowest scores were obtained in domain 5 ‘applicability’ (mean 58% [range 25-78%]), highest scores were reached in domain 4 ‘clarity of development’ (median 79% [range 56-94%]) ***[Appendix 1 – AGREE Scores]***.

The information from the guidelines could be divided into two major categories, including content of PA recommendations and delivery of PA interventions. Table 2 contains all recommendations related to the content of PA interventions; Table 3 contains all recommendations involving the delivery of PA interventions.

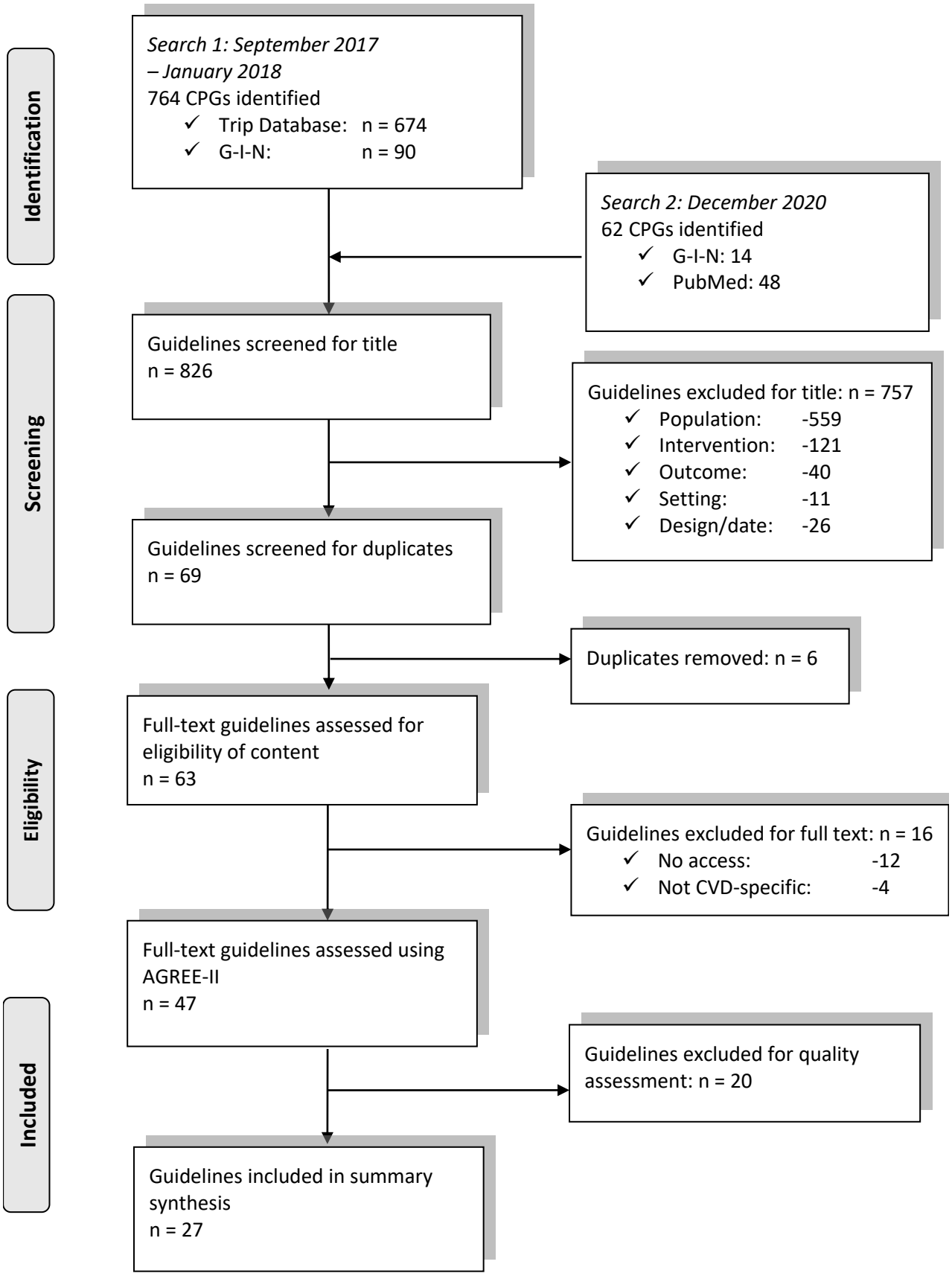

Figure 1 PRISMA flowchart of search, screen and quality assessment process

Table 1 Basic characteristics of included guidelines

CPG code	Year	Country	Developing Organization	Title
			Global cardiovascular disease	
CVD 1 (40)	2012	Australia	National Vascular Disease Prevention Alliance	Guidelines for the management of absolute cardiovascular disease risk
CVD 2 (19)	2014	UK	National Institute for Health and Care Excellence	Prevention of cardiovascular disease (PH25)
CVD 3 (15)	2016	EU	European Society of Cardiology	European Guidelines on cardiovascular disease prevention in clinical practice
CVD 4 (16)	2017	UK	Scottish Intercollegiate Guidelines Network	Risk estimation and the prevention of cardiovascular disease
CVD 5 (27)	2019	Netherlands	Dutch College of General Practitioners	Cardiovascular risk management (M84)
CVD 6 (20)	2018	Australia	National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand	Guidelines for the prevention, detection, and management of heart failure in Australia
CVD 7 (18)	2019	U.S.	American College of Cardiology & American Heart Association Task Force on Clinical Practice Guidelines	Guideline on the primary prevention of cardiovascular disease

			Lifestyle behavior	
LSt 1 (36)	2012	U.S.	U.S. Preventive Services Task Force	Behavioral counseling interventions to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors
LSt 2 (21)	2014	U.S.	American College of Cardiology Foundation & American Heart Association	Guideline on lifestyle management to reduce cardiovascular risk
LSt 3 (37)	2014	UK	National Institute for Health and Care Excellence	Behavior change: individual approaches (PH49)
			Overweight & obesity	
OW 1 (34)	2012	U.S.	U.S. Preventive Services Task Force	Screening for and management of obesity in adults
OW 2 (31)	2013	Australia	National Health and Medical Research Council	Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia
OW 3 (22)	2014	U.S.	American College of Cardiology Foundation & American Heart Association & The Obesity Society	Guideline for the management of overweight and obesity in adults
OW 4 (17)	2014	U.S.	Department of Defense & Department of Veterans Affairs& Veterans Health Administration	Clinical practice guideline for screening and management of overweight and obesity
OW 5 (39)	2014	UK	National Institute for Health and Care Excellence	Obesity prevention (CG43)

OW 6 (35)	2015	Canada	Canadian Task Force on Preventive Health Care	Recommendations for prevention of weight gain and use of behavioral and pharmacological interventions to manage overweight and obesity in adults in primary care
OW 7 (30)	2015	UK	National Institute for Health and Care Excellence	Maintaining a healthy weight and preventing excess weight gain among adults and children
			Blood lipids & cholesterol	
LCh 1 (23)	2014	UK	National Institute for Health and Care Excellence	Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease (cg181)
LCh 2 (29)	2014	U.S.	Department of Defense & Department of Veterans Affairs & Veterans Health Administration	Clinical practice guideline for the management of dyslipidemia for cardiovascular risk reduction
LCh 3 (56)	2018	U.S.	American College of Cardiology & American Heart Association Task Force on Clinical Practice Guidelines	Guideline on the management of blood cholesterol
LCh 4 (25)	2019	EU	The Task Force for the management of dyslipidemias of the European Society of Cardiology and European Atherosclerosis Society	Guidelines for the management of dyslipidemias: lipid modification to reduce cardiovascular risk

			Hypertension	
BP 1 (24)	2014	U.S.	Department of Defense & Department of Veterans Affairs & Veterans Health Administration	Clinical practice guideline for the diagnosis and management of hypertension in the primary care setting
BP 2 (38)	2014	U.S.	Community Preventive Services Task Force	Team-based care to improve blood pressure control
BP 3 (28)	2020	Canada	Hypertension Canada	Comprehensive guidelines for the prevention, diagnosis, risk assessment, and treatment of hypertension in adults and children
			Blood glucose & type 2 diabetes mellitus	
DM 1 (32)	2013	Canada	Canadian Diabetes Association	Clinical practice guidelines for the prevention and management of diabetes in Canada: Introduction
DM 2 (33)	2014	UK	National Institute for Health and Care Excellence	Type 2 diabetes prevention: population and community-level interventions (PH35)
DM 3 (26)	2019	EU	European Society of Cardiology & European Association for the Study of Diabetes	Guidelines on diabetes, pre-diabetes, and cardiovascular diseases

Content of PA Interventions (Table 2)

In the included guidelines, PA for the primary prevention of CVD was described by four dimensions: intensity, duration, frequency and type of the recommended PA activity. All CPGs advised interventions to involve moderate to vigorous PA intensity and a duration of PA sessions of at least 150 minutes weekly for moderate, or at least 75 minutes weekly for vigorous intensity PA. Four CPGs reported that several shorter PA sessions were as effective as one session of 30 minutes daily as they provided a similar total energy expenditure (15-18). The CPGs stated that PA should be conducted on a regular basis, meaning on at least five days of the week, preferably each day of the week (19, 20). Aerobic PA was reported to be the fundamental type of PA for the primary prevention of CVD in eight of the included guidelines (15-17, 21-25), which should entail occupational, leisure time, exercise and/or active living activities. Two guidelines recommended interventions with a combination of both aerobic and resistance training for the prevention of diabetes and its CVD complications (15)(26). Three other guidelines advised on including resistance training or muscle strengthening exercises for the primary prevention of CVD, such as carrying heavy load, heavy gardening, weight training, push-ups or sit-ups on at least two days a week (16, 23, 27), whereas three other CPGs merely stated that there is no evidence for excluding it from interventions (21, 24)(28).

Due to the inverse dose-response relationship between higher levels of PA and lower risk of CVD events as reported in the CPGs (16, 21, 29), a gradual increase of PA levels through a combination of changes to intensity, duration and/or frequency (15, 16, 26, 27, 30) should be encouraged. For example, a gradual increase in aerobic PA to 300 minutes a week of moderate intensity, or 150 minutes a week of vigorous intensity aerobic PA, or an equivalent combination thereof, is recommended for additional health benefits.

Specifically for the weight management in an adult overweight or obese population, the included guidelines proposed higher-intensity (duration of at least 6 months) comprehensive lifestyle interventions, including high basic levels (and gradual increase) of PA, diet and behavior change components (17, 18, 22, 25, 28, 30, 31). Regular PA with the aim of moderate weight loss is also advised to reduce the risk of Type 2 Diabetes in adults with impaired glucose intolerance and impaired fasting glucose (18, 32, 33). Five CPGs defined sedentary behavior as an independent CVD risk factor and urged to minimize the amount of time spent being sedentary over extended periods (16, 18, 27), by advising sedentary people to start PA at low intensity and progress gradually (15), and to reduce screen time and take breaks from prolonged sitting both at home and at work (30).

The included CPGs stated that PA interventions designed in line with these recommendations, will result in a decrease in CVD mortality and morbidity. Moreover, a wide range of indirect health benefits

were reported in the guidelines, such as: a decrease of systolic and diastolic blood pressure, body fat, body weight, LDL-C, triglycerides, total cholesterol, HbA1c levels and new onset type 2 diabetes mellitus (T2DM); and an increase of HDL-C and insulin sensitivity.

Table 2 Content of PA interventions for the primary prevention of CVD

Focus of physical activity intervention	Target population	Recommendation	Details of recommendation	Guideline reference number (see Table 1 for details)
Global CVD prevention	General adult population, regardless of CVD risk factors	All adults should be advised to participate in: At least 30 minutes of moderate intensity (aerobic) PA on at least 5 days of the week (minimum of 150 min/week), or preferably every day of the week. *OR* At least 15 minutes of vigorous intensity (aerobic) PA on at least 5 days of the week (minimum of 75 min/week), or preferably every day of the week.	PA: Any bodily movement produced by skeletal muscles that requires energy expenditure. Cardiorespiratory fitness: ability of the body to use oxygen to do PA, improved by PA. Aerobic PA: movements of large muscle mass in a rhythmic manner for a sustained period. Moderate intensity: breathing faster than normal / 3.0-5.9 METS / Increase of breathing rate, heart rate, & warmth, possibly accompanied by sweating / Can be continued for many minutes without exhaustion feeling. Prescription of 4 dimensions: Frequency, duration, intensity & type – Taking into account contraindications (individual's condition). Duration: No need for continuous PA to have benefit; longer sessions have no different effect on CHD risk compared with shorter sessions, as long as total energy expenditure is similar.	CVD 1 CVD 2 CVD 3 CVD 4 CVD 5 CVD 6 CVD 7 LSt 2 LCh 2 LCh 3 LCh 4 BP 1 BP 3 DM 2 CVD 3 CVD 7 LSt 2

		OR An equivalent combination thereof, performed in sessions with a duration of at least 10 min/session.		CVD 3 CVD 4 CVD 7 OW 4
		PA may include occupational and/or leisure-time activity and should incorporate accumulated bouts of moderate-intensity activities.	Type of PA: Active living (non-recreational active travel, household work, gardening), occupational activity (at work), leisure time activity (non-occupational) & exercise (structured and done for specific reason, e.g. brisk walking, cycling, hiking, jogging, swimming).	CVD 4 CVD 5 OW 4 OW 7
		All patients, irrespective of health, fitness or activity level, should be encouraged to increase activity levels gradually Those who are moderately active and are able to increase their activity should be encouraged to do so. Activity can be increased through combination of changes to intensity, duration or frequency For additional benefit in healthy adults, a gradual increase in aerobic PA to 300 minutes a week of moderate intensity, or 150 minutes a week of vigorous intensity aerobic PA, or an equivalent combination thereof is recommended.	Inverse dose-response relationship between PA levels and CVD risk Potential risk of adverse events associated with vigorous - & high-intensity exercise are extremely low (no significant difference when compared to moderate-intensity PA).	CVD 3 CVD 4 CVD 5 OW 7 LSt 2 LCh 2 DM 3
		Individuals should be advised to minimize the amount of time spent being sedentary (sitting) over extended periods; e.g. by reducing screen time and taking regular breaks from sitting both at home and at work.	Provide general advice to minimize periods of prolonged sitting: - High levels of total sedentary behavior are associated with higher risk of CVD & mortality. - High levels of sedentary behavior may be associated with additional CVD risk at any level of PA. - Undertaking very high levels of PA (>1h/day moderate to vigorous PA) may eliminate the association between excess sitting & CVD risk.	CVD 3 CVD 4 CVD 5 CVD 7 OW 7

Weight management	Adult population with overweight/ obesity	For adults who are overweight or obese, strongly recommend lifestyle change by participating for ≥ 6 months in comprehensive lifestyle interventions, including: reduced energy intake, increased PA and measures to support behavioral change (behavioral strategies).	<u>Comprehensive lifestyle interventions</u>: multicomponent interventions, with combination of 3 components nutrition, PA & behavior change (BCT). Less amount of activity is needed for weight loss (because of energy deficit from diet + PA together), BCT assists pat in adhering to intervention. <u>Prevent weight regain</u>: Maintaining high levels of PA (approximately 60 minutes per day) combined with other behavioral strategies.	CVD 7 LCh 4 OW 2 OW 3 OW 4 OW 7 BP 3
		For adults who are overweight or obese, prescribe approximately 300 minutes of moderate intensity activity, or 150 minutes of vigorous activity, or an equivalent combination of moderate intensity and vigorous activities each week combined with reduced dietary intake, to result in weight loss and gradually increase PA levels to prevent weight regain after initial weight loss.		CVD 3 OW 2 OW 4
	Adult population with combined CVD risk factors	Counsel overweight and obese adults with CVD risk factors (high BP, hyperlipidemia, hyperglycemia) that lifestyle changes that produce even modest, sustained weight loss of 3-5% produce clinically meaningful health benefits, and greater weight loss produces greater benefits.	<u>Dose-response</u>: between amount of weight loss & lowering of BP and improvements in lipid/glycaemia profiles.	OW 3
Blood glucose management	Adult population with hyperglycemia or T2DM	A structured program of lifestyle modification that includes moderate weight loss and regular PA should be implemented to reduce the risk of T2DM in individuals with impaired glucose tolerance (prediabetes, IGT) and impaired fasting glucose (IFG) and A1C 6.0-6.4%.	<u>Target population for primary prevention</u>: 1. High-risk individuals (e.g. obesity, IGT); 2. High-risk sub-groups (e.g. low SES); 3. General population.	CVD 7 DM 1 DM 2 DM 3
	General adult population, adult population with	Advise adults to engage in resistance (muscle-strengthening) training on at least two days a week, such as carrying heavy load, heavy gardening, weight training, push-ups or sit-ups (e.g. 9 exercises, 3 sets & 11 repetitions, intensity 70% of 1-max repetition).	<u>Resistance training</u>: Muscle strengthening of all major muscle groups (legs, hips, back, abdomen, chest, shoulders and arms).	CVD 3 CVD 4 CVD 5 LSt 2

	hyperglycemia or T2DM		Limited evidence for resistance training, but no evidence to exclude it from exercise programs (may confer pat benefits as well). Hypertensive individuals (SBP/DBP of 140-159/90-99 mm Hg): resistance or weight training exercise does not adversely influence the blood pressure T2DM: Specifically for DM prevention, combination of both aerobic & resistance exercise is effective.	LCh 1 BP 1 BP 3 DM 3

Strategies for delivery and implementation of PA advice (Table 3)

The recommendations on strategies for delivery and implementation of PA made by the included guidelines, could be structured into eight major categories: Support & follow up, Behavior change, Provider, Information & education, Patient-centered care, Self-management, Setting & referral, and Delivery mode.

Behavior change interventions are recommended to be preceded by raising awareness of the individual CVD risk in relation to lifestyle behavior and an assessment of the 'readiness to change'. It is advised to adapt the timing of such interventions to the stage of motivation, since people are most susceptible for lifestyle change interventions when they are sensitive to change (31). Guidelines recommended to provide structured counseling targeting lifestyle behaviors (17, 34-36), incorporating the use of cognitive-behavioral change techniques throughout the multicomponent interventions (e.g. motivational interviewing, shared decision-making, goal-setting, action planning and problem-solving) (15, 17, 25, 27, 37). Guidelines stated the importance of providing education and communicating clearly with individual patients about all aspects of PA interventions, according to health education principles (e.g. comprehensive amounts of information, reinforced by resources) and using elements of effective communication (e.g. non-judgmental interaction, reflective listening, showing empathy) (23-25, 30), hereby creating a shared understanding (17, 18). Two guidelines also advised to convey tailored messages to local populations using community resources, in order to raise general awareness (15, 33). Patient-centered care was recommended to entail tailoring interventions to groups and individuals and individualizing care plans throughout the entire follow-up pathway, as interventions are advised to meet individual needs, preferences and circumstances, taking into account social determinants of health (18, 25, 30, 33, 37). CPGs also proposed to integrate follow-up support and self-management strategies, such as self-monitoring (30), PA tracking (23, 24, 30) and relapse management (31) as part of a multicomponent intervention, in order to ensure that initial behavior change is maintained long-term (17, 24, 27, 37). The use of mHealth or eHealth applications was proposed to support self-management and follow-up interventions (15, 24).

Team-based multidisciplinary care was advised and guidelines recommended various ways of involving both professional and non-professional care providers (15, 18, 27, 38, 39), and linking medical and lay people, peers and family in the planning, design and delivery of interventions (33). CPGs reported various interprofessional collaboration models with clinicians and non-clinicians, and recommended organizing complementary competencies to be most beneficial for people (15), e.g. by task sharing and shifting in primary health care (24). We identified several recommendations around community-based support of behavior change interventions through the involvement of community health workers,

welfare organizations and social peer support. The included guidelines proposed multifaceted approaches with a clear linkage between primary health care and the community (e.g. by informing people and increase access towards opportunities for increasing PA behavior in the community), in order to increase the effectiveness of interventions (22, 23, 33, 36). However, they emphasized the importance of embedding lay/peer-led components in a wider team led by health care professionals (33) and underlined the need for appropriate training of both professionals and non-professionals involved in behavior change interventions (24, 33, 37). CPGs reported various advice regarding intensity and frequency of support and follow-up interventions, emphasizing that it is crucial to tailor this to the needs of each individual. They differentiated between very brief, brief or extended brief interventions, and recommended follow-up for at least one year (15, 24, 37, 40). High intensity interventions, with multiple contacts over extended periods, were recommended for active weight management and maintenance in three guidelines (17, 22, 31). The guidelines reported no clear precedence in group versus individual and face to face versus additional remote contacts (e.g. telephone or web-based) (22, 36).

The particular intervention delivery strategies as recommended in the included guidelines, can lead to improvement of the following non-clinical outcomes: Increase of motivation and self-efficacy, better adherence to behavioral elements of the interventions, higher participation and attendance rates in treatment activities, better coping with illness, and higher self-reported health behavior.

Table 3 Strategies recommended in clinical practice guidelines for the implementation of PA lifestyle advice for the primary prevention of CVD

Field *Subfield*	**Recommendation**	**Details of recommendation**	**Guideline reference number (see Table 1 for details)**
Support & follow-up *Global CVD prevention - low to medium intensity*	Patient be seen **within one month** of initiation of lifestyle therapy to determine adequacy of risk factor management, degree of patient adherence, presence of adverse effects.	Tailor the support and follow-up: Intensity & frequency based on individual need. Plan reviews: Before, during & after behavior change intervention to assess progress towards goals. Very brief intervention: *(10-15 min)* Target general public & focus on motivation & information. Brief intervention: *(15-25 min)* Target low SES people or people whose health/wellbeing could be at risk. Extended brief intervention: *(30 min or more)* Target people with high risk behavior; health problems; comorbidities; increased risk of harm; increased need for support to reach/maintain change. High intensity intervention: *(over 30 min)* Target people at high risk of causing harm to their health/wellbeing; who have not benefited lower-intensity interventions; who have medical condition that needs specialist advice/monitoring; overweight population who are aiming to lose weight.	BP 1
	Regular assessment and counselling on PA is recommended to promote the engagement and, if necessary, to support an increase in PA volume over time.		CVD 3 CVD 7
	Adults at higher absolute risk of CVD should be given **more frequent and sustained** lifestyle advice, support and follow-up to achieve behavioral change.		CVD 1
	Deliver **very brief, brief, extended brief and high intensity** behavior change interventions and programs.		LSt 3
	Ensure behavior change is maintained for **at least a year.**		LSt 3
	Once the patient's risk CVD factors are controlled, **at least annually follow-up** is suggested (more frequently as indicated), depending on patient preference.		BP 1
Weight management-high intensity	For **active weight management** in adults, prescribe on-site, high-intensity interventions= ≥ 14 sessions in 6 months with **fortnightly review for the first 3 months, and at least 12 contacts within 12 months).** Assess adherence to the weight loss program by measuring the patient's weight and providing feedback and ongoing support.	Intensive: Multiple contacts over extended periods (5-26 contacts/9-12 months) - *Short-term:* At least weekly. - *Intermediate-term:* At least weekly to monthly for another 6 months. - *Long-term:* After the first year, at least bimonthly.	CVD 7 OW 2 OW 3 OW 4

	Advise overweight and obese patients who have lost weight to participate **long term (≥1 year)** in a comprehensive **weight loss maintenance program** consisting of all behavioral components and ongoing support, with additional intervention as required.	Continued provision of comprehensive weight loss maintenance program, on-site or by telephone, for periods up to 2,5 years after initial weight loss.	CVD 7 OW 3 OW 4
Behavior change *Timing*	For adults who are overweight or obese, **discuss readiness to change** lifestyle behaviors.	Awareness: Make people aware of their level of CVD risk in relation to lifestyle behavior. Timing of the intervention: Conform to current stage of motivation since people are most susceptible for lifestyle change interventions when exposed at a time when they are most open to change (e.g. following profiling results revealing elevated CVD risk).	OW 2
Counseling content	Provide **structured information** and combined **behavioral counseling** regarding **lifestyle behaviors** (e.g. healthy diet & PA), in order to prevent CVD and to control CVD risk factors to patients with: 1. normal weight but positive for other CVD risk factors. 2. overweight without obesity-associated conditions.	Lifestyle: Based on long-standing behavioral patterns, maintained by social environment. Content: Focus on behavior change; didactic education & additional support; audit & feedback on progress; strategies for self-monitoring, plan for follow-up Incorporate at least 2 behavior change strategies: Match with patient's needs; other evidence-based effective behavior change techniques; define rationale for techniques included; evaluate novel techniques (limited evidence). Individualized counseling & care plan: patient-centered care as basis for motivation & commitment.	OW 4 LSt 1 OW 1 OW 6
	The use of **established (proven) cognitive-behavioral strategies** (e.g. **motivational interviewing**) to facilitate lifestyle change by evoking patient motivation to accept and participate in lifestyle treatments are recommended when designing interventions.	Goal setting: Specific, proximal, realistic, personal goals for behavior change/resulting outcomes to achieve/maintaining benefits. Moving forward in small, consecutive steps for changing long-term behavior). Consider achievement of outcomes & review further plans/goals. Action planning: Develop & prioritize actions, e.g. PA activity of choice & incorporated in daily life (developing routines & habits) for sustainability & acceptability Problem solving: Well-rehearsed coping plans to prevent/manage relapse, e.g. stimulus control, changes in physical environment. Motivational interviewing: Encouraging, enabling, verbal persuasion, modelling exercising behavior, discussing positive effects. Other techniques: Self-efficacy (Empower patients by building confidence); Feedback & monitoring (Encourage self-monitoring of behavior/outcomes, provide feedback at regular intervals); Social support (Advise /arrange for social network -family, friends, peers- to provide practical help, emotional support, praise or reward); Cognitive	CVD 3 CVD 5 LSt 3 LCh 4 OW 4

		behavioral strategies; Positive reinforcement; Cognitive restructuring; Shared decision-making (between HCP & pat/family).	
Provider *Team-based care*	**Team-based care** with the involvement of **multidisciplinary professionals** is recommended.	Multifaceted approach, supporting: Clinical decision-making, collaboration among providers, patient and family member participation. Team composition: Trained professionals - dietician/nutritionist, physiotherapist/exercise professional, health educator, psychologist, GP, nurse, pharmacist, social worker, community health worker. Roles & responsibility: Limited evidence on organization of complementary competencies. Task shifting and sharing: Adding new staff or changing roles of existing staff, considering licensure and responsibilities. E.g. for delivery in primary health care: Brief lifestyle interventions delivered by PN are more cost-effective than delivered by GP. Initiation of treatment & follow-up by credentialed provider (e.g. exercise on GP prescription; further educative/follow-up counseling & progress/adherence assessments by other HCP than clinician (e.g. nurse-directed behavioral management). Communication & coordination among various team members.	BP 1 BP 2 CVD 3 CVD 5 CVD 7
	Involve **lay or peer workers** to deliver interventions in high risk communities and ensure they are part of a wider team led by health care providers.	Involve peers/family in planning, design and delivery of credible appropriate messages and interventions (including helping people to develop practical skills to adopt healthy lifestyle). Management & supervision by professionals.	DM 2

	Lay/peer workers & HCP should identify and encourage '**community champions**' (e.g. religious and community leaders) to promote PA.	Encourage lay & peer workers to get other members of their community involved.	DM 2
Training	Provide **training for all professional practitioners and lay people** who are responsible for and/or involved in helping to change people's behavior.	Competency & confidence/motivation in: Person-centered care; insight in factors affecting behavior change (incl. psychological, social, cultural & economic) & adverse behaviors; health inequalities; select & tailor appropriate evidence-based interventions; intervention mechanism of action; behavior change techniques; access & refer people to local support services. Training model: Focused/structured; based on evidence based content & training models; practice new skills in community/practice, share knowledge amongst peers; identify skills gaps. Tailored to: setting, participant's characteristics, focus/priority (integral to main role vs. additional task).	LSt 3 DM 2 BP 1
	Monitor/assess behavior change practitioners, **provide feedback** and **give time/support** to develop and maintain competencies.	Monitoring & assessment: Competency frameworks & techniques (audio/video recording, observation tool) to monitor HCP's knowledge & skills (personal development plans, annual reviews), keep up-to-date. Ongoing development: Regular evaluation of outcome & process (e.g. using participant feedback), supported by feedback (oral/written), refresher trainings and clear action plans & goal setting in acquiring the necessary competences.	LSt 3 DM 2
Information & education *Communi-cation*	Provide **patient education** and **clearly communicate** in order to encourage the person to participate in reducing their CVD risk.	Health education principles: Small, comprehensive amounts, didactic education and additional support, reinforced by resources (e.g. written, web-based, audiovisual materials). Effective communication: Friendly & positive interaction; non-judgmental interaction (e.g. lower SES groups/minority groups), patient-centered; open-ended questions, reflective listening; show empathy. Content: Risk assessment; treatment; impact & benefits of behavior change; being more physically active and improving dietary habits; gradual improvements to PA; interventions/services available & how to use them.	OW 7 BP 1 LCh 1
	Exercise **prescription by physicians** (especially GPs), similar to drug prescription, should be considered for health promotion.		CVD 3

Sensibili-zation	Convey **messages to the local population** and **use community resources** to raise awareness and increase accessibility, such as short term community-based educational programs.	Lifestyle messages: consistent, clear, culturally appropriate, integrated within other local health promotion campaigns/interventions. Tailor messages to local community: Work with local practitioners, role models & peers; address misconceptions acting as a barrier; disseminate locally to groups at higher risk (e.g. low SES). Channels of delivery: Involve local community (e.g. Community-wide campaigns, social media, local newspapers/radio channels/shops & businesses/events, social establishments, educational institutions, workplaces, places of worship, local health care establishments, community organizations)	CVD 3 DM 2
Patient-centered care	**Tailor** interventions for specific groups and individuals in order to ensure interventions meet **individual needs, preferences & circumstances** and are **culturally appropriate** (especially in high-risk communities). **Social determinants** of health should inform optimal implementation of treatment recommendations.	Patient participation: At each step, beginning with assessment of 'readiness to change' & intention, capability, opportunity & motivation (e.g. if multiple behaviors need to be changed, assess which one the person is most motivated to tackle). Socioeconomic inequalities: determinants for CVD risk. Tailor advice to SES. Individualized approach & communication: *Assess & address* previous experiences, beliefs on perceived ability to change, thoughts, worries, attitudes, knowledge, context (physical, economic & social environment), physical and psychological capacity, skills, obstacles, feelings, stage of motivation, skills, self-confidence, barriers to change, self-image, group norms and level of autonomy *& tailor interventions and strategies to meet individual needs.*	CVD 7 LSt 3 LCh 4 DM 2 OW 7
	Shared decision-making should guide discussions about the best strategies to reduce CVD risk	Decisions should be collaborative between a clinician and a patient: Engage patients in discussions about personalized CVD risk estimates and their implications for the perceived benefits of preventive strategies (i.e. lifestyle habits & goals); hereby addressing potential barriers to treatment options	CVD 7
	Reach a **shared understanding** with overweight and obese patient about the risks of overweight and obesity and the benefits of weight management.	1. Ask permission to discuss health risks & potential benefits/risks of interventions 2. Explore understanding, knowledge, beliefs, experience, values, family/social network 3. Share information about potential risks based on health status 4. Emphasize the need for ongoing commitment 5. Provide small amounts of information/advice, tailored to individual values/preferences & easy to understand 6. Use teach-back method to confirm shared understanding	OW 4

Self-management	For adults who achieve initial weight loss, strongly recommend the adoption of **specific strategies, appropriate to their individual situation**, to minimize weight regain.	Strategies: Self-monitoring (e.g. regular self-weighing), tracking PA (mHealth/eHealth tools or noting activity in diary), relapse prevention & management (rehearsing action-plans e.g. contacting GP), development of routine, coping, self-care strategies.	OW 2 CVD 5
	For adults, include a **self-management** and/or **self-monitoring** approach to monitor their weight, BP, or associated behaviors.	NOT stand-alone: Self-management approach as part of multicomponent intervention. Self-monitoring of chosen behavior or goal (diet/PA/body weight) at least weekly for therapy adherence.	OW 2 OW 7 BP 1
	Consider the use of a **self-monitoring device/tracking system** (e.g. pedometer, mobile apps) to increase adherence to PA.	Internet-based programs for goal-setting/reminders; lifestyle diaries.	BP 1 LCh 1 OW 7
Setting & referral *Primary health care*	Managers and health professionals in all **primary care settings** should ensure that preventing and managing obesity is a priority at both strategic and delivery levels. Dedicated resources should be allocated for action.	*Brief interventions* in PHC.	OW 5
Community	Use **community links**, outreach projects and lay or peer workers (from lower SES groups) to deliver interventions.	Community-based support: Community health workers assisting HCP & pat by serving as liaisons tot the HC system & lay educators.	DM 2
	Commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed for weight loss, provided there is peer-reviewed published evidence of safety/efficacy.	Community schemes/facilities: Support & promote those that improve access to PA, combined with tailored information based on local needs.	OW 3
Navigation	Work in **partnership** to develop cost-effective PA interventions.	Multifaceted approaches with linkage between PHC - community - public health & health policy interventions.	DM 2
	Provide (written) information on local, affordable, practical and (culturally) acceptable opportunities for PA.		DM 2
	Recognize that people may **need support to change** their lifestyle. To help them do this, refer them to programs such as **exercise referral schemes**.	If no in-house program available or cost-effective option.	LCh 1

Delivery mode	Offer comprehensive lifestyle interventions 1. **face-to-face** in either **individual or group** sessions 2. **telephone based**, either as an alternative or an adjunct to face-to-face intervention, provided it includes personalized feedback from trained practitioner 3. **internet-based**, either as an alternative or an adjunct to face-to-face intervention, provided it includes personalized feedback from trained practitioner	<u>Providing interventions to groups:</u> Group discussions, group tasks (promoting interaction/bonding), mutual support within the group. <u>Remote intervention delivery: I</u>f there is evidence of efficacy (e.g. telephone, text messaging, apps, internet) for cost-effectiveness.	OW 3 OW 4 LSt 1

Discussion

The objective of this systematic review of guidelines was to identify recommendations regarding the design and implementation of PA interventions for the primary prevention of CVD on primary health care and community level supporting clinical practice, for the implementation and evaluation in the Horizon 2020 project SPICES sites. Using a systematic and comprehensive approach, we selected 27 high quality CPGs and summarized recommendations on the content of PA advice and provided an overview of recommended strategies for the delivery of PA interventions. The strength of this systematic review and pragmatic summary is that it can guide practitioners in designing and implementing PA interventions, embedded in a broader lifestyle program.

All CPGs alluded to a healthy lifestyle including regular PA as representing a major component of primary CVD prevention and should be recommended to the whole population. These findings are in line with more recent systematic reviews of primary studies, which concluded that given the great health benefits, comprehensively tackling multiple lifestyle risk factors should be the cornerstone for reducing the global disease burden (41, 42). Overall, the content (frequency, duration, intensity) of the PA message that should be given to the adult population in order to lower their CVD risk, was consistently outlined throughout the included CPGs. In their systematic review, Kraus and colleagues studied the different relationships between PA levels and patient outcomes and found that the associations of PA with beneficial health outcomes begin when adopting even very modest levels; meeting the recommendations reduces mortality and CVD risk to about 75 percent of the maximal benefit obtained by PA alone; and PA levels beyond the guidelines' recommended levels reduce risk even more (43). Nevertheless, the included CPGs identified an important gap in evidence regarding long-term effectiveness (interventions follow-up beyond 2-3 years), effect on CVD morbidity and mortality and the minimum required PA levels required to gain health benefits. We also found that recommendations remained inconclusive regarding advice on resistance training. Some CPGs suggested that a combination of aerobic PA and resistance training could be effective for people with T2DM, yet limited evidence on effectiveness in CVD protection was reported. Primary studies examining combined resistance and aerobic training reported that taking on both forms of exercise was effective for preventing and managing CVD (44, 45), and it was associated with decreases in body weight, BMI and abdominal subcutaneous fat, and improvements to abdominal fat, visceral fat, cardio-respiratory fitness and HbA1c levels (46). However, a recent systematic review found insufficient evidence to determine the potential beneficial effect of resistance training on non-fatal events or the effect of substituting aerobic exercise with resistance training (47). Five of the included CPGs in our review defined sedentary behavior as an independent risk factor for CVD morbidity and mortality. This is in line with a systematic review which concluded that higher levels of total daily sitting time are

associated with an increased risk of CVD and diabetes, independent of PA. The authors suggested that reductions in total daily sitting should be recommended in public health guidelines (44). However, there is insufficient evidence to support the assumption that decreasing sitting time would be easier than effectively promoting PA and evidence remains unclear whether reductions in sedentary time are associated with improvements to the CVD risk (48). Moreover, given the relative independence of sedentary behavior from PA, it is unsure if existing evidence-based behavioral strategies for increasing PA will also directly decrease sedentary behavior (49).

Various strategies for the delivery of interventions to achieve and sustain behavioral change for healthy lifestyle behaviors such as PA, were recommended by the included guidelines. Most CPGs recommended the use of multicomponent interventions, however, they remained unclear as to which are the most essential components in a package of interventions. Indeed, complex interventions make it difficult to define what exactly are the 'active ingredients' of an intervention and how they relate to each other, due to various interacting components; target behavior(s), groups or organizational levels targeted by the intervention; variability of outcomes; and the need for tailoring of the intervention (50). The use of behavior change techniques was strongly recommended in the included CPGs, although the developers identified an urgent need for future research to examine the most effective approach to deal with multiple behaviors; and the effectiveness of individual techniques on motivation and adherence. Recent studies showed that a combination of education and cognitive-behavioral strategies appears to be more effective than a single intervention (51). Interventions incorporating cognitive behavioral strategies, including goal-setting, action planning, self-monitoring, feedback and reinforcement are more likely to induce changes (52), as does increasing self-efficacy and action control skills (53). In some of the guidelines, technology was recommended as opportunity to improve provider-patient communication, self-monitoring, and patient motivation. Current literature reports a disconnect between behavioral strategies shown to be efficacious in face-to-face studies and the implementation of these strategies in technology-delivered interventions. The most common types of strategies (feedback, self-monitoring, and goal setting) are often integrated in technology interventions, whereas other evidence-based treatment components, e.g. barriers identification, relapse prevention, role modeling, motivational interviewing, are not (49). Team-based care, involving multidisciplinary professionals, was recommended in the included guidelines. They proposed task shifting and sharing strategies to meet time and resource limitations of primary care staff and in addition, engaging other deliverers in the community. In a systematic review of Fisher et al, peer support was shown to have effects in encouraging and helping to sustain a variety of complex health behaviors in prevention and disease management and in areas such as cardiovascular disease, HIV/AIDS, diabetes and other chronic diseases (54). Optimizing the engagement of innovative

providers requires clear definition of roles and scopes of practice, in-service training and formal supervision, and sensitization of health managers to the importance of counselling (55).

The included CPGs also identified some gaps in research and practice implications. The design and implementation of PA lifestyle interventions do bring resource implications, and guidelines proposed that future research should focus on the most effective and cost-effective ways of developing, implementing and assessing tailored and culturally appropriate interventions on primary care and community level. According to the CPGs, delivery of lifestyle advice requires a rigorous analysis of and tailoring to the context, vulnerable target population and individual. The guidelines reported that there was insufficient evidence available to give specific advice on particular population groups such as ethnic minority groups or different socioeconomic groups; yet they emphasized the importance of identifying and managing the needs of different population groups to address inequalities in health. CPGs could not report consistent information on acceptability and adherence to changes in different population groups, interactions between behaviors and processes for change and (cost-) effectiveness of interventions and strategies for those at higher risk or the entire population. Moreover, the guidelines identified a gap in evidence regarding factors that can influence implementation of the recommendations into practice.

This review has some limitations. All included CPGs in this review were developed in high-income western countries with extensive resources, whereas low-and middle-income countries might require a different approach. Second, our used strategy and instruments did not include an analysis of the CPGs' consistency, meaning that we did not evaluate the underlying strategies of summary and interpretation of the scientific evidence as well as the interpretation and formulation of the recommendations, leading to a possible interpretation bias.

By bringing the advice of current CPGs together in this review, we provided a comprehensive overview of reported evidence-based recommendations for stakeholders that are involved in the design and implementation of PA interventions in primary prevention programs. However, we acknowledge that additional steps are necessary to actually change practice and policy. Implementation studies, such as the SPICES project, can give more insight into contextual barriers and facilitators from the evaluation of implementation outcomes and process, so that closing the chasm between research and practice can be supported.

Conclusions

Current high-quality CPGs consistently highlight the importance of lifestyle interventions in primary prevention programs for CVD, with PA as one of the major components. PA interventions should be actively integrated in primary health care and community settings. Current clinical practice guidelines

recommend similar PA lifestyle advice, and they propose various delivery models to be considered in the design of such interventions. Guidelines identify a gap in evidence on the contextual barriers and facilitators to implementation of these recommendations, urging for future research to focus on closing the gap between research and practice.

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Chapter 5

Pre-implementation contextual analysis

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Abstract

Cardiovascular diseases are the world's leading cause of mortality, with a high burden especially among vulnerable populations. Interventions for primary prevention need to be further implemented in community and primary health care settings. Context is critically important to understand potential implementation determinants. Therefore, we explored stakeholders' views on the evidence-based SPICES program (EBSP); a multicomponent intervention for the primary prevention of cardiovascular disease, to inform its implementation. In this qualitative study, we conducted interviews and focus groups with 24 key stakeholders, 10 general practitioners, 9 practice nurses, and 13 lay community partners. We used adaptive framework analysis. The Consolidated Framework for Implementation Research guided our data collection, analysis, and reporting. The EBSP was valued as an opportunity to improve risk awareness and health behavior, especially in vulnerable populations. Its relative advantage, evidence-based design, adaptability to the needs and resources of target communities, and the alignment with policy evolutions and local mission and vision, were seen as important facilitators for its implementation. Concerns remain around legal and structural characteristics and intervention complexity. Our results highlight context dimensions that need to be considered and tailored to primary care and community needs and capacities when planning EBSP implementation in real life settings.

Introduction

Cardiovascular diseases (CVD) are the number one cause of death; more people die annually from CVD than from any other cause. In 2019, an estimated 17.9 million people died from CVD, representing 32% of global mortality (1, 2). According to estimates of the WHO, nearly 75% of premature CVD deaths are preventable (3). The current literature demonstrates numerous methods to reduce CVD risk with strong consensus on the importance of raising awareness of CVD risk factors, the asymptomatic course of CVD, and on the impact of health behavior and lifestyle on health outcomes (4, 5). The burden of CVD is highest among individuals in the lower socioeconomic status (SES) quintile as a strong relationship exists between cardiovascular health and education level, occupation, and income (6, 7). Studies suggest that where improvements in CVD-related outcome have occurred, there is an inequity in benefits with a lesser impact on those people of lower socioeconomic status (8). In order to increase quality and accessibility of care (9-12), new models of primary health care (PHC) are needed (13, 14) and primary prevention should be an important priority for health policy makers (15).

Health systems are reorienting towards health promotion, defined as “the process of enabling people to increase control over, and to improve their health” (16), and disease prevention. Nurses play a critical role in expanding, connecting, and coordinating primary and community care (17) and have the ability to make a difference in areas such as patient advocacy and education, and people-centered care (18). Clinical practice guidelines recommend active and systematic integration of lifestyle interventions for CVD prevention in PHC and community settings (19), adding to the importance of integrated care by general practitioners (GP) and practice nurses (PN) in general practice (20, 21). Such collaborations are only established to a limited extent in some contexts (22). The benefits of a nurse-coordinated approach on morbidity, mortality, and lifestyle-related risk factors in both primary (23-25) and secondary (26-29) prevention of CVD have been demonstrated. Moreover, evidence also shows intervention models that have successfully used peers and community partners as facilitators to enhance health (30, 31), and that they can be trained for CVD prevention and management in a cost-effective manner (32).

In Flanders, Belgium, only an estimated 30% of general practices are supported by a PN, and the job profile and ethical framework remain insufficiently clear (22). Furthermore, the link between PHC and the community is unclear. A reform of the health system is ongoing to establish the basis for strong integrated care and strengthen well-being initiatives, social care, health care and their interaction (33).

Studies show poor achievement of guideline-recommended CVD prevention targets (34, 35), as the translation of evidence-based interventions to practice remains limited. Moreover, little is known about how context (Definition: context reflects a set of characteristics and circumstances that consist of active and unique factors that interact, influence, modify, and facilitate or constrain the intervention and its implementation) can influence their implementation (36, 37). As such, there is an urgent need to investigate the factors that could facilitate or hinder the implementation process in specific primary care and community settings. With our study, we provide an approach transferable to other contexts. These insights will allow us to further contextualize and plan the implementation process of targeted interventions and strategies for detection and management of CVD risk factors in the general population as well as in vulnerable subpopulations. In addition, we provide recommendations for planning successful and sustainable implementation.

The primary aim of this study was to explore macro-, meso-, and microlevel stakeholders' views on implementation determinants of a comprehensive intervention for the primary prevention of CVD prior to its implementation in general practice and community settings. A secondary aim was to foster buy-in and sustainability through stakeholder engagement.

Materials and Methods

Study Context

This pre-implementation contextual analysis is part of the H2020 SPICES project, which intends to scale up packages of interventions for cardiovascular disease prevention in selected sites in Europe (France, UK, Belgium) and Sub-Saharan Africa (Uganda, South Africa). The Consortium developed the significant components of the intervention, referred to as "the evidence-based SPICES program (EBSP)", based on systematic reviews of international guidelines (19, 38). The first component is risk profiling and

communication for people between 40 and 75 years, applying the non-laboratory INTERHEART modifiable risk score (5). The second component comprises multi-lifestyle-behavior change counseling (BCC) for those at medium risk with follow-up for at least one year, focusing on the DASH diet, combined aerobic training or aerobic and resistance physical activity, and smoking cessation. Finally, the Consortium decided to incorporate at least the following behavior change techniques in the interventions: motivational interviewing, goal setting, action planning, and problem solving.

Study Design

We conducted this qualitative study within a transformative research paradigm which provided the participatory philosophical assumptions behind the change-oriented SPICES project (39, 40). The EBSP served as the basis to go into dialogue with our local key stakeholders to ensure its components and target implementation strategies (41-43) to take form through co-creation. Inspired by the WHO's Innovative Care for Chronic Conditions Framework, we focused on the partnership triad consisting of patient and family, community partners (CP), and PHC team (44, 45). We also selected the Consolidated Framework for Implementation Research (CFIR), a determinant framework, to guide our data collection and analysis and the reporting of our results (46-48).

Study Setting and Purposeful Sampling

This is a two-phased study. In the first phase, we performed key stakeholder identification and mapping during brainstorming sessions with the input of our local advisory board. In addition, we used the snowballing technique to identify additional key informants (49). We included key stakeholders on the national (Belgium), regional (Flanders), and local (city of Antwerp) level where the EBSP was planned to be implemented. Key stakeholders included relevant central and local government organizations and agencies, policy makers, nongovernmental and community-based agencies involved in the implementation of CVD services, development partners and study communities, representatives of patient organizations, PHC providers, and coordinators of welfare organizations.

In the second phase, we purposefully selected a heterogeneous sample of the organizations at PHC and community level, eligible for future implementation of the EBSP in Antwerp. This process was

carried out in consultation with key stakeholders from phase one who were familiar with the study context. We also used snowballing strategies; consulted the platforms of professional networks or associations; and utilized pre-existing networking structures. Local organizations were found eligible if they could facilitate reaching vulnerable populations (i.e., low SES). We only listed community health centers (in Belgium, a 'community health center' is a multidisciplinary PHC team which is embedded in a third-payer financial system, thus making PHC accessible for vulnerable populations) or general practices if they confirmed a planned or existing formal collaboration with a PN at the time of the study and if they were organized as a group practice. Welfare organizations needed to be non-profit and have a clear social engagement.

We contacted the selected respondents and organizations by e-mail and telephone to inform them about the study. Contact persons were asked to identify one or more appropriate stakeholders within their setting to participate in this study.

Data Collection

In phase one, we held focus groups for primary data collection with the available respondents, to raise a discussion between the stakeholders from different fields of expertise. In addition, we conducted individual interviews with respondents who could not attend one of the focus groups and with the stakeholders we recruited during phase 2. We involved some of the stakeholders through informal meetings, of which we kept meeting reports. We developed flexible, semi-structured data collection tools to guide the interviews. In consensus with the international SPICES consortium, we developed the topic guides using the CFIR interview guide tool (50), which we further adapted to our local context and stakeholder groups. The interview guides are available in Appendix A. An experienced team of qualitative researchers (NA, SA, HB) collected data until we reached data sufficiency. At least two researchers were present as moderators or observers in each focus group. All interviews were held face-to-face and were audio recorded. The interviewers took field notes of their experiences during data collection.

Data Analysis

We applied a descriptive, adaptive framework analysis with a mixed inductive and deductive analytic approach (51, 52). Verbatim transcripts were read several times to familiarize with the data and to generate analytic memos and reflections. One researcher (NA) conducted an inductive, open coding on the transcripts of six individual interviews and two focus groups. Transcripts were divided into meaningful segments that were assigned with open codes, which were then grouped around various aspects regarding the research topic, resulting in clusters of interrelated subthemes and themes. The research team then further refined this inductive preliminary coding structure (NA, SA, LP, HB). In the next step, we charted our preliminary coding structure into the CFIR by mapping interrelationships with domains and constructs (53). Operational definitions of CFIR domains and constructs were tailored to the study to improve coder consistency [Appendix B]. This iterative and reflective process required several discussion rounds within the research team (NA, SA, HB) and resulted in the adaptive analysis framework that we used to deductively code the remaining transcripts. Microsoft Excel 2016 software supported the charting of the data which involved summarizing the data by domain and construct or category from each transcript. The framework was flexible to new findings, thus it was regularly discussed and adapted when needed in team discussions (54) (NA, SA, HB). Finally, we triangulated the data from the study phases and sources by carrying out a framework-focused document analysis of the meeting reports to further substantiate our results (55).

The first study phase ran from July 2017 to December 2017 and the second study phase ran from November 2018 to April 2019. To meet the overall quality standards, we followed the COREQ checklist (56) for reporting the results of this study.

Results

In phase 1 of this study, 24 key macro-, meso-, microlevel stakeholders participated, and their characteristics are outlined in Table 1. In phase 2, lay CPs, GPs, and PNs from four welfare organizations and 12 general practices were involved. The characteristics of the included primary care settings and welfare organizations and their respondents are outlined in Tables 2 and 3, respectively.

Table 1. *Phase 1 macro-, meso-, microlevel stakeholder characteristics (n = 24).*

Stakeholder Level	Organization Type	Description Aims and Domain of Expertise	Job Description	Tenure in Current Organization (Years)	Data Source
Macro Level	Flemish Government-Dept. disease prevention (*n* = 3)	Department of disease prevention; related to health promotion and preventing diseases and disorders by (a) achieving the health objectives by implementing the accompanying action plans (e.g., healthy diet, physical activity, sedentary behavior), (b) recognizing and subsidizing partner organizations, organizations with field operations, loco-regional networks, (c) advising on and supervising a healthy environment.	Team leader Prevention Department	14	Interview
			Team member Prevention Department	10	Interview
			Head of Prevention Department	0.5	Interview
	City of Antwerp–Dept. health and welfare (*n* = 2)	Coordination of health projects with expertise in health inequity. Responsibilities regarding accessible health care: support and location of general practices (GP shortage and practice organization), promoting collaboration between welfare and health care partners, implementing health promotion and prevention, increasing access to care at community level and studying the use of the healthcare system.	Expert in accessible health care and health inequity	3	Focus group 2
			Healthcare Specialist: Health literacy and social health	1.5	Meeting report(s)
Meso Level	National cardiologists association	Information and exchange platform for CVD for patients. Primary and secondary prevention of CVD in the general population. Informing and early detection of CVD or risk factors.	Managing director	13	Focus group 1
	National health insurance organization	Expertise in health economics, public sector, data management. Coordination of research department. Innovation in health care networking and setting up projects.	Research and Innovation coordinator	20	Focus group 1
	Flemish general practitioners association	Promoting the interests of general practitioners in Flanders on a scientific, social, and syndical level through democratic decision-making and scientific foundation. Development and realization of a patient-oriented health care and policy. Expertise in prevention and health promotion.	Senior general practitioner coordinator	2.5	Focus group 1
	Primary care network	Networking organization, developing the Flemish government's health promotion and disease prevention policy. Using evidence-based methods, offered by partner organizations, Flemish health objectives are translated in a sustainable manner into local and regional policy, actions, and projects.	Health promotion coordinator	3	Focus group 2

Royal pharmacists association Antwerp	Professional association for pharmacists, developing the task of the pharmacist in health care and the pharmacist–population relationship. Supporting the patient in self-care and prevention.	Pharmaceutical Care Coordinator	3	Interview
Local Multidisciplinary Network Antwerp	Local network supporting multidisciplinary cooperation. Improving quality of care for people with chronic disease: supporting caregivers, stimulating interprofessional collaboration, and increasing self-management competences of patients.	Care path promotor	1	Focus group 2
Welfare linking organization in Antwerp	Focusing on exclusion due to poverty or origin by bringing people together. Providing opportunities for anyone experiencing exclusion. Experienced in reaching and working with people with low SES, setting up and running local projects on various (health) topics.	Senior regional volunteer	11	Focus Group 1
General welfare center in Antwerp	Working on social challenges related to (dis) well-being. Central, innovative partner in welfare. Expert in working with vulnerable target groups. Aiming for equal opportunities in society.	Policy Coordinator Mental and Somatic Health, Migration	1	Focus Group 1
Welfare and community development organization in Antwerp	Expert in working with socially vulnerable populations: people in poverty, social tenants, homeless people, single people, people without legal residence, low-skilled long-term unemployed. Fighting exclusion and disadvantage. Fundamental social rights as compass to realize structural changes: decent housing, education, social security, health, work, healthy environment, cultural and social development.	Team leader/coordinator	17	Interview
Association for people in poverty	Networking organization. Negotiation between people in poverty, society, and policy. Bringing people in poverty together to work on structural changes that increase their quality of life. Bottom-up approach: meeting each other, sharing experiences, building networks, and starting actions and projects from their needs and preferences.	Coordinator	2	Interview
Postgraduate training course 'Nurse in the general practice', University of Antwerp	Training course for nurses in specific general practice. Nurse autonomously supports GPs in treating, guiding, and caring for patients in primary care. Proactively responding to changing health care context.	Coordinator	2	Interview
Flemish Institute for Healthy Living (n = 3)	Stimulating the population to live healthy in an accessible way. Providing practical advice, packages, and trainings. Partnering organization in prevention expertise of the Flemish government.	Staff member physical activity	2.5	Meeting report(s)
		Staff member general health promotion	1	Meeting report(s)

			Staff member general health promotion	0.5	Meeting report(s)
Micro Level	General practice A	PHC, working with vulnerable population.	General practitioner	1	Focus group 1
	General practice B	PHC, large proportion of patients are in the vulnerable group, working with prevention consultation in the practice.	General practitioner	8	Focus group 2
	Community health center A	Prevention (CVD amongst other diseases), culturally sensitive care, working with vulnerable groups (low SES).	General practitioner	5	Focus group 2
	Community health center B	PHC, working with vulnerable population.	General practitioner	2	Focus group 1
	Physical activity on prescription	Referral from GP to a certified physical activity coach. Helping vulnerable groups to live healthier and more active lives in an accessible way, starting from information from the GP and the needs and preferences of the participant.	Physical activity coach	0.5	Interview

Table 2. *Phase 2 primary health care setting, practice nurse, and general practitioner characteristics.*

Primary Health Care Settings (*n* = 12)			**Practice Nurses (*n* = 9)**			**General Practitioners (*n* = 10)**		
Level of partnership between GPs	Community health center	3	Gender	Male	1	Gender	Male	4
	Duo practice	3		Female	8		Female	6
	Group practice	6	Tenure in practice (years)	>1	2	Tenure in practice (years)	1–2	3
Disciplines present, other than GP/PN	<3	5		1–2	5		>2–5	1
	≥3	7		>2–5	1		>10	2
Financial system	Fee-for-service	6		>10	1		>20	4
	Capitation payment	4	Postgraduate training	Postgraduate training	6	Data source	Interview	10
	Combination or other	2	Data source	Interview	9			
Level of PN involvement	Instrumental	5						
	Integrated	5						
	Planned in future	2						

Table 3. *Phase 2 welfare organization and lay community partner characteristics.*

Welfare Organizations (*n* = 4)		
Organization Type	**Description Aims and Domain of Expertise**	**Target Population**
1. Community work	Focusing on social networking, community engagement, integration. Strengthening peer networks. Offering social and administrative support	Vulnerable adults: poverty, homeless, single, without legal residence, low-skilled unemployed
2. General welfare center community team	Focusing on welfare support (door-to-door, community centers). Working on social challenges related to (dis) well-being. Activities: crisis counseling, housing assistance, psychiatric care management	Highly vulnerable populations (SES, psychiatric, drug-related problems)
3. Social services	Public center for social welfare provides a wide range of social services and thus ensures the well-being of every citizen	People living in poverty, underprivileged children and youngsters, single parent families
4. Service center	Meeting place for local residents, offering information, recreation, training, and services. Outreaching welfare support in neighboring communities and service flats	Young seniors, (frail) elderly people and families
Lay community partners (*n* = 13)		
Gender	Male	3
	Female	10
Position in organization	Social worker	9
	Coordinator/team leader	4
Tenure in organization (years)	>2–5	1
	>10	2
	Unknown	10
Data source	Interview	3
	Focus group	10

Our main findings are further reported below, according to CFIR domains and relevant constructs. A comprehensive summary of the results is provided in Figure 1.

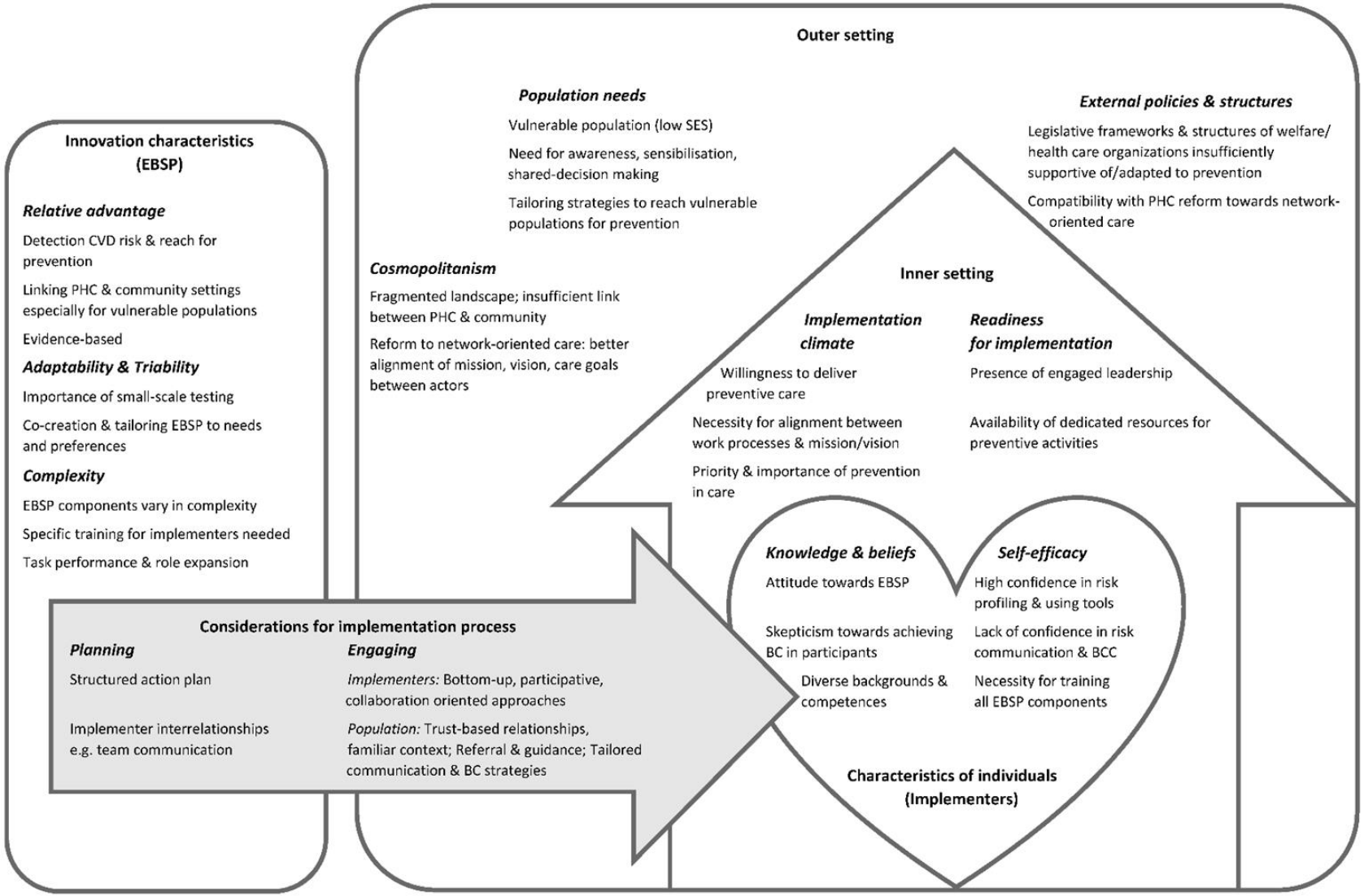

Figure 1. *Summary of main results structured into CFIR domains and relevant constructs.*

Intervention Characteristics

Relative Advantage

Our respondents indicated that implementing the EBSP will result in increased detection of people at risk that are currently missed for prevention. The combined strategy of implementing the EBSP in both general practices and in nonclinical community settings is expected to improve reaching vulnerable people for prevention.

"I think we reach many people with certain risk factors. So that is an advantage, because otherwise they are isolated… it concerns people who do not take the steps towards health care, who don't find their way there."
[CP]

The EBSP could give general practices the opportunity to improve current preventive practice by its systematic and structured implementation. Involving CPs, as well, is expected to reinforce integrated care with a holistic approach and will demedicalize CVD prevention. The opportunity to link the currently fragmented initiatives in PHC and community settings is considered a strong advantage of the intervention.

Adaptability and Trialability

Re-evaluating and adapting the EBSP to each setting's specific characteristics is seen as critical throughout each phase of the approach, so that it can be embedded in current workflows and systems. Potential implementers need the possibility to test the EBSP on a small scale, allowing them to iteratively co-create, test, and modify the intervention components and implementation strategies to their needs and preferences.

"In some settings it will run smoothly, but in other settings it just won't. We will then have to see how that fits into our system here. You have to start somewhere, of course… and then maybe re-evaluate and adjust it if necessary."
[CP]

Complexity

EBSP components vary in complexity; risk profiling and communication were estimated to be low in complexity, whereas BCC was predicted to be very complex, especially in vulnerable populations. Our respondents believed that the tools developed to support the EBSP are user friendly. Especially the selected profiling tool was considered easy to incorporate since it is clear and does not include sensitive questions. However, the measurement of hip and waist circumference is not common practice in community settings and could pose a barrier due to role confusion.

"I wonder whether people who come to a community center would appreciate having their waist circumference measured there by a social worker."
[GP]

"Behavior change is a very difficult thing. In my experience, I find that people rarely do really change their behavior…"
[PN]

Furthermore, our respondents felt that medical lay people do not have the appropriate profile to perform the complex BCC component, as this requires specific competences that cannot sufficiently be developed through a project-related training package. An extended PN role was believed to fit with all EBSP components in the general practice.

"Profiling is not carried out systematically in the general practice, not even for those health-related topics where it is perfectly feasible. And in our context, we don't have the volunteers at community level... so who's responsibility will it be?"
[Team leader dept. prevention, Flemish Government]

"The role of a 'PN' doesn't exist in every general practice yet, and each practice autonomously decides how that PN will be deployed exactly."
[Team leader dept. prevention, Flemish Government]

Outer Setting

Population Needs and Resources

Our respondents suggested to clearly define vulnerability for CVD based on the presence of CVD risk factors, lack of awareness of individual risk, and SES. They recognized the link between a low SES and poor health status, unhealthy lifestyle and habits, very limited access to health care, and low health literacy.

"The majority of people at high risk is not aware of it, because often these risk factors give little or no complaints and the GP is not systematically consulted to have this checked."
[Managing director National cardiologists association]

"People who live in poverty or who do not speak the language are less able to pick up information."
[PN]

Meeting the needs of the target population was an important implementation driver for potential settings and implementers of the EBSP. Respondents stressed the need to empower the target population to take informed health decisions by raising awareness for the prevention of CVD. However, they also discussed the financial, practical, and cultural challenges of reaching a vulnerable population for prevention. Respondents expressed their concerns around the relative priority of prevention in relation to multiple dimensions of the complex context around vulnerable populations.

"They disappear under the radar, and then reappear when they have an acute problem, where you don't really have the time for education."
[GP]

"Someone who does not have proper housing, does not have the mental capacity to discuss health."
[CP]

The EBSP should take a broader approach of health promotion, rather than focusing solely on CVD prevention. Patient advocacy is needed, especially in vulnerable populations requiring extra guidance and navigation to quality health care. Respondents also raised the need to support and empower people to become active participants of their health, e.g., by improving health literacy and self-management support.

"Poverty is mainly about social exclusion. And that's why, when you want to activate people towards regular care, it needs much more effort from us to get those people there and to keep them there."
[Coordinator Association for people in poverty]

Cosmopolitanism

Our context was described as a fragmented landscape of preventive care, with parallel initiatives at PHC and community level. The level of collaboration with external partners strongly varies amongst organizations and although certain forms of collaboration exist, formal collaborative structures are currently lacking.

"A whole network is formed around certain populations, with many actors all acting in related domains… in parallel, often without knowing about each other."
[Coordinator Association for people in poverty]

Respondents stressed that a shift towards network-oriented care is needed, urging better alignment of mission, vision, and goals. They recommended to primarily implement the EBSP in regions where the basic conditions for such a network are already fulfilled and to strengthen and scale up the link between existing initiatives and actors to enhance the impact on larger communities.

"If people are not working together in a good way, it will be difficult to launch a project like this. You should focus on regions where there is already a good collaborative network between different actors, based on mutual trust and know-how."
[Pharmaceutical Care Coordinator]

External Policies and Structures

Our respondents highlighted the compatibility with the ongoing macrolevel reform of PHC, with policy makers supporting the transition towards integrated care, prioritizing interdisciplinary collaboration within a person-centered care model. However, the extent to which the EBSP can be implemented in community and PHC settings, depends on the resource capacity of organizations, local policies, and

national guidelines. Organizations might be restricted when participating in the EBSP given the lack of clearly defined complementary responsibilities in preventive care and related financial compensation.

"The political government must continue to provide budget for us to be able to continue our preventive care initiatives… Unfortunately, the priorities are not always the same."
[Team leader dept. prevention, Flemish Government]

"The Flemish GPs Association has developed a very nice prevention plan, however, it doesn't seem to get implemented in practice. There is just no time and it is not reimbursed."
[GP]

Inner Setting

Implementation Climate

A need for change arises from dissatisfaction with the current approach to preventive care, which does not allow to adequately respond to changing care demands. It was emphasized that a holistic view of social and other determinants is needed to improve the overall well-being of people through strong partnership between welfare and PHC. Close collaboration and clear definition of complementary responsibilities and job contents through protocol care to guide interdisciplinary partnerships including task delegation and task shifting, were mentioned as facilitating factors. However, complex collaboration implicates difficulties in the organization of work processes, communication, keeping vision and mission aligned, and decision making, all of which could impact the EBSP implementation.

"It is often the case that the future situation of a person is disease-related, thus health is or will always be an issue for us as well. This could be a motivation for organizations like ours to participate in this project."
[CP]

"When it comes to shared responsibility, protocol care is so important."
[PN education coordinator]

The compatibility of the EBSP was reflected in its fit with norms, values, needs, existing workflows, and systems of eligible partner organizations. Therefore, the vision of partner organizations should contain aspects from the EBSP, such as focus on prevention; interdisciplinary collaboration and task delegation; accessibility and inclusivity of care; and outreaching community activity. In that case, it would be feasible that existing workflows are redesigned with the EBSP.

"We collaborate with our PN, who take the time to take up preventive tasks. In other practices, less time is invested in prevention. Care providers must also be open to work with a vulnerable population, and I am afraid that this is not always the case."
[GP]

"It could also turn out to be a great advantage that in our practice nothing has really been developed structurally around prevention, and that with this project we would be given the opportunity to translate our plans into something actionable… and also for me to expand my role as a PN."
[PN]

Respondents expressed their concerns around existing higher priority responsibilities posing a potential threat to the EBSP in both PHC settings and community settings.

"PHC is overburdened, we really feel this at practice level. Because of a high workload, prevention is often the first thing that is neglected."
[GP]

Readiness for Implementation

Next to active involvement and engagement from formal and informal leaders, the EBSP will need to be supported by the whole team involved in its implementation.

"According to our team leader, you cannot expect that the EBSP will be implemented, because the necessary time commitment cannot possibly be guaranteed by the managers."
[CP]

"It is also important for everyone to be open to new things, because one person who does not feel up to it can jeopardize the whole project."
[PN]

Our respondents anticipated some challenges around availability of resources in potential implementation settings. A high workload and the lack of structural financing for the cost of the implementers' dedicated time could hinder the implementation. Introducing creative solutions to facilitate interdisciplinary collaboration will be needed to increase the capacity to systematically implement the EBSP: e.g., task delegation and supportive financial systems and incentives.

"We chose to work under the capitation payment system from the beginning, which means that we are able to delegate a number of tasks to the PN who we supervise. But I must say that prevention is being put aside because there is simply no time for it at the moment."
[GP]

Characteristics of Individuals

Knowledge and Beliefs about the Intervention

Our respondents indicated that it will be important for all actors involved to have confidence in the EBSP. They expressed a positive attitude, but some were skeptical towards obtaining actual behavior change as a health outcome, especially in vulnerable populations.

"Behavioral change is very difficult...In my experience, people rarely really change their behavior. Motivation is something that has to come from the people themselves."
[GP]

Self-efficacy

The diverse backgrounds of potential implementers will determine their level of pre-existing competences in EBSP components. Respondents showed confidence in the competences required to perform the risk profiling using the project tools provided. However, they lacked confidence in the knowledge and skills related to risk communication and BCC techniques and stressed the major need for specific training in all EBSP components.

"During my studies, subjects were discussed about counseling groups and individuals... but most of the actual know-how you get from practice, I think."
[CP]

"I think we should organize more training within the practice. That is actually a permanent need."
[GP]

Implementation Process

Planning

Respondents recommended developing a structured action plan together with the potential implementers. In addition, implementer interrelationships, including communication, knowledge sharing, team-oriented problem-solving, and structuring collaborations through care plans, will be needed to accomplish successful implementation.

"In order to get something running in the practice, you have to sit together regularly with systematic follow up. That's also crucial for thorough planning and structurally incorporating the EBSP."
[GP]

Engaging Implementers and Intervention Participants

Long-term and sustainable partnerships will be challenging to develop and maintain. Respondents advised to use bottom-up and participative, collaboration-oriented strategies, alongside creating local project visibility, participating in structural platforms, investing time and effort to engage local organizations, and staying connected with implementers during each phase of the process.

"A participative approach, being in it, and creating it together -certainly not top-down… but growing something bottom-up."
[Team leader dept. prevention, Flemish Government]

"We should find ways to see that anything you will achieve with SPICES gets anchored, instead of losing everything that you built in the field."
[Health promotion coordinator, Primary care network]

Our respondents proposed to select and combine various recruitment strategies together with micro- and mesolevel stakeholders to overcome barriers in reaching vulnerable populations for preventive initiatives. Most importantly, interventions should be implemented in a familiar and psychosocially safe environment through the established trust-based relationship with the target population.

"We see that the role of the GP is crucial for our people. The GP is also a person they trust. It is the one person from the medical world they have the most confidence in, and who they can really talk to."
[Coordinator Association for people in poverty]

A combination use of active and passive communication channels was suggested. Activation of the social network around people, and intensive and personal referral and navigation of people towards community initiatives or health care, will facilitate the reach of participants.

"There is always someone from our organization that goes with them the first time. This way, the familiar and trusted environment comes along wíth them really. And we also try to make sure that they receive a warm welcome on the other side as well… You know, our people are so suspicious of everything that is unknown."
[Coordinator Association for people in poverty]

Working together in a participatory way with vulnerable people requires a sincere and open attitude towards their context. A barrier to the intervention could be that health care providers often lack the time to provide the follow-up that is needed to keep them involved long-term.

"A participatory approach is crucial. If you take people seriously, from the outset, about their story and what they encountered and what they think could be solutions, that's a very important first step."
[Coordinator Association for people in poverty]

Our respondents recommended the use of several communication and BCC techniques: such as, motivation to change, goal setting, result-oriented approach, shared decision making, tailoring messages, and supportive materials.

"By emphasizing what's in it for them, and if you start from the patient's perspective, you will get much further."
[GP]

Discussion

This study explored the views of macro-, meso-, and microlevel stakeholders on the contextualization of a comprehensive intervention program for the primary prevention of CVD, along with determinants to its implementation in PHC and community settings in a Belgian urban context. This pre-implementation study was carried out as part of the H2020 SPICES project since contextual factors may be necessary for implementing the EBSP. The CFIR identified determinants, barriers, and facilitators across its domains and constructs, providing an opportunity to inform further design of intervention

components and implementation strategies for implementation in new settings in the project's next steps.

The SPICES project specifically intends to improve reaching vulnerable low SES groups for CVD prevention. Reaching people with low SES by health promotion and prevention initiatives on a population level is challenging (57, 58). Our respondents stated that a combined approach of implementing a CVD prevention program in both PHC and community settings is needed to increase accessibility to the EBSP and to affect the prevalence of CVD, which is further supported by the literature (59). On the one hand, according to the literature, general practice plays an important role in reducing socioeconomic inequalities by maintaining a trust-based relationship, facilitating patient-centered communication and premising personal targets tailored to the local community context (60, 61). However, with regards to CVD, we also know that although detection levels of CVD risk factors by GPs may be improving, many people with increased risk remain undetected. PHC teams should therefore continue to use low-cost, practical approaches to detect people at risk (62). On the other hand, previous research also demonstrates that relatively high levels of community engagement can be attained by introducing community-based CVD prevention programs (63), and that it has the potential to effectively reach under-served groups (64). Community-based strategies previously have successfully led to an improvement in CVD risk factors (65), with especially positive impact on improving population knowledge on CVD and risk factors, physical activity levels, and dietary patterns (66, 67).

Consequently, the SPICES project may offer the opportunity to link the currently fragmented landscape of PHC and community organizations by proposing CVD prevention as a common goal. Stakeholders indicated that coordination and proactive alignment between different policymakers and other stakeholders and adequate funding are fundamental for reorientation towards community-oriented care, which is in line with previous study findings (68, 69). Such a reform requires advocating for a mission and vision focused on integrated care, fostering collaboration with a focus on population care, regional multisector collaborative partnerships, and comprehensive strategies to transform health and well-being in communities (70, 71). The literature also suggests that community leadership, shared decision making, linkages with other organizations, and a positive organizational climate are key for building such partnerships (72).

The complexity of the SPICES project mainly lies in sharing responsibilities, especially when roles will be expanded through task shift and delegation to PNs in general practices and medical lay people in community settings. Optimizing the engagement of innovative providers requires clear definition of roles and scopes of practice, sensitization, in-service training, and formal supervision (73). Trained nurses can easily take over preventive tasks without compromising quality of care and patient

outcomes (74). PHC can also be unburdened or supported by community approaches in implementing the EBSP. Previous research shows that community-based nurse-led interventions result in positive outcomes for patients with increased CVD risk. However, the success of such interventions needs to be facilitated by appropriate funding, thoughtful intervention design, and training opportunities for nurses (75). Furthermore, in noncommunicable disease control programs, community health workers (CHW) deliver preventive services using informational as well as behavioral approaches worldwide (31, 76). However, this strong community component is not yet embedded in Belgium, implying such roles are currently not supported. Integration of such roles into the general healthcare system and existing community structures should be considered, taking into account population needs, health system requirements, and resource implications (77).

In addition, with the introduction of new roles, it will certainly be important to provide training in all components of the EBSP, especially with regard to BCC. Several studies show heterogeneity across the reporting of BCC training program content and structure, despite the importance of increasing providers' competency to effectively counsel a population with increased CVD risk to change their lifestyle, and ultimately to improve healthcare services and health outcomes (78, 79). It will be important to properly explore the current competency levels and training needs of implementers, and to adapt the support from SPICES to fit. From previous studies, we do know that BCC training programs are mostly based on motivational interviewing and the 5 A's approach, using multiple BCC techniques, and delivered through seminars and workshops presenting opportunities for interprofessional education (79, 80). Competences seem to be best acquired through active, realistic practice and implementation of reminder and feedback systems within actual clinical practice settings (81).

Adaptability will allow practitioners to improve current practice with evidence-based interventions which will be tailored, tested, and evaluated together with the implementers. Adaptability is indeed a crucial element in order to meet local needs, to address barriers and leverage facilitators, and to preserve fidelity (82-84). It will be important to clarify the timing, context, and process of modifying interventions to facilitate their implementation, scale-up, and sustainment (85). We will need to take into account the needs and specific characteristics of a vulnerable population and to adapt interventions and strategies accordingly. The literature shows limited lifestyle effectiveness of behavior change interventions for low SES populations (86). Other studies highlight the urgency to tailor lifestyle interventions to the needs of vulnerable populations and call for health care providers and users to engage with behavior change techniques rather than focusing on information provision alone (87). Effective interventions have a tendency to have fewer techniques (88).

Our respondents made some suggestions to take on in the next steps of the EBSP implementation, especially with regard to planning the implementation and engaging implementers and target

population. We should take into account a thorough planning and implementer interrelations within the context of each organization. Previous studies show that organizational culture most commonly affects implementation and that leadership plays a crucial role in successful implementation of evidence-based practices (89). Factors contributing to engaging and sustaining partnerships with microlevel implementers include starting small-scale and focused to build trust among participants, working within the framework of integrated preventive care, and providing long-term support (90). Efforts to reach the vulnerable target group should be tailored and embedded in their familiar context, which is supported in previous studies suggesting face-to-face invitations from a reliable source and community outreach to raise awareness to facilitate participation (91).

We recognize that some limitations have to be considered when interpreting our findings. This study did not capture the perspectives of the target population; however, we did include stakeholders from organizations representing vulnerable groups. In the next steps of the SPICES project, it will be crucial to further explore members of the population's perspectives. Furthermore, our sample might have been biased since we purposefully included stakeholders from organizations or settings with a link to the concepts of our project. On the other hand, including a large sample of stakeholders from different levels offered us the opportunity to critically triangulate our findings during the different study phases, increasing credibility. The methodology we used allowed us to give responsive feedback to the participants through member checking. It also reinforced the transferability of our results beyond this context by employing the CFIR as an established conceptual framework, further strengthened by the detailed description of the context of this study. The use of the CFIR ensured that all critical implementation determinants were explored, increasing the chance of successful and sustainable implementation of the EBSP.

Our findings have the potential to inform the design and implementation planning of related health programs in similar contexts, and we have therefore translated them to key recommendations for planning successful and sustainable implementation as summarized in Box 1.

Box 1. *Recommendations for planning successful and sustainable implementation of a CVD prevention program.*

- Evaluate the unique context of a planned implementation and map potential barriers and facilitators. The CFIR is a useful tool to do so.
- Consider both general practices and welfare organizations as important avenues for primary prevention of CVD, especially when targeting vulnerable populations.
- Involve stakeholders, implementers and communities at all stages of the implementation, including project design and planning. Use participatory strategies to get and keep them engaged.
- Work towards stepwise implementation allowing adaptation to dynamic needs.
- Align intervention purposes with local policy, vision, and mission. Set achievable goals taking into account available resources.
- Design interventions in a way that they can be integrated in pre-existing workflows and systems.
- Offer support and develop tools mitigating the complexity of the intervention.
- Build networks between primary care and community partners.
- Explore collaboration models: practice nurses and lay community partners can play a critical role.
- Make sure that those who will provide the intervention have the necessary competencies or provide tailored training so they can be acquired.
- Generate ownership in members of local organizations.
- Take a broader approach of health promotion rather than focusing solely on CVD prevention.

Conclusions

Macro-, meso-, and microlevel stakeholders' views demonstrated various contextual dimensions to consider when implementing a comprehensive program comprising complex interventions for the primary prevention of CVD in PHC and community settings and underscored several criteria that seem necessary to transform health systems towards a network-oriented approach of health and well-being. These results form a solid foundation to tailor the H2020 SPICES project to the needs and preferences of the target population and potential implementers, but also, to better respond to policy evolutions. The next steps in our research project can clarify how these complex and dynamic determinants are interrelated and how they influence the outcomes and process of implementing the EBSP in real life settings. Ongoing stakeholder engagement is needed to develop sustainability in this multidimensional, multilevel, and dynamic field.

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Chapter 6

Development and contextualization of a cardiovascular disease prevention program

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Abstract

Introduction

Cardiovascular disease (CVD) is the world's leading cause of mortality. However, systematic implementation of primary prevention programs in primary health care and community settings is lacking and development of intervention programs is underreported. Little is known on how to design and contextualize interventions and programs to fit local needs for implementation.

Objectives

The aim of this paper was to describe the process of designing and contextualizing a comprehensive CVD prevention program and to report on all component details and modifications that were made during its implementation in primary health care and community settings in Belgium. This work is part of Horizon 2020 project SPICES, which aims to scale up evidence-based packages of interventions for CVD prevention.

Methods

This multi-method paper includes reviews of literature, contextual analysis, consortium discussions and nominal group, stakeholder meetings, expert consultation and phased implementation during the four phases of an iterative process model: Identification of core components (Phase 1); Contextual translation (Phase 2); Design of content, materials and protocols (Phase 3); and Implementation, evaluation and refinement (Phase 4).

Results

The SPICES consortium, key and local stakeholders, experts in health promotion and disease prevention, key implementers, and members of the target group who participated were involved in the development and contextualization of our CVD prevention program. Our phased approach led to an intervention basket, consisting of generic core components, which was translated into a local intervention plan for the Belgian context. The designed intervention program was described using the Template for Intervention Description and Replication and consisted of two major components: 1) a profiling component including CVD risk profiling using the Non-Laboratory INTERHEART risk score and risk communication, and 2) a coaching component including behaviour change and motivational interviewing techniques. Intervention piloting showed the potential of the intervention program especially after making the necessary adjustments.

Conclusions

This paper describes a practical example of developing and contextualizing a comprehensive intervention program for the primary prevention of CVD. An iterative and phased approach, involving multiple methodologies and perspectives, is crucial for the co-creation of intervention programs that have the potential to be successfully and sustainably implemented in daily practice.

Introduction

Cardiovascular disease (CVD) is one of the leading causes of death worldwide. In 2019, around 18,6 million people died from CVD, accounting for 32% of global mortality (1, 2). CVD represents 393 million disability adjusted life years (3-6). In Europe, more than 60 million potential years of life are lost due to CVD annually (7). In Belgium, over one in four deaths is due to CVD (8). CVD substantially hampers healthcare systems around the world in terms of related costs and supply-demand imbalance due to exceeded health care use (9). The burden of CVD is highest among individuals that are in the lower socioeconomic status (SES) quintile (10-12). The World Health Organization estimates nearly 75% of premature vascular events and disability may be prevented (13). Addressing unhealthy lifestyle behaviour is crucial in preventing CVD and its modifiable risk factors such as hypertension, (pre-) diabetes, dys- and hyperlipidaemia, overweight and obesity (14). The most important behavioural risk factors of CVD are tobacco use, unhealthy diet, harmful use of alcohol and physical inactivity (15, 16), which are more prevalent in low SES populations (17).

Although numerous strategies to improve risk perception and promote healthy lifestyle behaviour are evidenced to reduce the CVD risk profile in individuals (15, 16), the lack of protocols to guide practitioners impedes structural implementation of effective preventive strategies into practice (18). Moreover, current evidence discloses significant gaps regarding effective interventions and implementation strategies specifically targeting vulnerable populations (19, 20). Where improvements in CVD-related outcomes occur, there is an inequity in benefits with a lesser impact of preventive care including lifestyle interventions in people with low SES (12, 21, 22). Moreover, current primary health care (PHC) systems are heavily overburdened and fail to provide systematic support for all aspects of prevention (23-25). To achieve optimal outcomes, preventive action should be structurally embedded in health systems. Intervention design provides an opportunity to connect health systems and communities to achieve sustainable health and wellbeing enabling contexts (26).

There is an urgent need for the development and successful implementation of intervention programs aimed at the detection and management of CVD risk in PHC and community settings that improve the equitable distribution of the benefits of preventive action across the population, including vulnerable subpopulations. Although a broad range of approaches to intervention development have been published in recent years, the process of designing concrete interventions remains highly underreported (27). Moreover, despite the publication of available checklists enabling interpretation and replication of interventions and their components, reporting of intervention research remains inadequate. This leads to incredible research waste and an evidence base that is fit for purpose (28). Furthermore, interventions are often deployed in different contexts and populations with a ‘one size

fits all' approach. Little is known about the required efforts to adapt interventions to fit specific real-life settings and how to make a selection of implementation strategies to maximize implementation success and sustainability (29). Comprehensive and transparent intervention reporting strengthens the knowledge transfer to other contexts, cultures and settings; supports the methodological development of interventions; and facilitates the synthesis of emerging evidence on the effectiveness of novel approaches (30).

The aim of this paper was to describe the development process of a comprehensive intervention program for the primary prevention of CVD, consisting of core intervention components and implementation strategies that can be used in different contexts. Furthermore, it details the contextualisation of the core components and strategies specifically to fit the Belgian context, allowing it to be implemented in both PHC and community settings. Finally, we reported the details of our intervention program, including the adjustments that were made during its implementation based on implementers' and recipient's appreciation. We used the 'Guidance for reporting intervention development studies in health research' (GUIDED) checklist (31, 32) to support our intervention reporting.

Context and methods

Study context

Our research activities were conducted in the context of the international SPICES[5] project which was funded by the European Union H2020 program. The project aimed to implement evidence-based interventions for primary prevention of CVD in rural settings in low- (Uganda) and middle- (South-Africa), and urban settings in high-income countries (United Kingdom, France, Belgium). It was important to consider the unique characteristics of those different contexts that we expected would strongly interact with the development and implementation of SPICES (33). Therefore, we needed to distinguish between cross-setting applicable core components of the intervention and implementation strategies, and an adaptable part which all consortium partners could modify to fit within their local context (34). This paper describes the process of developing an intervention program, consisting of generic core components for the SPICES consortium, and the contextualization of that program to the Belgian context.

Belgium is a high income western European country with 11.590.000 inhabitants. The northern Flemish Region is one of the most densely populated regions of Europe with around 470 inhabitants per square

[5] Scaling-up Packages of Interventions for cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa

kilometer (35). The city of Antwerp, our study site, has a metropolitan population of 521.946 inhabitants spread across 9 districts, and 61% of the population is aged between 18-64 years old. Of the Antwerp inhabitants, 52% have Belgian backgrounds and 48% have migration backgrounds (36). Various city districts are highly vulnerable in terms of socio-economic deprivation index; calculated by means of the share of long-term unemployed people in the occupational age population; the amount of people receiving social and financial support; and the number of taxpayers with net taxable income of less than 10.000 euro per year (37-40). Moreover, there is a growing shortage of general practitioners (GP) in many city districts, hampering the access to PHC and preventive care. Critical regions are defined as such if there are fewer than 90 GP per 100.000 inhabitants. In this project, we therefore focused on working in socio-economically disadvantaged districts with a low GP density.

Research methods

The evaluation methods and frameworks used in the overarching SPICES project shaped the implementation-based development and contextualization process of our comprehensive intervention program (27), requiring a cyclical, flexible process and continued multi-level stakeholder involvement to encourage ownership throughout the entire process and to enhance acceptability and sustainability of the intervention program (32). As visualised in Figure 1, the iterative development and contextualization process consisted of four phases between which we regularly switched back and forth: Identification of core components (Phase 1); Contextual translation (Phase 2); Design of content, materials and protocols (Phase 3); and Implementation, evaluation and refinement (Phase 4). Throughout the different process phases of this multi-method paper, we incorporated multiple research methodologies and techniques.

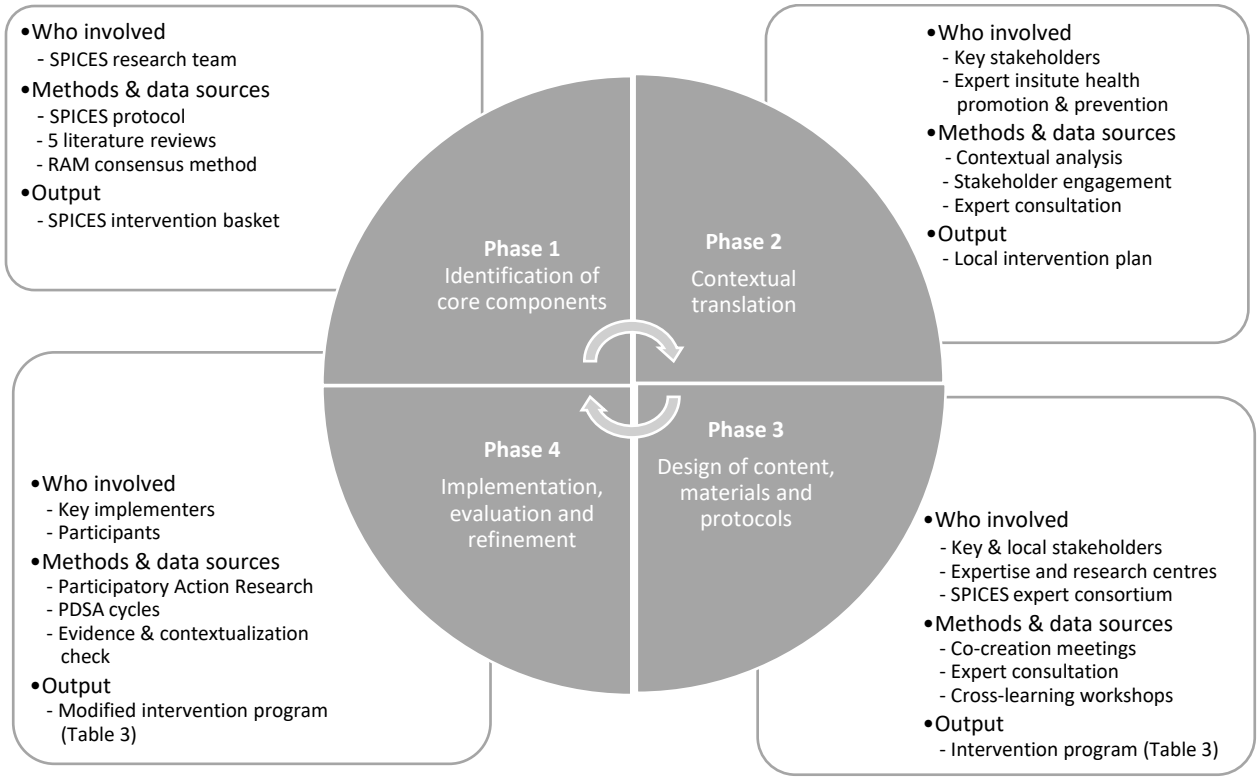

Figure 1 Overview of the four-phased development and contextualization process of the SPICES intervention program aimed at primary prevention of CVD in PHC and community settings in Belgium

Phase 1 Identification of core components

The objectives of the SPICES project formed the basis of identifying generic core intervention components and implementation strategies that had the potential for implementation across the different study sites. This phase was conducted by a cross-site multidisciplinary research team consisting of experts in the fields of medicine, sociology, psychology, health informatics, and nursing. The team was experienced in different research methodologies and were familiar with various health topics related to PHC.

Several literature reviews were conducted to identify, review and select relevant evidence. We conducted three systematic reviews of international clinical practice guidelines (CPG) on primary prevention of CVD and their recommendations regarding non-pharmacological interventions targeting risk-related health behaviours (diet including alcohol intake; physical activity (PA); and smoking) and implementation strategies. Methodological details are reported elsewhere (19, 20, 41). Furthermore, two rapid evidence reviews were undertaken: one to synthesise evidence on existing non-laboratory CVD risk scoring tools (42); the second to detect effective strategies for reaching low health literate people with disease risk communication, including CVD (42).

Phase 1 was finalized with a formalized consensus procedure with the SPICES research team, to select the generic core components of the intervention program. This procedure was guided by the

RAND/UCLA Appropriateness Method (RAM), a consensus method (43), combining the qualities of a Delphi process (44) and nominal group (45) (independent evaluation by experts, working blind, in order to remove any leader effect); and a focus group (communication, face-to-face debate and interaction about ratings). In a first round, the SPICES research team was asked to rate the effective intervention components as identified through the literature reviews, using a 9-point Likert scale with questions probing appropriateness, feasibility, efficiency and sustainability. Second, the results were discussed in adjoining small-group discussion rounds. In a third round, the experts voted for components in terms of feasibility, efficiency and sustainability for their context. Consensus was obtained if at least 70% of the experts agreed with the results (46). This phase resulted in a synthesis document including a cross-setting 'intervention basket' of generic core components of the intervention and implementation strategies, key points from the expert discussions and theoretical underpinning.

Phase 2 Contextual translation

To contextualize the core components from Phase 1 to the Belgian context, local policies and available resources regarding CVD prevention were mapped. Through focus groups and individual interviews, we explored macro-, meso-, and microlevel stakeholders' needs and preferences regarding CVD prevention; their views on acceptability and appropriateness of core components; and their beliefs on potential implementation determinants in PHC and community settings. At the same time, these activities could foster buy-in and sustainability through stakeholder engagement. The Consolidated Framework for Implementation Research (CFIR), a determinant framework (34), helped us to identify potential barriers and facilitators to consider further along the process. Details of this work are reported elsewhere (47). Contextual determinants were continuously monitored throughout the process allowing us to respond to contextual dynamics.

We collaborated with Flanders Institute for Healthy Living, an expert institute in the field of health promotion and disease prevention, and key stakeholders, to establish an optimal fit between the output from phase 1 and the context. We retained the generic core components from phase 1, yet highly contextualized the adaptable elements of both intervention components and implementation strategies to the specific characteristics of Belgian general practice and community settings, and vulnerable target populations (low SES). During this iterative process, we sought answers in the output from phase 1 to the concerns and priorities raised through phase 2 activities. Where needed, we considered additional evidence-based approaches beyond the SPICES intervention basket, and whether they had potential to answer the local needs and priorities. In this respect, we also aimed to integrate available resources yet currently underutilized resources into our SPICES program as much as possible, provided that they offered added value, were of high quality and were in line with our findings.

Phase 3 Design of content, materials and protocols

Principles of Prochaska's and Diclemente transtheoretical model (48), Ryan and Deci's self-determination theory (49) and the COM-B model (50) formed the basis to decide on the mechanisms of change and related actions to deliver them. Motivational interviewing (51) and brief action planning (52) were the main approaches to inform the design of our local intervention program's content and format, implementation materials and protocols. We also tailored our program and available resources to our target settings; including general practice and existing community organizations, and target population, including people living with low SES.

We collaborated with the key stakeholders from Phase 2 and experts affiliated with expertise and research centres on health communication, communication with vulnerable populations, health promotion and behaviour change. Additionally, we took a participatory approach and held regular co-creating meetings with local stakeholders from PHC and community settings that were going to implement the program. Since all SPICES research teams were simultaneously going through a similar process in each of their contexts, we regularly held cross-learning workshops to reflect, to exchange ideas and experiences, and to share content and materials that could be relevant for other sites. These meetings also allowed us to monitor the preservation of the core components from Phase 1. All input, expertise and feedback was integrated in the research team's desk work for further design.

Phase 4 Implementation, evaluation and refinement

We applied participatory action research (PAR); a commonly used approach to improve conditions and practices in health care environments (53). PAR is collaborative, undertaken by individuals with common goals, and requires situation- and context- specific tailoring (54). This approach allowed us to refine the SPICES program, including its intervention components and implementation strategies, during the implementation process. The program was revised during reflective "plan-do-study-act" (PDSA) cycles based on our experiences, and implementers' and participants' feedback. Each adjustment to the program was validated against the evidence and checked for consistency with findings from previous phases. We also regularly consulted the experts and key stakeholders from previous phases to seek their feedback and input. The implementers were asked to verify whether any adjustments were adequately adapted to the local context. The intervention program was introduced to the next setting after a minimum of three months of implementation and PDSA refinement in the previous setting. This allowed the program to be modified step by step so that its improved version could be implemented in subsequent settings.

Our CVD prevention program was implemented in five general practices and five community organizations in vulnerable city districts in Antwerp, Belgium. We conducted interviews with key implementers from all settings at various timepoints during implementation in the period from August

2020 to March 2022 and gathered information on the appreciation and acceptance of our intervention program. Key implementers were those who were directly involved in the planning, coordination and execution of the implementation. Additionally, we conducted interviews with members of the target population who participated in either the profiling component alone, or in both profiling and coaching components. The interviews were recorded and transcribed ad-verbatim. Both audio fragments and the transcripts were pseudonymized. A written informed consent and demographic sheet were completed at the start of each interview. The interviews lasted 30 to 90 minutes and were held at the study site, or by online meeting or telephone. Both data collection instruments and adaptive framework analysis (55, 56) were based on relevant CFIR constructs (34) and elements of the Template for Intervention Description and Replication (TIDieR) (57). We triangulated the data with document analysis of meeting reports with research team and implementers. Details of the included settings, methodology and process of the implementation are available in Chapters 7 and 8.

Results

The following section presents the main results of each phase of the development and contextualization process of our comprehensive CVD prevention program.

Phase 1 Identification of core components

The SPICES project focussed on evidence-based, non-pharmacological interventions for primary prevention of CVD. The Non-Laboratory INTERHEART Risk Score (NL-IHRS) was selected as CVD risk profiling tool since it has been validated across diverse geographic regions with evidence that it can reliably predict individual CVD risk across the various SPICES partner sites with good performance, while requiring few resources (42). Other reasons for this choice were its simplicity to be used by both medical professionals and lay people and the presence of behavioural risks in the risk score. The overall NL-IHRS (sum) score ranges from 0 to 48, with higher scores indicating a larger future risk of CVD. Participants who scored less than 10 were at low risk (green), 10 to 15 at intermediate risk (orange), and 16 or above at high CVD risk (red) (16). The tool allows for concise and integrated discussion of CVD risk (16). In doing so, it is important to define, give meaning to and visualise that risk. Communicating CVD risk to low health literate people requires targeted efforts (42). Integrating strategies such as heart age and imaging (58), simplified numerical risk information (59), positive and negative framing (60), and narrative-based communication (61) was proposed to communicate CVD risk information and to improve risk comprehension. CPG recommended multicomponent interventions combining smoking cessation (19), the Dietary Approaches to Stop Hypertension (DASH) diet (41), and regular, moderate-intensity, aerobic PA (20) to affect multiple risk factors for individual CVD risk reduction. A multidisciplinary team approach, training of providers, and adaptability of

intervention, were the main implementation strategies identified (19, 20, 41). The RAM consensus procedure concluding Phase 1 resulted in a cross-setting intervention basket, as visualised in Figure 2 (62).

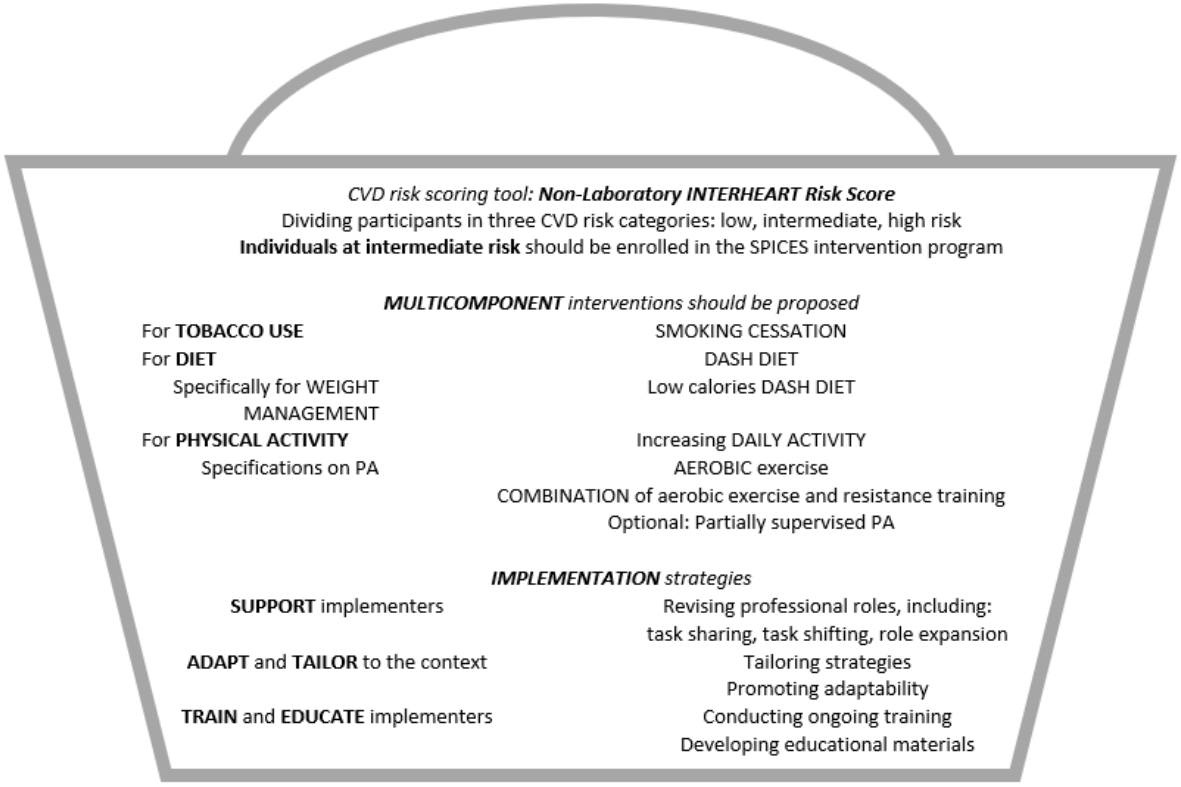

Figure 2 SPICES intervention basket comprising of generic core intervention components and implementation strategies

Phase 2 Contextual translation

We tailored the generic elements from the intervention basket to the needs and contextual dimensions of Belgian PHC and community settings, which we identified through our contextual analysis (47) and in close collaboration with key and local stakeholders. Table 1 provides an example of how this process was completed and how different information sources were aggregated to contextualise the generic implementation strategy 'train and educate implementers'. It illustrates how we have selected and further developed certain strategies based on practice needs and preferences, yet validated by the available evidence.

Table 1 Illustration of the contextualisation process of generic intervention components and implementation strategies. Example of translating 'train and educate implementers' to Belgian context.

Stakeholder quote	CFIR analysis	Recommendation CPG	Contextualized component
"The theory that we often use is Prochaska's circle ... I think we should mainly organize training within the practice. That is actually a permanent need." [GP]	**Innovation Characteristics** ***Complexity*** Risk detection and communication are valued as low in complexity, whereas behavior change is valued as very complex, especially in vulnerable populations. Facilitator: Training of implementers in using the tools, risk communication, motivational interviewing and other behavior change techniques.	Provide training for all professional practitioners and lay people who are responsible for and/or involved in helping to change people's behavior.	**Train and educate implementers on CVD risk profiling and communication & lifestyle coaching** - Develop training & educational materials in collaboration with experts - Use train-the-trainer strategies - Conduct ongoing (refresher) training - Provide ongoing consultation and appropriate support (needs and evidence) - Conduct educational meetings: supervision (video-feedback), intervision - Work with postgraduate education for PN
"If I gain more knowledge and practical experience, executing the intervention will not be a problem." [PN]	**Characteristics of Individuals** ***Self-efficacy*** Respondents express a lack of competence, and stress the major need for education/training for both professional health care providers and lay people for coaching behavioral change and motivational interviewing techniques. Facilitator: Need for specific training related to risk communication and applying behavior change techniques.	Monitor/assess behavior change practitioners, provide feedback and give time/support to develop and maintain competencies.	

GP: General Practitioner; PN: Practice Nurse

Our intervention program focused on general practice and existing community organizations, to increase the reach of people living with low SES through the trusting relationships. Stakeholders emphasized the importance of designing interventions to be sustainably integrated in pre-existing workflows and systems in each particular setting. This implicated developing tools, tailored to each setting and key implementers, to mitigate the complexity of the intervention which was seen as a major barrier to the SPICES intervention basket. Our project objectives however were in line with local policy, vision and mission to link the fragmented Belgian PHC and community partners to achieve a more integrated model of community care. This meant that our intervention program needed to further connect PHC and community partners; at least for referral and follow-up (47). The work in Phase 2 resulted in the local intervention plan for the Belgian SPICES site (Table 2).

Table 2 Local intervention plan, contextualized to the Belgian SPICES site

Intervention component	Aim	Target group	Setting
CVD risk profiling and communication	Early identification of adults at increased risk of CVD and detection of specific risk factors	General adult population in selected vulnerable districts	General practice and community settings
Health promotion/education	Promote CVD prevention through health literacy, awareness creation, knowledge translation and empowerment; provide BA	All individuals that participated in profiling	General practice and community settings
Lifestyle coaching and follow up	Individual-tailored behavioural interventions for selected risk factors (according to individual's risk level)	Individuals in the intermediate CVD risk group	General practice and community settings
Referral	Referral to general practices for further investigation and follow-up	Individuals in the high CVD risk group	Community settings

CVD: Cardiovascular disease; GP: General Practitioner; BA: Brief advice

Phase 3 Design of content, materials and protocols

We used the TIDieR (57) to fully and transparently report our intervention program including its content, materials and protocols. Items 1 to 8 of Table 3 describe our intervention program's brief name, why it was developed, the project materials it contained, its procedures to carry out the different components and the implementers who delivered them, the intervention format, the specific settings where it was delivered, and the timing and intensity of the intervention components.

Table 3 SPICES intervention program description based on elements of the TIDieR (57)

Intervention program description	
1. Brief name	SPICES Program
2. Why	The burden of CVD can be reduced by targeting lifestyle determinants such as physical inactivity, unhealthy dietary habits, smoking and excessive alcohol intake. Likewise, knowledge of behavioural risks is the central element of lifestyle change and individuals who perceive themselves at higher risk of CVD are more likely to adopt a healthy lifestyle. Interventions on risk profiling and lifestyle coaching can raise awareness on the individual risk and may have positive effects on risk perception, increase a participant's knowledge and skills to reduce the individual risk, and improve healthy lifestyle behaviours including healthy diet, PA, smoking cessation and reduction of alcohol consumption. By improving modifiable risk factors, the individual CVD risk will decrease. A combined approach of community- and primary care-based implementation of the interventions is expected to higher reach of (vulnerable) target populations and increase the uptake of interventions. Therefore, the SPICES program was meant to be implemented in general practice and various community settings. We target adults between 40-75 years old who are not yet diagnosed with CVD. People with known diabetes are excluded since they are already included in an existing national care protocol including lifestyle guidance.
WHAT	
3. Materials	**Training materials** Consists of three dynamic training modules, supported by training manuals, consisting of 1) a module on introduction to the SPICES project and its rationale, aims and explaining the intervention components; 2) a module on CVD, its (behavioural)on risk factors; basic recommendations on lifestyle behaviour and CVD risk profiling using the NL-IHRS and risk communication; and 3) a module on behaviour change theories and models, and hands-on guidance on health coaching and behavioural change counselling. Includes train-the-trainer techniques, role-play, refresher trainings and supervision sessions with expert video-feedback to support and strengthen the competences of the implementers carrying out the profiling and coaching interventions. All implementers receive the training modules containing basic information about the background, aims and activities related to the SPICES project; reaching and engaging (vulnerable) target populations; profiling scenario (semi-structured guidebook model-sentences); user guidance of devices and Redcap software/tools for data collection; risk communication techniques including self-perception; risk category; reflection; translating lifestyle advice; coping with resistance; long-term follow-up; and referral to PHC and community resources. Implementers carrying out the lifestyle coaching component (nurses in general practice and the SPICES coach) receive more in-depth training on determinants of CVD health; behaviour change theories (self-determination theory, Prochaska & DiClemente's theory); the Com-B model, Brief Action

Planning; and behaviour change techniques (e.g. goal setting, action planning, problem-solving); motivational interviewing techniques, and communication and interaction with vulnerable groups (e.g. empowerment, empathy, teaching-back method).

Informative invitation leaflet/poster

In general practice: Provided in waiting rooms and GP's and PN's offices, websites and context-specific communication channels

In community settings: Provided in communal and meeting spaces, local newsletters, websites and context-specific communication channels

Guidebook for participant invitation & risk communication

Implementers carrying out the profiling component receive a semi-structured guidebook including model-sentences (profiling scenario) to guide the participant invitation and engagement process. It also supports the CVD risk profiling procedure, including risk communication and tailoring the lifestyle advice. In addition, it assists the initiation of the appropriate follow-up trajectory.

Non-Laboratory INTERHEART risk score including brief lifestyle advice

The NL-IHRS was translated, back-translated and linguistically screened for its usability in low health literate people. We added instructions for the waist and hip circumference measurement to facilitate its use by medically lay people, and contextualized the automatically generated lifestyle advice to the Belgian study site. Implementers carrying out the CVD risk profiling use the NL-IHRS; a validated CVD risk scoring tool that captures demographics, SES, lifestyle patterns status history of CVD, other risk factors and anthropometrics (hip-waist ratio). The tool assigns people to one of the three risk categories: high, intermediate or low risk of developing CVD. The tool is available in Redcap for online use on personal computers (general practice) and tablets (community settings). The program automatically generates pre-set lifestyle advise that is adjusted to the risk score and the specific answer categories recorded per item, to assist implementers in risk communication and delivering BA.

Risk cards

Implementers carrying out the profiling and CVD risk communication are supported with risk cards. They combine visual/imaging approaches to communicate CVD risk information; simplified numerical CVD risk information; positive and negative framing; and narrative-based CVD risk communication. There are three versions available, adapted to each risk category: high (red), intermediate (orange); low (green) group.

Lifestyle plan

Implementers carrying out the coaching are supported with a 'Lifestyle plan' to guide their coaching sessions, in which behaviour change techniques, e.g. goal setting, action planning, problem-solving, were also incorporated. This tool is based on Brief Action Planning for health; highly structured, patient-centred stepped-care self-management support technique. It is composed of a series of 3 questions and 5 skills, the lifestyle plan is used to facilitate goal setting and action planning to build self-efficacy in CVD prevention.

Follow-up questionnaires

The follow-up questionnaires are mainly used for research measures; monitoring the effectiveness of the SPICES program. In addition, implementers can use this information to further explore and follow-up the participant's lifestyle behaviours and risk perception during coaching sessions.

- **ABCD questionnaire**: CVD knowledge and risk perception (validated in Dutch)
- **Short IPAQ**: Activity level using the shortened version of the International Physical Activity questionnaire (validated in Dutch)
- Improvement of diet & alcohol: **DASH-Q** (Dietary Approaches to Stop Hypertension) **Fout! Verwijzingsbron niet gevonden.**+ added questions from **Feel4Diabetes diet questionnaire** (validated in Dutch) & contextually adapted to national recommendations in Belgium and linguistically screened for use in low health literate people.

Data collection tablets

Implementers in community settings carrying out data collection during profiling and/or coaching are equipped with tablets to support them in mobile data collection on location.

Training videos

In collaboration with a local fitness centre, the team developed five 35-minute, moderate-to-high intensity work-out videos with minimum impact on joints (using a chair), that are available online for implementers to refer eligible participants to.

Informative leaflet with basic lifestyle advice

Available local resources on lifestyle advice (source: expert institute on public health, health promotion and disease prevention) are bundled in an informational leaflet. The leaflet contains concise and clear visual information about healthy nutrition, exercise, sedentary behavior, smoking cessation, mental well-being and general recommendations to maintain a healthy lifestyle. Implementers can distribute this leaflet widely within their target population, regardless of whether people participate in the SPICES program.

SPICES promotion materials

With the intension of increasing visibility of the SPICES project in (potential) partner organizations, we designed T-shirts with a brief motivational quote ("Prevent cardiovascular disease, live healthy!"), the SPICES logo and the logos of the funding body and research group institution. T-shirts were worn during activities related to project promotion, training implementers, and CVD profiling and coaching. We also designed a banner to set up at any event to recruit/engage/inform the target group and stakeholders and to promote the project.

Social mapping blueprint

The implementers at all participating general practices receive a digital blueprint for social mapping. The research team created a draft design, including regional community resources which are applicable in all settings, explaining how each general practice can achieve a tailored social mapping of local community resources relevant to the components. The tool consist of strategies on how to tailor the blueprint to the specific local context and an inventory of generic regional resources subdivided into relevant themes (diet, PA, smoking, stress, leisure activities, psycho-social aspects); including useful practical information on content, location, contacts, specific requirements, cost and reimbursement, etc.

Planning and follow-up tool

To support the implementers who carry out the coaching, we developed a tool in Microsoft Excel that facilitates the practical planning of the coaching sessions. Sessions can be scheduled from the time a participant entered for profiling; the 10 coaching sessions are then automatically scheduled according to the set intervals. The flexibility to deviate from the prescribed schedule is maintained to increase practical feasibility with regard to the agendas of both implementer and participant. In addition, it is used to support the follow-up of participants during their coaching trajectory ,facilitating the reporting of each profiling and coaching session which can be shared within the team of implementers. The tool also includes reminders for the coaches of the tasks they need to complete during each coaching session.

Disclaimer: All materials are in Dutch and are available upon reasonable request from the SPICES research team.

4. Procedures

Participant recruitment

Passive dissemination through informative invitation (digital) posters and leaflets, is rolled out in every setting.

In general practice, the strategies used to inform, invite and engage the target population differ in each setting. Examples of participant recruitment are: personal invitation by PN or GP during a consultation; personal invitation by PN or GP during the flue vaccination campaign; extracting the target population from the patient records and inviting participants through email or telephone. After giving potential participants information about the project, they are invited to make an appointment with the PN for a CVD risk profiling.

Likewise, *in community settings,* participants are invited personally or by letter invitation, e-mail or telephone by trained volunteers or social care staff. People are then invited to predetermined walk-in moments for their profiling and coaching sessions. These walk-in moments are deliberately held in the 'public' meeting spaces of the community settings, to increase the visibility of the SPICES project and to create an environment of social support and safety in order to recruit more potential participants on the spot.

Training and education of implementers

Prior to the implementation, all implementers receive relevant training modules to develop and strengthen their competences regarding participant recruitment, risk profiling and communication and lifestyle BCC, using the training materials. They are also granted access to the project tools designed to support all intervention components.

CVD risk profiling and communication component

Profiling takes place with the NL-IHRS and as a result, the participant is assigned to a risk category. The result is communicated with the aid of the automated lifestyle advice and risk cards. Based on their individual CVD risk, the appropriate follow-up trajectory is proposed using motivational interviewing techniques. Every participant, receives BA on how to maintain a healthy lifestyle based on national recommendations, the red group is referred to usual care (general practice), and the orange group is invited to participate in the lifestyle coaching component.

Participants either received a very BA (low risk score), or information on appropriate follow-up trajectories based on their individual risk score (intermediate and high risk score).

Lifestyle coaching component

The coaching trajectory consists of multi-lifestyle BCC The lifestyle coaching sessions are focused on raising awareness of individual CVD risk and modifiable risk factors related to lifestyle (diet, PA, smoking). With the aid of the lifestyle plan, the participant and the coach work together towards behavior change. Depending on the selected behavior change goals that are set by the participant and the coach, coaching sessions are focused on DASH diet; combined aerobic training or aerobic and resistance training and smoking cessation. Several behaviour change techniques are embedded within the coaching; goal setting, action planning, problem-solving and motivational interviewing.

Implementers are encouraged to refer participants to existing community resources.

5. Who provided

In general practice, profiling and coaching are carried out by the PN within the general practice team. All team members (GP, PN, general practice office assistant or manager) are involved in the project to inform, engage and follow-up the target population. In case of high-risk participants, a shared decision on the appropriate follow-up trajectory is made in the multidisciplinary team, together with the PN and the GP.

	In community settings, profiling is carried out by lay people (e.g. peers, social workers, student interns) who are not medically trained but able to understand how to use tablets and apply measurements with minor training. Coaching on the other hand is carried out by a qualified SPICES coach with previous lifestyle coaching experience.
6. How	The intervention is delivered face-to-face in individual sessions.
7. Where	*In general practice;* including five multidisciplinary general practices with capitation payment system, one of which is located in a rural area and four of which are located in vulnerable, urban districts in the city of Antwerp in Belgium. The intervention program is carried out in the implementers' offices. *In community settings;* including a local services centre, a community centre, a local health point of a Belgian health insurance fund, a centre for general welfare work and the Health Kiosk. All organizations are existing welfare organizations except for the latter, which is a low-threshold, bottom-up community-based initiative aimed at outreaching vulnerable populations concerning their health and well-being. The intervention program is carried out in the 'public' meeting spaces of each setting.
8. When and How much	The **profiling component**, including NL-IHRS, risk communication and follow-up initiation, is delivered in one session. The duration is approximately 20 minutes. The **coaching component** is delivered in 10 sessions with set intervals and spread over 12 months. The duration is approximately 30 to 45 minutes. The follow up sessions (Sessions 1-10) are planned as follows: Month 1 • Session 1 - One week after profiling: Start up coaching with 'Lifestyle Plan' + Follow-up questionnaires • Session 2 – Two weeks later (mid-month 1): Coaching + Did red group contact their physician yes or no (if no: reason why) • Session 3 – Two weeks later (end month 1): Coaching Month 2 • Session 4 - Two weeks later (mid-month 2): Coaching • Session 5 - Two weeks (end month 2): Coaching Month 3 • Session 6 – Four weeks later (end month 3): Coaching

	Month 4 • Session 7 – Four weeks later (end month 4): Coaching + NL-IHRS + Follow-up questionnaires Months 5 & 6 • Session 8 – Two months later (end month 6): Coaching Months 7, 8 & 9 • Session 9 – Three months later (end month 9): Coaching Months 10, 11 & 12 • Session 10 – Three months later (end month 12): Closing session planning long-term sustainable change + NL-IHRS + Follow-up questionnaires
9. Tailoring	We conduct a process evaluation with 'plan, do, study, act' cycles every two to three months during implementation. We assess the intervention components, the supporting project tools and the implementation strategies used. This entails interviews and meetings with the implementers in each implementation phase and the co-creation and adaptation of the intervention components that are implemented.
10. Modifications (& rationale)	**COVID-19 related (temporary) modifications** • During the first lockdown period in Belgium (starting in March 2020) the interventions were moved online due to physical distancing recommendations during the COVID-19 pandemic lockdown. Participants were informed through the webpage of local partner organizations. Participants were then asked to complete the NL-IHRS online CVD risk profiling tool after an instruction video. They received an information e-mail and a qualified SPICES coach contacted them by phone to discuss their CVD risk profile and further course of the follow-up if needed. • In the same period, we focused more on population level health promotion activities. In order to support vulnerable communities during this period, we developed low-threshold messages based on existing advice and recommendations from national /regional public health expert organizations. These messages were disseminated weekly through the social media channels and other communication channels (website, newsletter) of our local partner organizations. **Modifications in primary health care settings** • Participant recruitment strategies (as described in above in 4. Procedures) were tailored and adapted to the general practice needs and context. Practices shifted or adapted their strategies to increase or specify the reach of the target group, including passive (e.g. posters, leaflets) and active (e.g. personal invitation during flu vaccination campaign) recruitment strategies. • The implementers suggested to include not only participants at intermediate CVD risk but also participants with high-risk score (red group) in the coaching sessions if they are willing to be enrolled. Since this regards patients at high risk of developing CVD, general practice teams were urged to develop an internal protocol or procedure for the evaluation of the individual patient situation (e.g. discussion between PN and GP regarding medical background and medical treatment status, potential health benefit versus risks of participating in coaching trajectory) before

considering the participant to be included in the red group follow-up. Such a procedure also ensures the patient safety and continuity of care for patients at high risk of CVD who often have a more elaborate medical background. Based on these rationale, the research team decided to enrol red groups to the coaching and follow up session only in the general practice setting.
Note: Patients who already have a history of an event are still excluded from the intervention program. This is mainly done by consulting the patient file to assess the patient's medical history.

- For participants who were either orange or red group and interested to participate in the coaching, the follow-up questionnaires on level of CVD knowledge and perception, PA and dietary habits, are collected either automated through online surveys, or face-to-face in the general practice prior to the coaching session. This was a modification that was made in one general practice, since the online approach would help the implementers to cope with any time restraints and would minimize practical barriers for participants who are capable to complete the forms independently.
- In some cases, the format and intensity of delivery of the interventions were tailored to the needs and preferences of the participant. This means that sometimes the coaching sessions are held online in order to remove practical or contextual barriers. Also, the set intervals and number of coaching sessions could differ on the participant's request, based on their individual needs and preferences, although the implementers always suggested the intervention as planned to be the best option.
- During the implementation of the SPICES program in the first general practice, we received feedback from the PN that they needed confirmation of their performance. The lack of self-efficacy and competencies, in combination with the often very small results visible in the short term among the participants, resulted in a need for personalized feedback and tools for further growth. That is why, after consultation with the Flanders Institute for Healthy Living, we introduced an online supervision session with expert video-feedback. PN were asked to video record a profiling and coaching session (with participant consent). The expert then prepared the session by selecting key video fragments to be discussed during the session. The PN were first challenged to self-reflect, and finally the expert provided feedback on communication and behavior change techniques that were or were not applied. Finally, the PN were also provided with tools to carry out intervision within their team in the future. This supervision session was offered as standard in the other general practices.

Modifications in community settings:

- The original protocol considers different actions for each risk-group of participants. Participants in the green group receive BA and health tips to maintain a healthy lifestyle. The orange group is invited to enrol in the coaching session and follow up assessments, whereas the red group is being advised to contact their GP for further assessment. However, after discussion within the research team and following up on feedback of the implementers, we realized that it is necessary to check whether advised participants in the red group actually contacted their GP. Therefore, we added a few follow up questions after a week whether they contacted a GP or not. The data are collected through phone calls and are stored in the REDCap database.

Modifications in all settings:

- Planning and follow-up tool: After implementation in 3 welfare organizations and before implementation in general practice, implementers raised the issue of the complexity of planning all coaching sessions. Therefore, we developed a planning and follow-up tool (See 3. Materials)

HOW WELL	
11. Planned	The coaching intervention was planned for intermediate risk groups and referral for high risk groups.
12. Actual	Except modification of eligibility for the coaching intervention in PHC settings (See No. 10), most of the intervention activities including risk profiling, risk communication, coaching and referral were implemented as planned. The NL-IHRS was used as a profiling instrument in all settings throughout the intervention period.

SPICES: Scaling-up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and Sub-Saharan Africa; CVD: Cardiovascular Disease; PA: Physical Activity; PN: Practice Nurse; GP: General Practitioner; BCC: Behaviour Change Counselling; NL-IHRS: Non-Laboratory Risk Score; BA: Brief Advice

Phase 4 Implementation, evaluation and refinement

Key implementers were involved in multiple interviews at various timepoints during implementation. In the general practices, seven GP, 11 practice nurses (PN), one nursing assistant and one practice manager were included. In the community settings, we interviewed 46 implementers including social care staff, volunteers and the SPICES coach. In addition, we interviewed 57 participants; 17 of which were recruited in general practice and 40 in community settings. Our participant sample included a mix of cases at low, intermediate or high risk of CVD risk and they were interviewed after the profiling session or after one or more coaching sessions. The socioeconomic characteristics of the participants in general practice and community settings are reported in Chapter 8. The main results are structured following relevant TIDieR items and are illustrated with verbatim quotes from the respondents. Table 3 lists the refinements in detail across items 9 to 12.

MATERIALS

In general, the implementers were positive about the **training materials**. Especially the elements focusing on strengthening competencies of BCC and motivational interviewing added great value, especially for the PN who carried out the coaching component in general practice. The manuals were also regularly consulted afterwards during spare moments or even during coaching sessions.

"I especially found the part about motivational interviewing very useful. I always keep the manual with me in case I need it during a session. I also found the BCC strategies very interesting, I learned a lot."
(PN)

Implementers emphasized the importance of tailoring the training further to each specific setting, e.g. by considering the target audience, geographical location and neighbourhood characteristics, available expertise and common practice. According to the implementers, the basic training modules generally remained too theoretical and they suggested to focus more on practical examples and role-play. They also implied the need for long-term support and feedback within a learning community.

"It would have also been very useful to analyze certain cases in depth to learn from. Or to share our experiences, positive and negative, and pressing issues and pitfalls, and receive input from an expert or and peers."
(GP)

To answer to the needs implementers raised to increase their self-efficacy and competencies, we provided expert supervision sessions in general practice at a later stage during implementation. PHC teams also received tools for intervision allowing them to take charge of their learning process.

"The expert used concrete examples to show us how our actions influenced the participant's motivation. The session also taught us how to observe each other and to give constructive feedback. It was the missing part we needed to consolidate the competencies we acquired in the basic training module."
(PN)

Both implementers and participants considered the **NL-IHRS** valuable with its clear, simple questions and feasible to incorporate into daily practice. Participants were positive about the assignment to risk categories. However, according to the implementers, some crucial topics were missing from the questionnaire, such as alcohol and sugar consumption.

"The NL-IHRS is very concrete and easier for our population to answer compared to other surveys we have previously used on social care topics."
(social worker)

Specifically in the context of general practice, the lack of objective measurements such as weight and blood pressure was perceived negatively, which had both implementers and participants questioning the reliability of the instrument. Participant's expectations from an examination in a clinical setting were not fully met, and PN felt that their expertise was not being utilized to its full extent.

"I think it would be better if we could make more use of data that have already been recorded in the medical file or measure certain parameters ourselves."
(PN)

"I participated in the profiling , but afterwards it didn't seem very correct to me. Not a single objective measurement had been made. Weight, height, body fat percentage,… nothing. It feels like I don't have a goal to work towards."
(participant general practice)

The visual aspect of the **risk cards** was experienced as an added value in communicating and interpreting CVD risk. However, the narrative-based message did not seem relevant to participants. According to some implementers, the numerical information led participants to minimize their CVD risk. Clarifying CVD using common and specific terms such as myocardial infarction or stroke, and emphasizing the long-term risk, were mentioned as areas for improvement.

"One of my participants scored 'orange' and when I read that message that there was x chance on a hundred... He just responded 'Oh well, but that's not too bad at all!'".
(PN)

"That card was simple and clear, not too complicated. It was motivating because it confronted me with the facts."
(participant general practice)

Implementers praised the **lifestyle plan's** design in which behavior change techniques were embedded to support the coaching sessions. In addition, respondents stated that the tool clarified the goal of the coaching sessions and that it provided participants the structure they needed to work towards their target lifestyle behaviours. Most participants however needed assistance to get familiar with the tool before they could continue to use it independently.

"The lifestyle plan is very useful. With a new participant, we fill it in together. 'When do I start?' 'How exactly am I going to do that?'… It provides guidance for both me as a coach and the participant."
(PN)

Some implementers used the **follow-up questionnaires** to gain more insight into the knowledge, perception and lifestyle behaviour of participants, and to tailor their coaching accordingly. This was particularly useful at the starting point of a coaching trajectory because it filled the gaps that were identified in the NL-IHRS. Others used it merely as follow-up data for research purposes and suggested to introduce a lifestyle diary to gain more insight into participants' behavioural patterns.

"The questionnaires are very useful to know 'Where is that patient at, what is his insight?' I have them fill it out and then discuss it together and explain 'No, that is not a correct idea of your CVD risk.'. Otherwise I assume too much that they just already know all that."
(PN)

The extensive time investment for administering the questionnaires was a barrier for both participants and the implementers especially because some questions were complex and required additional explanation. In general practice, people with sufficient digital skills were offered to complete the questionnaires independently online prior to the coaching session, with the option to discuss unclear items together with the coach during their next session.

"One of the questionnaires contains a lot of questions that need to be read two, three times to finally understand the meaning. It's difficult for non-native speakers or low health literate people to understand."
(PN)

The **planning and follow-up tool**, which was developed and implemented based on the needs of the implementers, was positively received. It turned out to be a very user-friendly tool to facilitate practical planning of the coaching trajectory and to structure follow-up of participants.

"I really like the new planning tool. It is very useful that you can report on whether the goal was achieved, what the obstacles were or what was successful. It also shows where we are in the process and when the participant should come next."
(PN)

PROCEDURES

With regard to **participant recruitment**, participants felt that they received sufficient information, allowing them to make a well-considered and conscious choice whether or not to participate in the intervention program. A personal invitation, often during a consultation on another issue, proved to be particularly effective to recruit the target population.

"The information was very clear and correct, it was explained very well, as was the leaflet I received. I had no further questions about the program afterwards."
(participant general practice)

Following implementer and participant feedback in general practice, we made the adjustment of allowing people with a high risk of CVD to participate in the coaching component, if they showed interest to enrol and after consultation with the GP.

"I was told that I did not belong to the target population because my CVD risk score was too high. I was very disappointed because the coaching trajectory might help me to reduce my risk."
(participant general practice)

Furthermore, the implementers indicated that it would be desirable to reconsider the age category of the target population for these and other interventions aimed at primary prevention of CVD, allowing younger people to also benefit from these kinds of programs in the future.

"We see people here aged 35 who were actually seriously overweight, who might also benefit from lifestyle coaching."
(PN)

Participants found it particularly useful that they received their results from the **profiling component** immediately. They received clear information, but for some people the amount of information was overwhelming.

"Those are the results. I like such direct communication. I did receive a lot of information…it was a bit too much to follow."
(participant general practice)

According to the participants, the **coaching component** was very well structured due to the behavior change strategies and motivational interviewing techniques that were applied.

"When things get difficult, it is confrontational, but we were also able to talk about that. The coach and I reflect together on what the reasons could be that things did not go well on those days, and how it can be improved."
(participant general practice)

"My coach asks the right questions, really listens to me and wants to know what I think of it. The coach really activates me."
(participant community organization)

The involvement of the coaches and their supportive and stimulating roles, and the trusting relationship that is built during the coaching sessions, were identified as crucial factors by participants.

"I gain confidence during those sessions. The PN also sympathizes with my situation and tries to find solutions together with me. And offering support by often saying 'you are doing so well'… that is so motivating."
(participant general practice)

HOW

Although implementers appreciated the individual, face-to-face format of the intervention, some pointed out the added value of group sessions to improve social cohesion. For vulnerable people a face-to-face format was most desirable, for others telephone feedback was sometimes provided. To optimally meet individual needs and preferences, these types of interventions should be offered under different formats.

"The individual format ensures that people gain more insight, because the advice and interventions are then really adapted to individual needs and preferences."
(volunteer)

WHEN & HOW MUCH

The intervention intensity was predetermined by a defined frequency of the profiling and coaching sessions, which was considered an appropriate standard for most cases. However, both implementers and participants suggested adapting their duration and intervals in between sessions to the course of each individual process in consultation with the participant.

"When the sessions followed each other so quickly, there was nothing left to discuss with the coach. At a certain point there was more time in between the coaching sessions, which gave me the chance to work independently towards my goals more."
(participant general practice)

"I once rescheduled a session to three weeks instead of two, at the request of the participant. Scheduling in an extra appointment is also a possibility. But mostly, we just follow the planned schedule. It all depends on what the participant needs."
(PN)

Discussion

In this paper, we applied multiple research methodologies and approaches to develop and highly contextualized a comprehensive intervention program for the primary prevention of CVD aimed at PHC and community settings in vulnerable city districts in Belgium. During a four-phased iterative process, we used a consensus procedure within the SPICES expert consortium to identify generic core intervention components and implementation strategies based on several literature reviews. We also conducted a contextual analysis and involved key stakeholders and experts on health promotion and

disease prevention to translate the SPICES intervention basket to a local intervention plan for the Belgian study site. The content, materials and protocols were designed through co-creation meetings with local stakeholders, consultation of experts and key stakeholders, and cross-learning workshops with the SPICES consortium. The intervention program consists of two major components: 1) a profiling component including CVD risk profiling using the NL-IHRS and risk communication, and 2) a coaching component including behaviour change and motivational interviewing techniques. It was implemented in general practices and community organizations to evaluate key implementers' and participants' acceptance and views of the program. Our intervention program has proven to be acceptable and feasible to be integrated into routine practice in PHC and community settings, especially after making the necessary adjustments. The intervention components and implementation strategies show great potential to be scaled-up to similar real life settings and to be transferred to other contexts.

In recent years, many studies have tested the effectiveness of various strategies for the primary prevention of CVD, leading to a solid evidence base (63). However, minimal attention has been paid to developing and contextualizing these evidence-based strategies. Our paper is one of the few that examined how these different strategies can be brought together into a comprehensive intervention program, and how it could be adapted for its integration into routine practice. In addition, few recent studies describe the details the intervention program and the lessons learned. However, the limited impact most individual interventions have on the burden caused by CVD and their risk factors, leads to the conclusion that we can no longer overlook the development and contextualization process of those interventions. Indeed, this process is believed to have major influence on the intervention's intended effect in a specific target population, but also on implementation success and sustainability (27, 32, 64). Future research should therefore focus on implementing and assessing tailored and culturally appropriate interventions at primary care and community level. It requires a rigorous analysis of and tailoring to the context, vulnerable target population and individual.

Literature reports critical gaps in evidence on how to tailor interventions to specific populations, in particular those of low SES; despite the importance of identifying and managing the needs of different populations to address inequalities in health (65). To this end we applied the principle of proportionate universalism in developing and contextualizing our intervention program. Our intervention components were universal but with a scale and intensity that was proportionate to the level of disadvantage of our target population (66). We intended to increase the reach of people with low SES, to reduce CVD burden in all target populations and to minimize health disparities. For example, in the design of the coaching component, we opted for content that applies to the entire population as recommended by international clinical guidelines, but our strategies were based on the thresholds experienced by vulnerable groups -such as the need for self-confidence and social support that form

important barriers to lifestyle behaviour change. In addition, we deliberately chose implementation settings that had a relationship of trust with vulnerable target groups, such as general practice or community organizations. Moreover, we invested additional resources in the risk communication component through visual support materials and by providing training for implementers in the field on their communication skills especially targeting people with low health literacy. To increase its impact, proportional universalism should be applied as a touchstone in the development of all policies, laws, regulations and methods or actions related to in any policy, method development or action to promote healthy living and a healthy environment (67). However, there are still many methodological and ethical challenges regarding the design and evaluation of such interventions, including how to apply proportionality (68). Therefore, it is necessary to clearly define the principle for use in each context (69).

Furthermore, our systematic reviews revealed the lack of knowledge about factors that can influence implementation of the evidenced recommendations into practice and how to overcome them (19, 20, 41). We therefore tailored the generic implementation strategies from Phase 1 to what we found through contextual analysis. Supporting implementers and revising professional roles was further defined to enhance task sharing or shifting and role expansion among implementers; particularly in relation to nurses in general practice (70, 71) and lay welfare workers or peers in community settings (72, 73) who play a crucial role in implementing prevention programs. A phased implementation allowed for sequential stepwise adaptation to dynamic needs, which is in line with recommendations from other research on adapting evidence-based complex interventions for new contexts (74). Training and educating implementers made sure that those who would be providing the intervention had the necessary competencies or providing tailored training so they could be acquired. It was also important that the training materials and the acquired lifestyle counselling competencies could be used widely, also for other non-communicable diseases (75). Finally, we added using participatory and iterative strategies to our implementation strategies, to maintain long-term engagement and to generate ownership in members of local implementing and networking organizations. Stakeholder engagement in implementation research has indeed become increasingly prominent in finding ways to design, implement and sustain evidence-based policies (76).

This paper has both strengths and limitations to consider wile interpreting our research. First of all, it is crucial to enhance participation and, if possible, co-creation to vulnerable target groups and relevant organizations in designing and adapting interventions (77). Although we did use participatory and bottom-up approaches with multi-level stakeholders from the local context during the development phase, including those from representative organizations of disadvantaged populations that were included in the contextual analysis, we did not involve the target population in the initial drafting our

local intervention plan and its design. We did however use participant feedback to evaluate and refine our intervention program during its implementation. Altogether, our research does provide a real-life perspective to interventions for the primary prevention of CVD. As a consequence, our findings may be better adapted to the needs and preferences of PHC and community settings in Belgium and the populations they reach.

The ultimate goal of this research is successful and sustainable implementation. For this reason, we did not start from behaviour change theory and the explicit link between mechanisms of action and related to behaviour change techniques (78, 79) that were embedded in the intervention components. However, extensive literature review and the input of health promotion and disease prevention experts, allowed us to incorporate the necessary theoretical underpinning into the various parts of the intervention program.

Another constrain related to the focus on implementation research is that we did not strictly follow a systematic, published approach to intervention development and contextualization. Although we examined existing approaches to developing interventions (27) for their alignment with our research aims, they were considered too rigid. Our implementation research objectives indeed required a more pragmatic approach, allowing us to utilise mixed and multi-perspective research methods and techniques and to make timely and flexible adjustments where necessary. With our four-phased iterative approach, we gave much attention to developing an intervention program that has the potential to be effectively and structurally integrated in daily practice. The GUIDED checklist (31, 32) however proved to be useful not only to report afterwards, but also in the planning phase of intervention development processes. As such, we assessed the relevance and value of the proposed actions in relation to our particular development and contextualization process which were intertwined during the four phases of the process. For future research, we recommend to consider the recently updated Medical Research Council framework (80, 81); the six core elements of which strongly align with our experiences and that can give direction to the conceptualization, planning, execution and evaluation of future intervention development and contextualization, as well as its implementation.

Finally, the insights we provide here on the process we have gone through with our international ‘SPICES’ research group can serve as inspiration for other researchers that are faced with the challenge of developing an intervention aimed at implementation in diverse settings. Our phased, collaborative approach resulted in concrete actions that can be taken to address difficulties such as the different speeds and levels at which different research groups operate in their context, and the difficult balance between adaptability to the local settings versus fidelity to generic cross-setting components, as also reported by others (29).

Conclusions

This paper describes a practical example of developing and contextualizing a comprehensive intervention program for the primary prevention of CVD. It indicates the importance of translating evidence into practice and provides insight in actions that can be taken to overcome challenges when transferring and scaling up evidence-based interventions to real life settings in various contexts. An iterative and phased approach, involving multiple methodologies and perspectives, is crucial for the co-creation of intervention programs that have the potential to be successfully and sustainably implemented in daily practice. This research has implications beyond the SPICES project and can be of interest to other researchers and all those involved in planning for the implementation of interventions related to disease prevention and health promotion.

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Chapter 7

Process evaluation of the implementation of a cardiovascular disease prevention program in general practice

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Aerts N, Van Royen K, Van Bogaert P, Peremans L, Bastiaens H. Understanding factors affecting implementation success and sustainability of a comprehensive prevention program for cardiovascular disease in primary health care: a qualitative process evaluation study combining RE-AIM and CFIR. Primary health care research & development. 2023;24:e17. https://doi.org/10.1017/S1463423623000063

Abstract

Aim

Our aim was to evaluate the implementation process of a comprehensive cardiovascular disease prevention program in general practice; to enhance understanding of influencing factors to implementation success and sustainability; and to learn how to overcome barriers.

Background

Cardiovascular disease and its risk factors are the world's leading cause of mortality, yet can be prevented by addressing unhealthy lifestyle behaviour. Nevertheless, the transition towards a prevention-oriented primary health care remains limited. A better understanding of factors facilitating or hindering implementation success and sustainability of prevention programs, and how barriers may be addressed, is needed. This work is part of Horizon 2020 project 'SPICES', which aims to implement validated preventive interventions in vulnerable populations.

Methods

We conducted a qualitative process evaluation with participatory action research approach of implementation in five general practices. Data were collected through 38 semi-structured individual and small group interviews with seven physicians, 11 nurses, one manager and one nursing assistant, conducted before, during and after the implementation period. We applied adaptive framework analysis guided by RE-AIM QuEST and CFIR.

Findings

Multiple facilitators and barriers affected reach of vulnerable target populations: adoption by primary health care providers, implementation and fidelity and intention to maintain the program into routine practice. In addition, our study revealed concrete actions, linked to implementation strategies, that can be undertaken to address identified barriers. Prioritization of prevention in general practice vision, ownership and shared responsibility of all team members, compatibility with existing work processes and systems, expanding nurse's roles and upskilling competence profiles, supportive financial and regulatory frameworks, and a strong community – health care link are crucial to increase implementation success and long-term maintenance of prevention programs. COVID-19 was a major barrier to the implementation. RE-AIM QuEST, CFIR, and participatory strategies are useful to guide implementation of prevention programs in primary health care.

Background

Cardiovascular diseases are the world's leading cause of mortality with around 18,6 million deaths in 2019, representing 32% of global mortality (1, 2); and 393 million disability adjusted life years (3, 4). The financial burden of cardiovascular disease and its risk factors on society and the healthcare system is substantial (5). The burden is highest among individuals with lower socio-economic status (6, 7). Current evidence underpins the association between low socio-economic status and cardiovascular disease; its risk factors; and unhealthy lifestyle behaviours (8).

The World Health Organization estimates that nearly 75% of premature deaths are preventable (9). Healthy lifestyle practices including smoking cessation, healthy diets, physical activity and alcohol reduction are important in the prevention of cardiovascular disease and its modifiable risk factors such as hypertension, (pre-) diabetes, dys- and hyperlipidaemia, overweight and obesity (10). Current evidence demonstrates numerous strategies to reduce cardiovascular disease risk with strong consensus on the importance of raising awareness of risk factors and on the impact of lifestyle on health outcomes (11-13). Clinical practice guidelines yet fail to consistently propose structured protocols to guide practitioners, and gaps in evidence are reported especially regarding strategies targeting vulnerable populations (14, 15). Consequently, people with low socio-economic status tend to benefit less from preventive care including lifestyle interventions (16, 17).

A critical research-practice gap on actual implementation of structured preventive interventions indeed remains. Studies show poor achievement of guideline-recommended cardiovascular disease prevention targets (18, 19). As such, there is an urgent need to further develop and implement interventions and strategies for detection and management of risk factors, in the general population as well as in vulnerable subpopulations. Horizon 2020 funded 'Scaling-up Packages of Interventions for cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa' (SPICES) project was established with the aim to implement evidence-based interventions for primary prevention in the population, including vulnerable groups, in low-, middle-, and high-income countries such as Belgium, where this study was carried out.

In Belgium, as in other high-income countries, prevention is primarily performed in primary health care, yet health systems fail to provide systematic support for all aspects of prevention. General practice plays a critical role in prevention and can be valuable in addressing socio-economic health differences due to frequent contact with a large and often diverse target populations (20). However, prevention-orientated services are not systematically provided in Belgian general practice. Clinical practice guidelines report various interprofessional collaboration models, including role expansion and task delegation in primary health care (15). Integrated care delivered by physicians and nurses in

general practice brings the opportunity to increase quality and accessibility of preventive care (21-25). However, little is known about how to implement validated preventive interventions in a specific real-life context of general practice and to which extent new interdisciplinary, collaborative forms can enhance their uptake.

This study aimed to explore how a comprehensive cardiovascular disease prevention program can be implemented in general practice in a high-income country as Belgium. The aim of this study is to understand the influencing factors and facilitators for a successful implementation and sustainability, and to learn how to overcome barriers. Through insight into the implementer's experiences with the process and in the critical role of nurses, these findings provide guidance for research and practice groups that wish to scale-up validated interventions for the prevention of cardiovascular disease in primary health care.

Methods

Study design and frameworks

This paper reports the qualitative process evaluation of an implementation carried out from an empowering, collaborative and change-oriented research perspective and framed within the transformative paradigm (26, 27). We applied principles of participatory action research (28, 29) to guide the implementation process, meaning that key stakeholders were involved in the co-creation, critical reflection and dynamic, context-specific tailoring of the program throughout the different stages of our implementation study.

The expanded RE-AIM Qualitative Evaluation for Systematic Translation (RE-AIM QuEST) framework, as proposed by Forman et al. (7), guided our formative process evaluation to identify real-time implementation barriers and explain how the context may influence sustainability and scale-up to other settings (30, 31). The complexity of the implementation context supports the use of qualitative methods as proposed by Holtrop et al., as they provide insight into 'why and how' our implementation process led to certain results, but it also encouraged collaborative stakeholder engagement (32). In this paper we report on the qualitative evaluation of RE-AIM dimensions 'reach' (participation of the target population), 'adoption' (participation of general practices and implementers), 'implementation' (including fidelity) and 'maintenance' (of the intervention). The quantitative evaluation, as well as the qualitative evaluation of RE-AIM dimension 'effectiveness' from participants' perspective, are reported in **Chapter 8**.

The consolidated framework for Implementation Research (CFIR) (33-35), a comprehensive framework consisting of constructs associated with successful implementation, was applied to further gain

understanding in implementation determinants influencing the RE-AIM dimensions. The complementary use of the RE-AIM evaluation framework and the CFIR determinant framework was previously demonstrated by King et al. (2020) (36).

Description of the intervention and target population

The evidence-based SPICES program combines principles of Prochaska's and Diclemente transtheoretical model (37), self-determination theory (38), motivational interviewing (39) and brief action planning (40), and consists of two major components. The first 'profiling' component included cardiovascular disease risk stratification and communication applying the non-laboratory INTERHEART modifiable risk score (41). We selected this tool because of its practical usability by nurses without needing supervision or intervention of physicians. The tool uses simple questions related to lifestyle behavior risk and a waist-hip circumference measurement to allocate ones individual risk to a high, intermediate, or low risk category. The profiling component was carried out by the nurse during a single session with an average duration of 20 minutes. The nurses used risk communication and motivational interviewing techniques to discuss the result and to initiate the appropriate follow-up trajectory. Participants either received a very brief advice on how to maintain a healthy lifestyle (low risk score), or information on appropriate follow-up trajectories based on their individual risk score (intermediate to high risk score).

The second 'coaching' component, consisted of multi-lifestyle-behaviour change counselling for those at medium to high risk with one year follow-up, spread in ten sessions following a set interval and with a duration of approximately 30 to 45 minutes. The coaching sessions were focused on Dietary Approaches to Stop Hypertension (DASH) diet (42, 43); combined aerobic training or aerobic and resistance physical activity; smoking cessation, and comprised behaviour change techniques such as motivational interviewing, goal-setting, action-planning and problem-solving. The intervention was delivered face-to-face in individual sessions. We targeted vulnerable communities using the principles of proportionate universalism (44), focusing on (sub-) population level vulnerability rather than on individual level, thus the intended group was reached on the level of study setting. On individual level, we targeted adults between 40-75 years old who were not diagnosed with cardiovascular disease. People with known diabetes were excluded since they are already included in an existing care protocol including lifestyle guidance. The strategies that were used to inform, invite and engage the target population differed in each setting, e.g. passive invitation through posters; personal invitation during a contact; email or telephone invitation. Prior to the implementation, all relevant implementers received training on techniques for participant recruitment, risk profiling and communication and lifestyle behaviour change counselling. They were also granted access to the project tools designed to

support all intervention components. Both training and tools were developed by the research group in collaboration with experts in the field. A comprehensive description of the intervention, based on the Template for Intervention Description and Replication (TIDieR) checklist (45), and its development, are fully described in **Chapter 6**.

Study setting and implementation

The intervention was rolled out in general practices in the Dutch speaking Antwerp region. Multidisciplinary general practices with nurse integration were eligible for inclusion. General practices were eligible if they served a diverse population including vulnerable people with low socio-economic status and/or if they were located in vulnerable city districts in Antwerp. Districts' vulnerability was identified based on socio-economic health deprivation index, limited access to primary health care, and density of households with social support. Twenty eligible practices were contacted by e-mail or telephone, five of which were willing to participate initially [Setting characteristics are summarized in Table 1]. Two practices (practice D & practice E) decided to stop participation before actual implementation took place. The three remaining settings (practice A, B and C) completed all implementation phases and fully implemented all intervention components. General practices did not receive any financial incentive or compensation for study participation since this would hamper sustainability of the implementation beyond the study period. They were encouraged to embed project-related activities in their regular financial system as outlined in Table 1.

Table 1: Characteristics and description of contextual factors and implementation details of included settings

		PRACTICE A	PRACTICE B	PRACTICE C	PRACTICE D	PRACTICE E
SETTING CHARACTERISTICS	*Type*	Group, multidisciplinary	Group, multidisciplinary	Group, multidisciplinary	Group, multidisciplinary	Group, multidisciplinary
	Geographical location	Inner city	Inner city	Urban	Urban	Rural
	Financial structure	Capitation system	Capitation system	Capitation system	Capitation system	Capitation system
POPULATION CHARACTERISTICS	*# Patients*	4539	4027	3217	3217	2100
	# Age 40-75	1491	1296	1358	*	1042
	# Increased reimbursement	1670	765	670	*	633
IMPLEMENTATION ROADMAP		PRE	PRE	PRE	PRE	PRE
		PER 1 > PER 2 > PER 3 > PER 4	PER 1 > PER 2 > PER 3	PER 1 > PER 2	EXIT	EXIT
		POST	POST	POST		
KEY IMPLEMENTERS	*General practitioner (physician)*	1	2	1	1	2
	Practice nurse	2	3	2	2	2
	Practice nurse assistant	0	0	1	0	0
	Practice manager	1	0	0	0	0
PARTICIPANT REACH	*# Profiled*	37	20	13	N/A	N/A
	# Started coaching	15	7	7	N/A	N/A

PRE-IMPLEMENTATION CONTEXTUAL INFORMATION	*Vision and mission*	Practice in transition: integrated interdisciplinary care; High quality care; Accessibility of care; Holistic approach	Accessibility of care; Supporting vulnerable population; Holistic approach; Interdisciplinary care; High quality care; Training- and research-oriented	Accessibility of care; Empowering people for health; Equal partnership and interdisciplinary care	Accessibility of care; Interdisciplinary care; Community link; Prevention	Practice in transition: interdisciplinary team expansion & capitation system; Empowering population; Prevention
	Pre-existing community link	Current gap; Planned team expansion with social worker; Insufficient knowledge of community resources	Referral to physical activity on prescription; Referral to external care partners; Planning to focus on community-oriented care in future	Current gap; Mainly internal follow-up; Referral to physical activity on prescription; Referral to external care partners	Link with local welfare organization; Referral to external care partners; Planning community-outreaching initiatives in future	Current gap; Mainly internal follow-up
	Current practices for prevention	Focus on secondary prevention; Lack of structural organization and integration of primary prevention protocols	Focus on secondary prevention; Primary prevention of lower priority; Clear care plan and lifestyle follow-up for diabetes; Unsuccessful previous attempts to implement prevention protocols	Lack of structural organization and integration of primary prevention; Lack of continuity on lifestyle advice; Planning to introduce prevention consultation in future; Existing prevention protocols are too complex	Ad hoc prevention consultations; Clear care plan for diabetes; No structural focus on cardiovascular disease	Ad hoc prevention consultations; Clear care plan for diabetes; No structural focus on cardiovascular disease; Lifestyle trajectory in collaboration with multidisciplinary team
	Practice nurse integration level	Transition from instrumental towards more integrated, autonomous role; Level of task delegation depends on individual physician; Limited role in prevention	Transition from instrumental towards more integrated, autonomous role; Integrated through protocol care in management of chronic diseases	Transition from instrumental towards more integrated, autonomous role; Central role in planned prevention consultations	Combined instrumental tasks and integrated through autonomous consultations for prevention and follow up of chronic diseases	Combined instrumental tasks and integrated through autonomous consultations for diabetes follow up

group practice: >2 general practitioners; *missing data; N/A: Not applicable

A stepwise implementation of the intervention, developed in August 2019, was planned so that the key learnings and good practices could be scaled-up from one setting to the next one. All five settings completed the *pre-implementation phase*, which included thorough context analysis, implementation planning and preparation of intervention components and key implementers. In practice A, implementation took off in September 2020; practice B started in February 2021; and for practice C this was in July 2021. Implementation in all settings ran until December 2021. Our stepwise approach implies a difference in duration of the *per-implementation* phase in each of the three implementation settings; a phase where every two to three months, we undertook reflective action research spirals, allowing the researchers and key implementers to continuously monitor the dynamic course of the implementation and to incorporate new understandings into the ongoing process. The *post-implementation phase*, which ran from January up till June 2022, was mainly focused on providing necessary key requirements to consolidate intervention components long-term, and to see how this can be scaled-up to a broader context. The implementation 'roadmap' of each of the settings is incorporated in Table 1.

All members of the primary health care teams in each of the five included settings were considered 'implementers', since all of them were directly or indirectly involved in the implementation process. However, the most critical role was laid out for the nurse who carried out the intervention. The target population was approached and informed by their primary health care provider, and, if interested, they were invited to make an appointment with the nurse. In the included settings, nurses (and one nurse assistant) carried out all intervention components. In case of high-risk participants, a shared decision on the appropriate follow-up trajectory was made between nurse, physician, and participant. A total of 70 participants were profiled, 29 of which were enrolled in the coaching trajectory [Table 1].

A comprehensive analysis of the study context, including the needs and anticipated challenges to implementation, is available elsewhere (46).

Data collection

Data collection for this process evaluation ran simultaneously to the implementation process in each setting and was completed by March 2022. Data collection primarily consisted of 38 individual or small group interviews conducted at various stages of the implementation process. Small group interviews usually consisted of two to three implementers from the same setting, providing insight into the team's shared implementation experience through interaction. A total of 20 key implementers from the five included settings were interviewed. Key implementers were defined as implementers who were closely involved in the planning, coordination and/or execution of the implementation, and consisted of seven physicians, 11 nurses, one nursing assistant and one practice manager. The interviews were

conducted face-to-face when feasible, or online in video conferences depending on COVID-19-related government guidelines at the time, and each lasted between 30 to 90 minutes. Interviews were carried out by a team of five research assistants under the supervision of an experienced research team. All interviews were audio recorded and the interviewers took extensive notes during and immediately after the interviews. The interviews were transcribed as soon as possible afterwards.

The main issues brought up during the interviews were regularly discussed with the larger group of implementers during their pre-existing team meetings in the primary care practices. On its turn, this input was fed back to the researchers during other contact moments. This way, we ensured that the entire primary health care team in each setting was always challenged to reflection and their experience was also incorporated in our process evaluation. Additionally, we documented all implementation activities, progress and all communications in a logbook of each setting. We kept meeting reports from all informal meetings with the implementers in order to further support thorough process mapping.

Semi-structured interview guides based on the CFIR and RE-AIM QuEST, tailored to the context and targeted implementers, were developed to answer our research questions related to each data-collection phase (pre-, per-, and post-implementation) [see supplementary material 2]. The topic guide included specific questions on each setting's context, the implementation process, the facilitators and barriers to implementation of each component, adaptations that were needed, and factors influencing implementation sustainability. During this process evaluation, we also assessed the intervention components, the supporting project tools and the implementation strategies used. In order to map the barriers and facilitators to adoption and to understand reasons for dropping out, exit-interviews were also conducted with the practices that decided to drop out. We pilot tested the interview guides and made refinements based on respondent's feedback and researcher's experience.

Data analysis

We analysed all interview transcripts and documents using adaptive framework analysis (47, 48) based on RE-AIM and CFIR; ensuring the possibility to also integrate text fragments that could not be placed in rigid pre-existing categories. An a priori codebook was created based on RE-AIM and CFIR domains and constructs. The analysis was guided by operationalization of the four target dimensions for this study (reach, adoption, implementation, maintenance). These clear descriptions supported the coders' process in assigning relevant text to one of the four dimensions. Furthermore, operational definitions of CFIR domains and constructs were tailored to the study to improve coder consistency [see supplementary material 3]. In the first phase of the coding process, text fragments that represented one of the four dimensions were identified. The output of the first coding phase was reviewed within

the larger team of researchers and discrepancies were solved through team discussion until consensus was reached. In a second phase, all allocated text fragments per RE-AIM dimension were subjected to a more in-depth coding procedure with the goal to further structure the text into relevant CFIR domains and (sub-) constructs. The output of this second phase was also discussed and refined based on iterative reflection cycles of the research team. Once analysis of interview data was completed, we conducted a document analysis of logbooks and meeting reports guided by the final codebook. This analysis was used for the purpose of data triangulation of our primary interview data. Our data analysis was supported by QSR NVivo software version 1.5.1. This paper is built up using the Consolidated criteria for reporting qualitative research (COREQ) checklist (49) and Standards for Reporting Implementation Studies (StaRI) statement (50) as guidance.

Table 2 Barriers and facilitators to reach, adoption, and implementation; structured by CFIR domains and constructs

RE-AIM domain	CFIR domain	CFIR construct	Facilitator	Barrier
REACH	Intervention characteristics	Adaptability	The intervention fits the needs and preferences of the target population, and is adaptable further along the implementation process	
		Complexity		Intensity of coaching trajectory, regarding number, frequency and duration of sessions, is discouraging
	Outer setting	Target population needs and resources	Target population is open to and interested in learning more about the intervention	Prevention is not a priority in vulnerable populations due to invisibility of the (potential) cardiovascular disease risk and presence of other multilevel complex issues
				Lack of ownership over own health
			Positive expectations regarding potential health benefits of the intervention	Low health literacy including knowledge and skills on how to access primary care services and the intervention
			Favourable stage of change: Intrinsic motivation and willingness to (think about) changing behaviour	
			Fit with need for social support and connectedness is appreciated	
		Variable factors		COVID-19 pandemic causes fear in target population of going to 'contaminated environment' and of unnecessarily burdening health care providers
	Inner setting	Structural characteristics	Low threshold financial system increases accessibility of care, including the intervention	
	Characteristics of implementers	Self-efficacy		Nurses' low confidence in own competences affects reach results in consciously excluding/avoiding certain sub-populations (e.g. 'difficult to change')
		Other personal attributes	Nurses' and physicians' values of genuine interest and involvement in health and wellbeing of target population	

	Process	Engaging participants	Giving tailor-made information to target population, using supporting materials	Insufficient or inconsistent information during invitation to participate
			Empowering target population by respecting autonomy and ownership	
			Combining recruitment strategies with case finding	Systematically inviting target population by e-mail, letter, telephone implicates high administrative burden and low response rates
			Taking personal approach in addressing and inviting target population	
		Executing	Critical role of physicians' trust-based relationship with target population for active recruitment	Low relative priority for active recruitment in physicians
			Regular reminders for recruitment and use of supporting materials; e.g. information sheet in physicians' and nurses' offices	Low fidelity of planned recruitment strategies in physicians
ADOPTION	Intervention characteristics	Relative advantage	Opportunity to improve current prevention practices, or to introduce a prevention program, in a structured way with support from project team	
			Focus on cardiovascular disease with population-wide impact potential	
			Expected health gain in target population	
			Access to evidence-based project tools and supporting materials; e.g. profiling tool, lifestyle plan, training	
			Opportunity to explore and expand nursing roles	
		Adaptability	Flexibility of the intervention to be tailored to each specific setting's needs, preferences and capacity	
		Complexity		Intensity of the intervention and level of engagement, including the research component-related burden (e.g. data collection)

		Cost		Estimated personnel cost, especially regarding intensity of nurse project activities
	Outer setting	External policies and incentives		Lack of appropriate legal and financial frameworks to support prevention in primary health care and collaboration with nurses in general practice
		Variable factors		COVID-19 poses a major burden general practice with very high workload and unpredictable impact on practice
	Inner setting	Structural characteristics	Multidisciplinary group practice capacity	Lack of structural collaboration amongst disciplines
		Implementation climate	Supportive leadership	Differing receptivity to the intervention amongst involved members of larger teams
			Strong need for improving and more systematically embedding prevention in general practice	
			Strong need to expand nursing roles	
			Compatibility of the intervention with practice vision and mission	Insufficient compatibility of some project tools with existing workflows and systems
		Readiness for implementation		Insufficient resources for new capacities; both time and financial
	Process	Engaging Implementers	Creating wide support within the team by involving all team members from earliest stages	
			At least one nurse and one physician willing to lead, support, and reinforce the implementation (internal implementation leaders and champions)	
		Planning		Ambiguous implementation plans and tasks in the earliest stages of the project
IMPLEMEN-TATION	Intervention characteristics	Relative advantage	Training on behaviour change techniques widely transferable to general practice	Initial training proposed by project team remains theoretical and lacks concrete applicability to practice

		Additional expert supervision session on behaviour change counselling strongly increases competences and self-efficacy	
	Adaptability	Flexibility of the intervention components and implementation strategies allow necessary adaptations	
	Trialability	Aligning project targets with setting-specific feasibility; e.g. by limited and stepwise recruitment of participants	
	Complexity		Coaching component intensity and prescribed format hindering fidelity
			Behaviour change counselling-related challenges; e.g. reaching behaviour change in vulnerable participants, insufficient insight in 'active ingredients' for behaviour change
	Design Quality and Packaging	Project tools including strong visuals and useful, informative, relevant elements; guiding and supporting behaviour change counselling and facilitating activity planning and follow-up of participants; increasing feasibility and fidelity of intervention components	Project tools including complex and ambiguous elements; increasing time investment needed and hindering fidelity
		Attractive format and design	
Outer setting	Target population needs and resources	'Warm referral' to community resources; including personal introduction and practical support from nurses' trust-based relationship (built during coaching sessions)	Lack of active partnership and input from participants
			Financial barriers and need for trust-based relationships hindering the referral of participants to community resources
	Cosmopolitanism	Getting personally acquainted in building a network for gaining trust in care partners and defining (shared) responsibilities	Lack of a team member (e.g. social worker) with dedicated time to map and engage community resources to refer to
		Coaching component triggering implementers to purposefully build health care and welfare partnerships meeting participants' needs	

	Variable factors		COVID-19-related workload and governmental measures posing major barriers to implementation and continuity of planning and performing project activities
Inner setting	Structural characteristics	Financial system supporting prevention and collaboration with nurses	Discontinuity of team composition
	Networks and communications	Regular team meetings to discuss participant cases and implementation; increasing involvement, adoption and collaboration in team members; platform for raising concerns and actively solving problems	Lack of coordination and insufficient structural communication, hindering project follow-up
	Implementation climate	Delegation of cardiovascular disease prevention to the nurse; interdisciplinary collaboration fits within existing workflows and systems	
	Readiness for implementation		Inadequate resources for new capacities; limited time availability for implementers to perform project tasks
Characteristics of implementers	Self-efficacy	Targeted training support and regular practice, increasing nurses' self-confidence especially regarding the behaviour change counselling (coaching) component	Lack of feedback on performance from participants and/or knowledgeable expert
		Sharing experiences with peers, adding to professional growth	Tension field of to what extent to rely on own capabilities and when to call in other expertise (health care/welfare partners, community resources)
		Visible results and progress regarding lifestyle, wellbeing and risk perception in participants, confirming nurses' feeling of being capable	Limited reach and loss-to-follow up of target population for profiling and coaching, causing low confidence in own capabilities; and hindering further development of essential competences
	Other personal attributes	Strong 'basic profile' of nurses' learning capacity and (potential) competence	Poor involvement and interest of other team members (especially physicians), diminishing nurses' motivation
		Visible results and progress on lifestyle, wellbeing, risk perception in participants, boosting nurses' motivation	Limited reach and loss-to-follow up of participants for profiling and coaching, diminishing nurses' motivation
			Pitfall of health care providers to taking the lead hinders fidelity to patient-centred approach

Process	Planning	Recognizing the time that is needed for the project and drafting a feasible plan; re-evaluating and adapting this plan along the way	Lack of dedicated time for implementers to carry out intervention components; due to low relative priority of the implementation
	Executing	Appointing internal practice manager, coordinating project activities	Lack dedicated time for central coordination of the intervention amongst other practice activities
		Nurses' ability to use clinical judgement in profiling and coaching within setting of general practice	Lack of overarching internal protocols for management and follow-up of participants for cardiovascular disease, resulting in discontinuity in care
			Insufficient description of physicians' roles (e.g. high risk group)
		Support from project team: easily accessible, personal contact, understanding and knowledgeable, participator approach to overcoming barriers, flexible	
		Executing intervention components on a regular basis, with balanced participant flow and intensity ensuring progress on several aspects	
	Reflecting and evaluating	(re-)Defining roles and responsibilities along the way, reflecting on project status and adjusting goals and processes in internal team meetings and with project team	

Results

With Table 2, we provide a comprehensive summary of facilitators and barriers to reach, adoption, and implementation; structured around relevant CFIR domains and constructs. Key findings of our per- and post-implementation process-evaluation are presented in the following paragraphs structured by the covered RE-AIM domains, reinforced by implementers' quotes. Table 3 consists of some clear examples of how barriers that were encountered by the implementers, were addressed during the cyclic participatory action research process. We hereby give an overview of the implementation strategies that were applied, adapted from Powel et al (2015) & Waltz et al (2015) (51, 52), together with associated concrete actions as taken by implementers and the project team.

Table 3 Examples of how barriers were addressed along the process; translated into implementation strategies and actions related to RE-AIM dimensions*

Finding	Implementation strategy	Action
REACH		
Participant recruitment strategies have limited effect on reach; difficulties in reaching vulnerable target population	Adapt and tailor to context	The project team promoted adaptability of recruitment strategies; e.g. using flu vaccination campaign as entry point to invite eligible participants to increase reach; developing setting-specific information poster to better inform and activate the target population; engaging other team members such as receptionist for a low threshold and personal approach.
	Use evaluative and iterative strategies	Project team and implementers obtained and used participant's feedback on facilitators and barriers they experienced by semi-structured telephone interviews and informal dialogue. Participant's feedback was implemented; e.g. emphasizing (health) benefits, giving small stepwise parts of essential information.
	Support implementers	Together with the implementers, the project team developed information sheets to be placed on desks in physicians' offices, to remind them about the project and help them recall essential information about it, and to prompt them to actively recruit eligible participants.
	Develop stakeholder interrelationships	The project team captured good practices and local knowledge on strategies that work from implementation settings and shared it with the other sites to be contextualized and scaled-up; e.g. information sheet (implementers) and poster (target population) and case finding strategies.
ADOPTION		
Adoption is hindered by the intensity of intervention and variable COVID-19-related workload; adoption differed between	Adapt and tailor to context	The project team promoted adaptability by giving implementers the opportunity to tailor frequency of the coaching sessions to the needs and preferences of participants. Also, implementers could define periods of decreased participant inclusion in order to be responsive to the context of the pandemic and still be able to guarantee high quality of care.

implementers in general practices	Develop stakeholder interrelationships	The project team worked closely together with champions and early adopters in each general practice; e.g. nurse, general practitioner, student intern; to learn from their experiences and to disseminate those amongst other team members, using pre-existing communication channels such as team meetings.
IMPLEMENTATION		
Problems related to technicalities and project tools; low self-efficacy of implementers; insufficient collaboration with community resources; and aspects of implementer roles and responsibilities	Provide interactive assistance	The project team facilitated implementation by introducing weekly informal contacts with key implementers from each setting for interactive problem-solving, responsive troubleshooting and vital support. The project team appointed members to offer local technical support for electronic data capture system and other tools. The project team also facilitated use of community resources by providing a basic overview of initiatives in the neighbourhood of each setting and providing assistance and advice from an expert in the field to find care partners to answer specific participant needs.
impede implementation	Use evaluative and iterative strategies	The project team conducted a needs assessment to identify gaps in knowledge and skills of implementers; process bottlenecks and emergent or potential problems to gain insight in the support that was needed.
	Train and educate implementers	In response to the implementers' needs, the project team: - Conducted ongoing (refresher) training on all intervention components. - Developed and distributed educational materials to all implementers by different means, e.g. risk profiling and risk communication guidebook; behaviour change counselling manuals to guide nurses' coaching sessions, and to inform physicians and other implementers. - Introduced dynamic elements to the basic training (e.g. role play) - Used train-the-trainer strategies in collaboration with an expert centre, so that implementers acquired skills to guide other team members. - Created a learning collaborative by organizing expert-led supervision sessions for nurses of the same practice. The session included feedback on nurses' performance and tools for intervision so that they could further develop their competences. - Worked with educational institutions and expert organisations to develop evidence-based educative materials of high quality.
	Develop stakeholder interrelationships	The project team captured good practices and local knowledge on implementation and shared it with the other sites to be contextualized and scaled-up; e.g. the benefits of a central coordinating person (e.g. practice manager); advice on implementation and use of tools and materials; experiences with behaviour change counselling expert supervision session. The project team promoted using internal communication networks to elicit ownership and discussion around project activities. The project team also identified a local implementer (e.g. practice manager) to be responsible for follow-up of project status; aligning project activities with existing workflows and systems; ensuring the implementation was on meeting agendas; stimulating evaluation and reflection within the team; coaching the nurses. The project team also promoted identifying and building networks in the

		community; e.g. by inviting (potential) care partners in the practice to get acquainted and discuss collaboration.
MAINTENANCE Sustainable change requires alignment with local policy and incentives; structural educational support; supportive networks; but also compatibility with primary health care characteristics and target populations.	Develop stakeholder interrelationships	The project team created and engaged a 'resonance group' with macro-, meso-, and micro-level stakeholders that came together every few months to elicit recommendations for sustainability and maintenance.
	Train and educate stakeholders	The project team secured the sustainability and further dissemination of project tools and educational materials by making them available through the project's website. The team also engaged the regional postgraduate education "Nursing in the general practice" to embed essential elements of the developed training in their curriculum. Moreover, the project team also organized several educational meetings with local associations for physicians and community partners.

*Adapted from Powel et al (2015) & Waltz et al (2015) (51, 52)

Reach

Personal invitation during a consultation appeared to be the best strategy to engage the target population; a strategy that was scaled up to all settings, reinforced by a poster design to inform and activate the target population.

"For example, during our flu vaccination campaign. Most of the people we saw were eligible to participate. So we explained the project during the flu vaccination and we immediately received a lot of response."
(Nurse, Practice A)

Implementers described several factors that were taken into account when engaging people. In addition to the objective inclusion criteria, selection was also based on e.g. estimates of stage of change and the probability of effect.

"If there are some psychological problems or they are having a hard time with something else at that moment, then I feel like that might not be the right time to open a conversation on prevention."
(Physician, Practice C)

For some of the implementers, the extent to which they felt competent also influenced the reach.

"Certainly if they are people who have the tendency to 'know better', or already have their answer ready before you can propose something… I don't want to coach such people, because it makes me feel so insecure. My knowledge is limited and then I come across as unprofessional." (Nurse, Practice C)

Although active involvement of physicians in engaging the target population clearly improved reach, other priorities and insufficient involvement hindered adequate uptake of their role. The nurses developed information sheets to remind, inform and activate the physician as one of the actions to address this barrier.

"I think the doctor can give some information, but I doubt if they are truly familiar with all components of the project. We actually get very few patients referred. I think they just forget about it, they have a lot on their plate already during consultation."
(Nurse, Practice C)

The implementers felt the populations' need for genuineness, authenticity and active involvement of health care providers had become increasingly important during the COVID-19 pandemic. On the other hand, they felt that the pandemic has mainly had a negative effect on participation rates.

"After the lockdown, we noticed that they are actually happy that they can come to us with their story, because we listen to them and show interest in their general well-being."
(Nurse, Practice B)

"We actually see less people coming to the practice; out of fear of entering a contaminated environment ... especially vulnerable people. Or fear of burdening us unnecessarily."
(Physician, Practice C)

Adoption

The implementers indicated that the implementation climate in their setting was one of the determining factors for participation in the project. There was a very strong need for a more systematic approach to prevention.

"Prevention must absolutely improve in primary health care. That's a fact. I think we must play a more active role in it."
(Physician, Practice E)

The project's intervention protocols and guidance were therefore seen as a major advantage for optimizing prevention in their practice.

"I do think the project is very valuable. It gives us the chance to specifically focus on prevention… for the first time! And it also helps that we receive support and guidance."
(Nurse, Practice A)

At the same time, implementers indicated that change is needed in the currently limited task profile of the nurse. Implementation of the intervention was therefore seen as an excellent opportunity to explore further differentiation and expansion of the professional role of nurses.

"I think it was a good first step for the nurses to take up new tasks. They felt the need to do more than only 'the basics' they were doing before."
(Manager, Practice A)

"So many protocols have been written and yet nothing has actually changed so far. While us nurses were asking for new, challenging opportunities… I actually felt a bit useless here."
(Nurse, Practice C)

The complexity and intensity of intervention components, and the associated personnel resources, were mentioned as the main barriers to adoption. This is reinforced by the lack of a financial framework for prevention and interdisciplinary collaboration from the government, which was one of the main reasons for practice E to drop out of the study since they struggled with fitting in the project activities in their regular financial system. In response to intensity as a barrier, the settings altered participant recruitment activity to the dynamics of the COVID-19 pandemic. The resources required for project- and COVID-19-related activities could not be reconciled in practice D; the main reason why this setting has also decided to discontinue study participation.

"Because of the time investment... I just don't think it is feasible in this setting. And it is not only the contact with the patient, but also the burden of questionnaires and administration."
(Nurse, Practice D)

"The government should really be encouraged to better subsidize or finance such projects. Because we have to pay for our nurses ourselves and they can't take on other tasks during project activities."
(Physician, Practice E)

When engaging implementers, it is important that everyone is involved from the start, so that the project is supported by the entire team. Moreover, it is crucial that one or more people lead the implementation within the setting, according to our respondents. The local champions and early adopters in each setting shared their experiences with the project during team meetings, in order to encourage team engagement.

"Before a practice decides whether or not to get involved, it is important that everyone knows about it, and then collectively can decide whether or not they go for it together. Of course there must be a few team members really driving through the implementation."
(Physician, Practice D)

Implementation

One of the key facilitators, mentioned by the implementers, was the adaptability of the project to each setting.

"I think there was a lot of freedom to adapt everything to the context of our practice."
(Nurse, Practice B)

For example, the group with a high-risk (red score) was also given the opportunity to participate in the coaching trajectory, after a shared decision with the nurse and physician.

"Most people hope to get into the orange group for follow-up… they are even disappointed when they score red. So now we have decided that they can be followed up after we have consulted the doctor."
(Nurse, Practice A)

The COVID-19 pandemic was defined as one of the main barriers to the implementation.

"We don't know anymore… is it that we are structurally understaffed, or is it because of COVID-19. We are actually completely dependent of how the pandemic evolves, and it has a major impact on how we can plan our care and the project activities."
(Physician, Practice B)

Nurses felt that initially, physicians were not very involved, partly because the physician's role was insufficiently clear. Implementers emphasized the importance of regular team meetings and discussion during the implementation process. Implementing the intervention has encouraged implementers to collaborate more closely in their settings, which can be facilitated by someone from the team who takes up a formal coordinating role.

"I still miss the involvement of the doctors. I expected more feedback and more collaboration from them. I still think that they don't really know what is expected of them."
(Nurse, Practice A)

"The communication in our practice has also improved as a result from implementing the intervention… because we need to discuss thinks like 'How is everything going?' and 'How can we do better'? We actually have to work together. We have to discuss together. We have to sit down together to see how we tackle barriers."
(Nurse, Practice C)

"I think our practice manager has a good influence. Since she became more involved, she has proposed to bring the project on the agenda of our weekly team meeting."
(Physician, Practice A)

In all three settings, nurses have been given a more extensive and autonomous role within this prevention project. They proved to be crucial actors in the implementation.

"I think the nurses have acquired a new role with this project. They now do part of the follow-up, which we normally did to a lesser extent. With this we were able to transfer an essential task. I think they are very suitable for this."
(Physician, Practice B)

It was seen as a major added value that nurses are able to carry out the project components from their expertise, clinical reasoning and within the medical context of a general practice.

"We actually look beyond the profiling tool. Which makes sense, because we are trained to do so. We often measure blood pressure, or consult the patient record to see whether they take medication,… things like that."
(Nurse, Practice A)

Although they feel that the intervention matches well with their competence profile, nurses emphasized the complexity of the coaching sessions with the aim of achieving behavioural change. After the first implementation round in Practice A, based on the nurses' needs, the project's training content and format were modified to increase proficiency in relevant competencies for their new role in behavior change counselling, and scaled up as such in all settings.

"Motivational interviewing... It's difficult. I don't really have much experience with that. With some of the participants you feel such resistance and a lack of motivation, and then I find it very difficult to get them to change their behaviour."
(Nursing assistant, Practice C)

Self-efficacy, job satisfaction and motivation in nurses strongly depended on the results they do or do not achieve in the participants. They indicated that they needed confirmation of their abilities. In response to this need, the project team created a learning collaborative through expert-led supervision sessions where nurses received video-feedback on their performance and tools for further intervision within their team.

"I was able to give one patient a lot of information on healthy food, and he was completely open to that, while he usually is care refuser. So that went really well, and such 'wins' give a lot of satisfaction."
(Nurse, Practice B)

The implementers also experienced the tension field between applying their own expertise and referring participants to community resources. The project team facilitated networking and making use of community resources, by providing assistance in navigating through the potential partnering initiatives and providers.

"It is expected of us that we do everything ourselves. Both from the doctors and from the patients. But we aren't specialists. We must indeed sometimes just refer people."
(Nurse, Practice C)

Maintenance

Supplementary material 4 summarizes the intervention components that the implementers intend to sustain, as well as the end-user requirements to do so, linked to relevant CFIR domains and constructs. Implementers stated that the implementation process serves as a solid basis for continuing to develop and embed the general practice-level prevention policy in the future.

"I notice that it has triggered something in our team, … We also want to do more than providing basic care and follow-up."
(Manager, Practice A)

The need for further reflection within the team was mentioned, to outline future prevention policies and to translate and tailor good practices from the project to sustainable action plans.

"We will have to sit down together as team to see how we are going to proceed exactly. Are we only going to focus on disease prevention or more general health promotion? How are we going to invite the patients? Which profiling tool are we going to use?"
(Nurse, Practice A)

The implementers emphasized that sustaining the project requires close follow-up and communication in order to safeguard the continuation towards common goals.

"I think we have really learnt from this project that we need to be more responsive in the future. In the beginning there were frustrations around the project, which were left unaddressed for too long. We need to communicate about this more quickly, sit together and look for solutions."
(Physician, Practice A)

The degree of compatibility with the current system and work processes also plays a major role to what extent this will be further embedded in general practice in the future, according to the implementers.

"Prevention is just part of our responsibility, isn't it. We certainly try, because we have the conditions to do it here too. We work with nurses, the doctors have a very clear vision, we work with a capitation system,..."
(Nurse, Practice B)

Implementers emphasized the tension field between the relative priority of prevention compared to other core tasks of general practice, which is strongly influenced by external factors. They mentioned that reorientation towards prevention requires investment in innovative capacity building of primary health care systems.

"The general practice is consulted for all possible problems, which makes the workflow difficult to manage... You never know what the week is going to bring, and we have especially felt it with COVID-19. We urgently need to work on resilience of the system."
(Physician, Practice B)

According to the implementers, this is also possible through role expansion of interdisciplinary team work. The nurse in particular has proven to fulfil an essential role.

"The project proofs that primary health care is broader than the general practitioner alone. What I especially learned from that... is that you can perfectly delegate prevention to the nurses. Even better."
(Physician, Practice A)

It was mentioned that there is a need for further consolidation of nursing roles through structural and ongoing growth and strengthening their competency profile. A crucial action we undertook was to engage relevant educational institutions to respond to this need.

"As nurses become more involved in these kinds of processes, they should receive ongoing training, e.g. in intervision groups with others in similar trajectories."
(Physician, Practice B)

Additionally, they stressed the importance of a strong primary health care and welfare network with care partners to rely on for certain expertise. The project team reinforced this by resonating the findings in stakeholder meetings and educational meetings with local health care and community partners.

"We have now seen how intensive this is. It is not possible for us to acquire all that knowledge, or to offer all that in our setting. So we need a strong network actually, in the region. The practice could take on a coordinating role."
(Physician, Practice C)

Discussion

This paper describes the process evaluation of implementing a comprehensive program for the primary prevention of cardiovascular disease in five general practices in Belgium. We identified the factors that affected implementation success and sustainability, and illustrated how barriers were addressed during the process by employing specific implementation strategies linked to concrete actions. Furthermore, we gained insight in the experiences of the primary health care teams with the implementation and examined nurse's roles. These findings are meant to provide guidance for all relevant stakeholder groups that wish to scale-up validated interventions for cardiovascular disease prevention in primary health care.

Several lessons have been learned during the implementation process. Foremost, the great potential of general practice as an important setting for primary prevention of cardiovascular disease, including risk profiling and lifestyle behaviour change counselling. This study especially highlighted the essential role of nurses in a transitioning primary health care towards health promotion and disease prevention; and served as an opportunity to expand their scope of practice. Other studies show that nurses play a critical role in broadening, connecting, and coordinating primary and community care (53), by applying competencies such as patient advocacy, education and people-centred care (54). Recent evidence states that nurses have the extensive clinical experience to deliver major improvements in primary health care (55). In various contexts, nurses increasingly and most effectively manage and coordinate care for people with, or at risk of, chronic disease, including tasks related to lifestyle risk counselling

(56, 57). Despite competency potential to carry out intervention components, nurses initially felt underprepared; especially given the complex nature of behaviour change interventions. Limitations of relevant competences have been previously identified as a barrier to nurses' active involvement in preventive care (58). Our experiences are consistent with literature describing the need for ongoing education for upskilling existing nursing profiles to a more advanced level (55, 56, 59), especially with regards to patient-centred communication (60), behaviour change theories and counselling, and motivational interviewing; optimizing nurses' effectiveness in communicating about lifestyle risk reduction and the reduction of chronic disease (61, 62). Pioneering countries in integrating nurses in general practice, such as the United Kingdom, Australia and Canada, demonstrate that introducing quality standards, linked with quality performance reimbursement, may support ongoing professionalization, unambiguous articulation of roles and scope, and development of formal educational and career pathways; hereby enabling nurses to practice to their full scope in primary health care teams (63, 64).

Second, this study highlights a number of barriers to reach vulnerable populations for prevention, despite the positive effects of combining engagement strategies. Reaching vulnerable populations for health promotion and prevention interventions is indeed challenging (65, 66). When further scaling-up similar preventive programs, more emphasis should be put on low-threshold approaches; population empowerment by enhancing health literacy; and social and health determinants of health care access. Our findings are supported by other research reporting on the promising context of primary health care to increase equity of health care access (67), and to decrease socioeconomic inequalities (68, 69).

In this study, our attempts to bolster collaborative action between general practice and community resources were limited to referral of participants to community resources, which were hindered by the lack of a strong linkage between primary health care and community organizations and lack of suitable community-led services. Our study shows the need for the currently fragmented landscape to shift towards integrated health care and welfare, by weaving networks with collaborative partnerships. In a related study within the SPICES project, which will be reported elsewhere, we also explored the opportunities of reaching vulnerable populations through existing community welfare organisations. In order to improve reach in future program planning and development, literature indeed recommends the integration of health and social care for vulnerable populations through multisectoral and community-based strategies (67, 70). Previous studies have shown that this has great potential to increase community engagement levels and the reach of currently under-served populations; resulting in a positive impact on cardiovascular disease and its risk factors (71-73).

Next, the lack of supportive financial and regulatory frameworks clarifying roles and shared responsibilities for interdisciplinary collaboration within primary health care teams were identified as main barriers to adoption. These findings are consistent with other studies describing the need for adequate funding, along with sufficient time and resources to facilitate the uptake of preventive actions in general practice and to mitigate the role constraints practitioners experience within current health systems (58, 74). Such support is also essential to enhance the continuity of preventive care and implementers' commitment, confidence and capacity to expand their scope of practice to systematically taking up preventive tasks (56, 59). In accordance to our insights stipulating the structural integration of health promotion and prevention into existing work processes and systems, evidence recommends policy makers to facilitate the delivery of such interventions during routine practice (75). Lastly, our study revealed characteristics of the implementation setting such as networks and communications, type of collaboration, and engagement of leaders as important influencing factors to implementer commitment and fidelity. Consistent with these insights, Russell et al. emphasized the importance of tailoring preventive interventions to practice size, implementer engagement and, especially the organisation of, and relationships between, the members of the primary health care team (76).

The COVID-19 pandemic has severely impacted the implementation in terms of increased workload; focus on acute care diminishing prevention; avoidance of unnecessary patient contacts in the context of non-urgent care and disruption of health care planning. Our experiences are in line with a study exploring the impact of the pandemic on the core competences of primary health care. They reported that preventive care was compromised and chronic care was mostly postponed; and raised concerns on the profound impact of the pandemic on health, and psychological and socioeconomic well-being in vulnerable populations (77). In addition, COVID-19 patients with pre-existing non-communicable diseases are at higher risk of severe outcomes and mortality (78). Many studies during the past few years have demonstrated the negative impact of the pandemic on lifestyle behaviours related noncommunicable diseases, such as increased snacking and alcohol consumption and consequently decreased adherence to healthy diets (79, 80), higher incidence of overweight and obesity (81); reduced physical activity and increases in sedentary time (82). It is clear that cardiovascular disease prevention should increasingly gain the attention of primary health care providers and policy makers in order to mitigate its burden especially in vulnerable populations. We therefore argue for reprioritising health promotion activity within primary health care systems, and for shifting towards a more preventive and integrated approach (83).

Strengths and limitations

This is the first recent study that we are aware of to combine both RE-AIM-QuEST and CFIR frameworks to examine the implementation process of a complex multi-component intervention in real life settings in a structured and systematic way. This approach enabled us to give a comprehensive insight into key factors, set out across the different CFIR domains and constructs, that can influence the reach, adoption, implementation and maintenance of prevention programs in primary health care. Moreover, our flexible overall study design provided 'actionable findings' as defined by Keith et al. (7) (84); valuable information and scope for adaptations that could be made to improve the uptake into general practice, through concrete actions addressing identified barriers across the various RE-AIM domains. This study therefore provides a practical example with broad application of how the complementary use of evaluation and explanatory frameworks, nested within a participatory action research design, can explain and improve implementation success and sustainability. Our study was further strengthened by the inclusion of all key implementers of the intervention in the different settings, and by the longitudinal evaluation during the implementation process. These methods have resulted in very rich qualitative data exposing the layered effort that is required to translate evidence-based preventive interventions into daily practice. Many of our findings as well as the used methodology, could be of interest to research groups, policy makers, practitioners and all those involved in implementing related health programs in similar contexts or those tackling the challenges related to transformations in primary health care. Transferability of our findings is further reinforced by in-depth description of our study context and the rigorous use of robust implementation frameworks.

Some limitations to this study should be considered when interpreting this work. One limitation relates to the timing of the post-implementation interviews which were intended to capture information on long-term sustainability. Since we were bound to the SPICES project's time frame and planned the interviews shortly after the implementation period, we were only able to capture the end-user requirements to realize their intention of sustaining the program. Finally, this study focused solely on implementer's perspectives. We recognize the critical importance of the views and experiences of the vulnerable target population, as evidently they are directly affected by the integration of preventive interventions of novel nature into the services provided by their trusted general practice. We did in fact include patient participants to the profiling and/or coaching components in our project evaluation, but since this called for a different methodology, we have decided to describe these findings separately.

Conclusions

The complementary use of RE-AIM QuEST and CFIR frameworks can be useful to guide the qualitative implementation process evaluation of a comprehensive intervention program for the primary prevention of cardiovascular disease in primary health care. General practice is an important setting for primary prevention of cardiovascular disease, and expanding nurse's roles has great potential to build the capacity that is needed for scale-up and sustainability. Participatory strategies allow ongoing adaptation, enhancing uptake in practice. Actions related to adaptation to context; development of stakeholder interrelationships; and training and educating implementers, are crucial to address barriers. Supportive financial and regulatory frameworks and a strong integrated community health model are needed to engage vulnerable populations and to increase long-term maintenance of prevention programs. Although COVID-19 has severely hindered implementation, our experience reinforces the urgency of health systems to shift towards a more health promotion and prevention-oriented care.

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Chapter 8

Lessons learned from implementing preventive interventions across various primary health care and community settings to reach vulnerable communities

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Hassen HY & Aerts N, Van Royen K, Peremans L, Abrams, S, Bastiaens H. Implementing an intervention for primary prevention of cardiovascular diseases in vulnerable communities in primary care and community settings in Belgium: A mixed method evaluation. Health Expectations - [Submitted manuscript, under review].

Abstract

Background

Cardiovascular disease (CVD) preventive interventions targeting individuals and the general population are evidenced to be effective. A critical research-practice gap exists on implementation of such interventions in a real-life context. This study aimed to evaluate implementation and effectiveness of primary CVD preventive interventions in Antwerp, Belgium.

Methods

A participatory action research approach was used to support implementation of the intervention in primary care and community settings. We used an effectiveness-implementation Hybrid type III design focusing on evaluating implementation strategy to enhance translation and integration into routine practice. The intervention consisted of various components including CVD profiling and risk communication, brief behavior change counseling, and tailored lifestyle coaching. A mixed-methods evaluation was employed using the RE-AIM QuEST framework, i.e., Reach, Effectiveness, Adoption, Implementation, and Maintenance.

Findings

Of 350 participants with a complete risk profile, 120 (34.3%), 130 (37.1%), and 100 (28.6%) were categorized as at low, intermediate or high risk for CVDs, respectively. A significant improvement was observed in risk perception (p=0.019), intention towards physical activity (p=0.041) and healthy diet intention (p=0.037). Commitment of physicians and nurses, having a shared vision on health and wellbeing, and perceiving added value of the project were important facilitators of adoption and implementation in primary care settings. In contrast, limited physicians' engagement, lack of time, lack of legal and financial framework were major barriers. In community settings, having compatible target groups and perceived quality of the program were facilitators, and having other priorities and presence of research activities linked to the evaluation of the program were barriers of adoption and implementation.

Conclusions

Although major implementation barriers exist, primary CVD preventive interventions have great potential to be implemented and integrated in primary care and community organizations. Existing legal and financial frameworks need to be restructured giving more attention to prevention in these settings.

Patient or Public Contribution

The study was designed in consultation with community volunteers and nurses & general practitioners in primary care settings. Furthermore, participants were also involved in adaptation of intervention components.

Introduction

Cardiovascular diseases (CVDs) are highly prevalent and continue to be the leading cause of a disease burden accounting for one-third of total deaths globally (1). CVDs therefore put considerable pressure on the healthcare system in terms of both costs and supply-use-balance. In Europe, CVDs cause more deaths than any other health condition, in which nearly half of all deaths in the region are caused by CVDs (2, 3). Within Europe, mortality rates vary across regions, for example, a higher rate is observed in Central and Eastern Europe as compared to Northern and Western Europe (4). In Belgium, a country in Western Europe, nearly one in three deaths is caused by CVDs (2).

Although most CVDs are preventable by targeting modifiable metabolic and behavioral risk factors (5-9), little attention is given to preventive measures. In 2019, behavioral and metabolic risks including high blood pressure, high body mass index (BMI), high low-density lipoprotein (LDL) cholesterol, smoking, unhealthy diet, and alcohol intake, to name a few, were among the top-10 risks of global deaths (10). Particularly in Europe, more than half of the adults older than 50 years have at least two behavioral risk factors (11).

Fortunately, addressing behavioral risks both at individual and population level minimizes the burden of modifiable risk factors and consequently the one of CVDs. Several guidelines emphasize the role of lifestyle modification in prevention and control of CVDs. However, passive dissemination of prevention guidelines alone is ineffective and results in subtle changes in the intended lifestyle (12, 13). Furthermore, sometimes this approach widens the health inequality favoring those with higher levels of education and income. Thus, an integrated and interdisciplinary team-based approach is valuable in addressing risk factors for primary prevention of CVDs in all population groups (14, 15). Comprehensive interventions targeting individuals and the general population must be developed and implemented (16). Active profiling of individuals' CVD risk level, raising awareness and communicating risk in relation to risk behaviors, are crucial to potentially trigger behavior change (17, 18).

A critical research-practice gap exists with regard to the implementation of efficacious interventions to the wider public (19). Translation of findings from controlled research and academic settings to a pragmatic context remains challenging (20). Evidence is limited on how to implement validated preventive interventions in a specific real-life context, particularly in vulnerable communities. Implementation research project 'SPICES' (Scaling-up Packages of Interventions for Cardiovascular diseases in selected sites in Europe and Sub-Saharan Africa), which ran from 2017 to 2022, aimed to address the above mentioned needs and challenges. At the Belgian study site, the SPICES project targeted vulnerable communities and activities were focused on implementing a CVD prevention program across a variety of settings at both primary care and community level.

This study aims to address the lack of pragmatic evidence on preventive interventions in primary care and community settings, by evaluating the implementation of the aforementioned CVD prevention program in Antwerp, Belgium. We aimed to identify real-life facilitators and barriers explaining implementation dimensions, reach, effectiveness, adoption, implementation and maintenance; and how identified factors can influence translation into practice and further scale-up. We also discussed the potential of primary care and community settings in primary prevention of CVDs through risk profiling and lifestyle coaching. Furthermore, we summarized lessons learnt during the implementation of the intervention in terms of reaching vulnerable groups, sustaining the intervention impacts and the potential of integrating the intervention components into routine practices.

Methods

Study setting and design

The SPICES project in Antwerp targeted vulnerable communities with vulnerability defined at the (sub) population level rather than the individual level. Of the nine city districts in Antwerp, two were selected based on a higher socioeconomic deprivation index (SDI), lower access to primary care, a higher density of households with social support, and a higher density of older inhabitants. The SPICES project activities were rolled out in settings that were located around those two vulnerable city districts. Details of the study settings, contextual analysis, selection of districts and recruitment of participant organizations are available elsewhere (21, 22).

Based on the contextual analysis, existing community welfare organizations (local service centers, community centers, center for general welfare work, and local physical service points of a health insurance fund) from vulnerable districts were selected for participant recruitment and implementation of the intervention. During the implementation phase, one more setting, a low threshold health literacy hub (‘Health Kiosk’) was developed in collaboration with other local organizations. Furthermore, due to their central role for prevention-oriented activities within primary care in the Belgian context, general practices were also included. Selected practices were organized as multidisciplinary group practices with integration of practice nurses, taking into consideration the proportion of patients with the right to increased reimbursement in the practice population (an indicator of households with lower income).

We used a participatory action research approach to enhance implementation of the intervention in the included primary care and community settings. The intervention activities were participative and collaborative with implementers in the community and general practices, and the intervention was tailored to the context and the individual’s risk level. Due to their advantage of evaluating both

implementation and intervention effectiveness simultaneously, we used an effectiveness-implementation Hybrid type III design. In particular, type III design emphasizes examining implementation strategies, and related implementation outcomes, while also monitoring effectiveness (23). Since the effectiveness of selected intervention components and strategies used in this study is evidenced (19, 24, 25), we mainly focused on evaluating the utility of implementation strategy to enhance translation and on investigating the potential of integration into routine practice.

Intervention and target population

The intervention consisted of various components including CVD risk profiling and communication, brief behavior change counseling, and tailored lifestyle coaching. A summary of the intervention components and target group is summarized in Table 1. Details of intervention settings, components and how it was developed are available in the Template for Intervention Description and Replication (TIDieR) checklist in the supplementary material (Table S1). All adults aged 18 to 75 years in the selected districts were eligible for CVD risk profiling. However, those individuals between 40 and 75 years of age were targeted for customized coaching intervention.

CVD risk profiling and communication

Risk profiling and communication are crucial for decision making either for preventive interventions or referral for further investigations and management. In this study, risk stratification was performed using the non-laboratory INTERHEART risk score (NL-IHRS) (26); a validated tool for quantifying risk-factor burden and risk stratification without the use of laboratory testing. The NL-IHRS tool was selected for two reasons: 1) simplicity to be used by both medical professionals and lay people and 2) presence of behavioral risks in the risk score.

The overall NL-IHRS (sum) score ranges from 0 to 48, with higher scores indicating a larger future risk of CVD. Participants who scored less than 10 were at low risk (green), 10 to 15 at intermediate risk (orange), and 16 or above at high CVD risk (red). The risk profiling was carried out in selected community organizations and general practices. In community settings, employees of welfare organizations familiar with interacting with individuals facilitated participant recruitment, mainly in vulnerable groups. In general practices, practice nurses performed the profiling, targeting individuals who visited the practice for health issues other than CVDs. The follow-up trajectory as described next, was initiated by the profilers using motivational interviewing techniques in their risk communication.

Interventions for each risk category

Immediately after risk profiling, all participants received advice on healthy lifestyle regardless of their risk category. Additional customized interventions were carried out for each risk category based on responses to individual components of the NL-IHRS tool. Individuals in the low risk group received

information on their risk score, brief advice to maintain their healthy lifestyle, and a specific demonstration on how the risk score would change for a certain change in behavior. Individuals in the intermediate risk group were offered tailored lifestyle coaching sessions, a package developed by the SPICES project based on evidence-based behavior change interventions. In general practices, practice nurses facilitated coaching activities and follow-up of the change in outcome measures. Whereas in community settings, coaching was delivered by trained coaches through individual and group sessions. In both settings, the intervention package included 10 coaching sessions of 30 to 60 minutes. In community settings, high risk group members received brief lifestyle counseling and were referred to routine general practice for further investigation and management. A follow-up phone call was made after one week to assess whether individuals contacted a physician. In general practices however, individuals in the high-risk group were also invited to be enrolled in the coaching intervention given the specific opportunities in this context.

Table 1. SPICES intervention framework.

Intervention	Aim	Target group	Setting
CVD risk profiling and communication	Early identification of adults at higher risk of CVD and detection of specific risk factors	General adult population in selected vulnerable districts	Community and primary care settings
Health promotion/education	Promote CVD prevention through health literacy, awareness creation, knowledge translation and empowerment; provide brief advice	Individuals participated in profiling	Community and primary care settings
Lifestyle coaching and follow up	Individual-tailored behavioral interventions for selected risk factors (according to individual's risk level)	Individuals in the intermediate and high (specific to GP practices) CVD risk	Community and primary care settings
Referral	Referral to general practices for further investigation and follow-up	Individuals in the high CVD risk group	Community settings

CVD: Cardiovascular diseases; GP: General Practitioner

Implementation strategies

The main implementation strategies were task sharing to lay people, training of implementers, community engagement and using electronic profiling and coaching tools which are evidenced to be effective (27-32). Certain tasks such as profiling and coaching were shared from healthcare professionals to trained lay people in community settings. An ample evidence is available on the effectiveness of sharing or shifting some activities of NCD prevention to non-medical trained people or community health workers in different contexts (28-32). Lifestyle interventions are more effective when multidisciplinary professional and non-professional actors are also involved (33). Implementers

in the community settings and GP practices have received training on techniques of approaching participants, behavioral change counseling, CVD risk profiling and communication. The training was supported by regular contact to evaluate process and implementation outcomes. Community engagement strategies are evidenced to be effective in improving lifestyle in different contexts and have the potential of reducing disparities (34). Participation of community members was enhanced through various communication formats, including flyers, posters, and personal invitations. To facilitate risk profiling, intervention activities and follow up, we used tablets, mobile phones and/or online coaching sessions whenever required. Furthermore, during the COVID-19 pandemic, videos and healthy lifestyle advice and tips were disseminated through social media channels of community organizations.

Evaluation framework and data collection

To improve the success of implementation across real-world settings, it is crucial to evaluate multiple dimensions using implementation research (16). Glasgow and colleagues designed a RE-AIM framework specifying outcomes that are important for decision makers, i.e., Reach, Effectiveness, Adoption, Implementation, and Maintenance, based on quantitative measures (35). Forman et al. added a qualitative component, RE-AIM Qualitative Evaluation for Systematic Translation (RE-AIM QuEST), a mixed methods framework to identify real-life implementation barriers and explain how the context may influence translation (36). This would enable us to understand the translational potential of the intervention for wider implementation in primary care and community settings. Specific components of the RE-AIM QuEST used in this study, including tailored quantitative and qualitative research questions related to each dimension, are available in the supplementary material (Table S2).

One of the effectiveness outcome measures, the CVD risk score was measured using the NL-IHRS during baseline for risk stratification, at month 4 and after 1 year of follow-up (26). Furthermore, CVD knowledge, risk perception and intention towards healthy diet and physical activity were measured using the modified and Dutch-translated Attitudes and Beliefs about Cardiovascular Disease (ABCD) Risk Questionnaire, which was validated in the Antwerp setting (37). Participants' level of physical activity was assessed using the International Physical Activity Questionnaire short form (IPAQ-s). Quantitative data was collected either electronically with tablets and information on the number of participants approached, profiled and enrolled in the coaching intervention was obtained from REDCap hosted at the University of Antwerp. Furthermore, field notes from the SPICES project coaches in community settings and nurses in General Practices were also consulted.

For the qualitative evaluation, multiple semi-structured individual and small-group interviews were carried out for each stakeholder group before, during, and after implementation. A total of 60 semi-

structured interviews were conducted with key implementers from all settings. Key implementers were those who were closely involved in the planning, coordination and execution of the implementation, and consisted of managers, nurses, physicians, other related health or social care staff, coaches and volunteers. Additionally, the research team conducted interviews with 17 members of the target population that participated in either profiling only, or in both profiling and coaching. A semi-structured topic guide was developed and used in the interviews based on the contextualized RE-AIM QuEST framework (Table S2). The interviews were recorded and transcribed ad-verbatim. Both audio fragments and the transcripts were encoded and pseudonymized. A written informed consent and demographic sheet were completed at the start of each interview. The interviews lasted 30 to 90 minutes and were held at the included setting (local organization or general practices), online or by telephone. The interviews were carried out by a team of five research assistants under the supervision of a research team highly experienced in qualitative research (NA, KVR, LP, HB). Implementation and data collection took place in the period from August 2020 to March 2022.

Data Analysis

We summarized baseline sociodemographic characteristics of study participants. Continuous variables were summarized using mean and standard deviation (SD) or median and interquartile range (IQR) after checking for symmetry. Absolute and relative frequencies were used for categorical variables. The adoption rate was calculated by dividing the number of organizations that participated in the intervention with the number that were approached. Similarly, the enrollment rate of participants was computed by dividing the number of participants with the total number of individuals eligible for coaching. Changes between baseline and month four or between baseline and after 1-year of follow up were also summarized. A nonparametric Friedman test is used to study temporal differences in means for continuous outcomes and pairwise comparisons were performed using the Wilcoxon signed rank test. Furthermore, the number of community organizations and GP practices invited and enrolled were summarized using relative frequencies. Two-sided p values are reported throughout the manuscript. All quantitative analyses were performed in the R statistical software package version 4.0.2 by formally trained biostatisticians (HH, SA) (38).

For the qualitative analysis, semi-structured interviews were audio-recorded, anonymized, transcribed and uploaded to QSR NVivo software version 1.5.1. The adaptive framework analysis method was applied (39). In the first step, the data was made familiar by thoroughly reading all transcripts. A codebook was created by the investigators to define key themes and concepts using the contextualized RE-AIM Quest framework. Afterwards, each transcript was re-read and individual pieces of text were assigned a descriptive 'open' code. The initial coding was conducted by KVR and NA. Coding reports

were generated and the data were summarized in coding memos. Fundamental statements or findings to the research questions were highlighted in color to filter important data and to obtain a common thread. The coding reports were iteratively reviewed within the larger team of researchers (NA, KVR, LP, HB) and discrepancies were resolved through team discussion until consensus was reached. Lastly, we summarized the analysis across each RE-AIM dimension and relevant context; being primary care or community settings.

This implementation research is reported in accordance with the Standards for Reporting Implementation Studies (StaRI) Statement (40) and the checklist is available in the supplementary material (Table S3).

Results

Reach

A total of 359 adults (282 from community settings, 70 in general practices, and seven through an online platform) were profiled for CVD risk level. Of those, nine had missing data in part or all of the NL-IHRS components, leading to 350 participants with appropriate risk scores. Of those who were profiled, 22 (34.9%) individuals from general practices and 159 (55.0%) persons from community settings had increased reimbursement of their health insurance, which provides an indication of low socioeconomic status. Moreover, 17.4% of participants from community settings and 1.6% from practices experienced a maximum of six years of education. Sixteen (5.7%) individuals in community settings and two (3.2%) in general practices do not have a regular family general practice. Details of socioeconomic characteristics of participants in each setting are summarized in Table 2.

Table 2. Socioeconomic characteristics of participants in general practice and community settings.

Socioeconomic characteristics	**Frequency (12)**		
	General practice	Community setting	Total
Age (mean - SD)	56.9 (9.1)	57.7 (10.9)	57.6 (10.6)
Sex			
Male	34 (54.0)	127 (45.0)	161 (46.7)
Female	29 (46.0)	155 (55.0)	184 (53.3)
Ethnic group			

White	53 (85.5)	180 (63.4)	233 (67.3)
Black	1 (1.6)	18 (6.3)	19 (5.5)
Asian/Pacific Island Origin	1 (1.6)	14 (4.9)	15 (4.3)
Chinese, Japanese or other Southeast Asian	1 (1.6)	14 (4.9)	15 (4.3)
Arab or North African	4 (6.5)	44 (15.5)	48 (13.9)
Others	2 (3.2)	14 (4.9)	16 (4.6)
Highest education completed			
Primary school or less (≤6 years of school)	1 (1.6)	49 (17.4)	50 (14.5)
First 3 years of secondary education (7-9 years at school)	12 (19.4)	23 (8.2)	35 (10.2)
Last 3 years of secondary school (10-12 years in school)	11 (17.7)	79 (28.0)	90 (26.2)
7th year of vocational education (13-14 years at school)	10 (16.1)	36 (12.8)	46 (13.4)
Bachelor or above (≥ 15 years in school)	28 (45.2)	95 (33.4)	123 (35.6)
Increased health insurance reimbursement			
Yes	22 (36.7)	159 (56.4)	181 (52.9)
No	38 (63.3)	123 (43.6)	161 (47.1)
Have regular GP			
Yes	61 (96.8)	267 (94.3)	328 (94.8)
No	2 (3.2)	16 (5.7)	18 (5.2)

SD: standard deviation; GP: General practitioner

The main reasons for the target population to participate in the profiling were (41) the highly valued theme and quality of the project, (2) the low threshold approach, (3) the feeling of being part of something meaningful for society, (4) the expected benefits for their own health and personal experience within their close network, and (5) the support that is provided in the coaching trajectory.

"I thought maybe I would benefit from it, it's worth trying. I know what I should change to be healthier, but I just can't do it alone. I hope that within a year I can say: 'This has effectively changed me.' And I hope that this will also help others, because too many people die from heart diseases."
(Participant, general practice 1)

In addition, sufficient and tailored information on the project and the applied communication style, embedded within a trust-based relationship and personal invitation were mentioned as important factors influencing the willingness to participate.

"She (nurse) gave me a lot of information in the practice, and she also gave me a folder. So I have to say that I had few questions left to ask afterwards… The course of the project and what I could expect were all very clear. It was a nice conversation, in a very open and friendly way… it really didn't feel like an obligation at all."
(Participant, general practice 2)

Of those individuals with a complete risk profile, 120 (34.3%), 130 (37.1%), and 100 (28.6%) were categorized into low, intermediate and high risk categories, respectively. Twenty-five (39.7%) and 105 (36.6%) individuals in general practice and community settings, respectively, were in the intermediate risk category while 21 (33.3%) and 79 (27.5%) individuals, respectively, were categorized as at high CVD risk. In the general practice setting, 46 participants (both in intermediate and high risk categories) were eligible for coaching and 29 (63.0%) participants were enrolled. On the other hand, in community settings, 105 individuals were eligible (within the intermediate risk category), but only 32 (30.5%) participants were interested to be enrolled in the coaching trajectory. All enrolled participants took at least one coaching session. Of those enrolled, 11 (37.9%) individuals from GP practices and 3 (9.4%) recruited from community settings continued the intervention until the fourth month, meaning that they completed at least 7 coaching sessions (Table 3).

Table 3. Risk category and enrollment rate in primary care and community settings.

Setting	**Complete risk profile**	**Risk category**			**Enrolled**
		Low	Intermediate	High	
General practices	63	17 (27.0%)	25 (39.7%)	21 (33.3%)	29 (63.0%)
Community	287	103 (35.9%)	105 (36.6%)	79 (27.5%)	32 (30.5%)
Total	350	120 (34.3%)	130 (37.1%)	100 (28.6%)	61 (40.4%)

Those who were eligible for coaching sessions after risk profiling, but were not interested to participate, were asked for their reasons not to participate. The main reasons mentioned were (41) lack of motivation to change, (2) time investment, (3) preference of another approach such as medication, (4) having other personal priorities, and (5) practical barriers.

"I don't see the point in wasting my time with this… and wasting the nurse's time. Because, you know, it is clear that I am not going to quit smoking. And I am not going to give up drinking."
(Participant, general practice 3)

From the implementers' perspective, recruitment strategies involving personal invitation by the nurse or physician during consultation, and the active involvement of physicians in the recruitment process, were facilitators for reaching more participants in general practice. On the other hand, limited physicians' engagement in the project and lack of self-efficacy were among the barriers of reaching more participants. Furthermore, due to the overburdening of the healthcare system, COVID-19 was the most important barrier for reaching more participants.

"I don't think they (physicians) really understand the depth of the whole project. They do refer people who need health prevention, but sometimes those people fall outside the target population, and also did not receive the correct and complete information."
(Nurse, general practice 2)

In community settings, the engagement procedure being personal invitation and organizational characteristics were the most important facilitators of reach.

"We went from table to table. We looked inside and we thought hmm there are also people under 75. Then we actually stepped inside and (name of woman) started to explain herself at a table. Then I went to another table, tables where a few people are already sitting who we actually already knew from an activity and then things started. Because then (another woman) said, for example, at that table "Oh yes, write me down, I want to participate."
(Implementer community setting)

Language and cultural differences, inability of implementers to understand what participants really need, fear of getting a negative result, insufficient time and having competing priorities were barriers to reach vulnerable groups.

"… it is because of a language barrier that is often present and on the other hand, it is a lack of motivation to participate. It is very difficult to approach people here and get them to participate effectively."
(Internee, Health Kiosk)

Effectiveness

Risk profiling and communication were activities related to one of the main components of the intervention. Overall, 100 (28.6%) and 130 (37.1%) participants were identified to be at high and intermediate risk of having CVDs, respectively (see Table 3). Furthermore, out of 79 individuals who were in the red group and advised to contact their GPs, 37 (46.8%) were reachable via phone call. Of those who were reached, 37.8% of them contacted their GP as advised and discussed the possible risks and intervention options, and three (8.1%) of them made an appointment to visit the GP.

The retention rate was low to evaluate effectiveness of the intervention in improving outcomes at an individual level. Using available samples, the mean knowledge score was 5.8 (standard error (SE): 0.42) at baseline which increased to 6.0 (SE: 0.62) at month four and 6.4 (SE: 0.51) one year after the intervention. However, the observed difference in mean scores was not statistically significant ($p = 0.324$). Similarly, the mean risk perception score improved from 17.7 (SE: 0.62) at baseline to 18.4 (SE: 0.88) at month four and further to 19.4 (SE: 1.21) at year 1. A pairwise comparison showed that the increase in risk perception from baseline to month four was statistically significant ($p = 0.019$). The mean intention towards physical activity score also significantly increased from 18.8 (SE: 0.95) to 21.0 (SE: 0.80) and 21.4 (SE: 1.08) after four months and one year of follow-up (FU), respectively ($p = 0.041$). The mean intention towards diet score was similar at baseline (20.1, SE: 1.19) and at month four (20.0, SE: 1.67), though increased one year after the intervention (23.0, SE: 0.63). A pairwise comparison showed a significant change from month 4 to 1 year FU ($p=0.037$). However, there was no change in physical activity and CVD risk score at individual level.

Based on the implementers' interviews, an improvement was observed in perceived self-efficacy and job satisfaction of practice nurses related to obtained results in participants.

"I see that a lot of the participants became aware of a problem that they were not aware of before. And that's nice… that you can make a real difference with this project."
(Nurse, general practice 3)

Nurses also perceived changes in participants' awareness about their risk level, attitude, and motivation towards a healthy lifestyle. However, nurses also felt that lack of immediate change demotivated participants and that there was a gap between awareness and actual behavior change.

"We have seen it in past initiatives and it's the same in this intervention program. People all know that and they also know that there are health benefits to gain from it, but to persist and maintain this in the long run, is always the hardest thing, isn't it."
(Nurse, general practice 1)

Participants' interviews also identified an improvement in self-reported awareness regarding risk factors, and also a change in their actual lifestyle behavior and health.

"At the end of the day I am curious: how many steps have I taken today? How many stairs did I do today? So I'm constantly working on it, yes. I also feel much better, physically and mentally. I feel like a completely different person since I started the program."
(Participant, general practice 1)

According to the implementers, duration of the intervention and follow-up assessment were crucial factors influencing effectiveness. It needs a longer duration for the intended effects to be observed. Moreover, implementers also suggested the sustainability of the intervention and its effects need to be assessed at some point post intervention.

"… I am convinced that it makes a difference… in the long term. But actually, such projects should last much longer. Or at least the gathering of data."
(Physician, general practice 3)

Adoption

A total of 20 general practices were invited, five of which agreed to participate in the intervention. However, two of them dropped out after the pre-implementation phase. Out of 29 organizations invited within the community settings, six agreed to participate, but one dropped out before the implementation phase. In general, active participant recruitment and enrollment was performed from three general practices and five community organizations. The adoption rate was 15% in general practices and 10% in community settings. Of those participating community organizations, four (80%) target relatively vulnerable communities. A total of 16 profilers and coaches in community settings were trained on participant recruitment procedures, profiling techniques, coaching and follow-up assessment, and 11 of them participated in those activities. Likewise, 12 nurses in general practices were trained on profiling, follow-up assessment and coaching, and seven of them actively participated in carrying out the intervention components.

In community settings, having compatible working procedures, support and motivation within the organization, the added value of the program, better perceived quality of program and having similar target population, i.e., vulnerable groups, were the factors that facilitated adoption of the implementation in some organizations. For non-participating organizations, having priorities other than CVD prevention, presence of other similar ongoing projects, involvement of a research component in the implementation were among barriers of adoption or reasons for drop out.

"Yes and certainly also with the health partners, ... there are also a lot of them in the area. And we don't know all the services either, so that's also a social map that we can improve ourselves for us and the clients. We will therefore learn more from you about the possibilities to exercise or play sports or do something."
(Implementer, community setting)

In general practices, a need for a more systematic approach to CVD prevention and shift in primary care towards prevention and health promotion, compatibility of the intervention aim with vision and mission of practices, support within members of the practice team, and perceived added value of the project to improve prevention in the practice and to expand nurses' roles and increase their competency, were facilitators of adoption.

"We really want to work around prevention, to help people to stay healthier and to live longer. It is embedded in our practice vision. We have been looking into starting a cardiovascular prevention project, but we have not yet had the time and the right support to get started."
(Nurse, general practice 2)

In contrast, project intensity compared with available human resources, lack of time for profiling, follow-up assessments and coaching, insufficient financial and legal framework of prevention in practices, and the urgency of COVID-19 were some of the felt barriers in general practices for not participating in the intervention.

Implementation

Most of the intervention activities including risk profiling, risk communication, coaching and referral were implemented as planned. The NL-IHRS was used as a profiling instrument in all settings throughout the intervention period. In general practices, minor adaptations were made regarding eligibility criteria of enrollment in the coaching intervention in response to the request from participants and practice nurses. The initial plan was to invite only members of the intermediate risk group for coaching sessions and referral for high risk participants as it was in community settings. This plan was consistent and implemented as planned in community settings. In general practices, however, individuals in the high risk group were also considered for coaching sessions since physicians and nurses had the capacity to monitor high risk groups closely. The contact moments between coaches and participants were adjusted as convenient. There was no difference in the training content and intervention package across settings. During the COVID-19 pandemic lockdown, profiling and coaching activities were adapted to virtual platforms using pre-recorded videos and live sessions.

In community settings, supporting materials were adapted to the needs of the target group and coaching sessions were flexible. Perceived good quality intervention packages and well-designed supporting materials were facilitators of implementation. In contrast, complexity of the intervention, lack of available time, doubts on the risk stratification tool (NL-IHRS), the physical contact necessary to

do the waist and hip measurement and COVID-19 social distance measures were barriers for successful implementation of the profiling and coaching. In addition, lack of specialized referral such as psychologists for those with psychosocial factors and dieticians for dietary factors was also one of implementation barriers.

"I actually thought it was very good that you had prepared it in such a way in terms of material. Also that I got a laptop, that they could do it themselves, I found that very positive, also easier for me actually."
(Implementer General welfare center)

In general practices, the potential of project adaptability, physicians' and nurses' genuine interest and commitment, trust-based relationship of practitioners with their patients and the invitation mode being personal were some of the facilitators of implementation. Furthermore, nurses were interested to apply tools and acquired competences related to profiling and coaching, even beyond the project aim as it supports future patient care in the practice.

"I think that the motivational interviewing skills that we acquired can be used in any lifestyle advice and in all types of consultations."
(Nurse, general practice 2)

In addition, one of the main factors with regard to implementation success was expansion of the role of nurses within a general practice, meaning that they have been given a more extensive and autonomous role within this prevention project. They proved to be crucial actors for implementation fidelity, as valued by both general practitioners and members of the target population.

"I think this has shown that the nurse can play a greater role in this, and that prevention is much broader than the GP alone.
(Physician, general practice 3)

Limited physicians' involvement, nurses' lack of confidence in provision of coaching and the workload of general practices due to COVID-19 were some of the major barriers. From the participants' perspective, low health literacy level, prevention being their least priority and intensity of the intervention package were among the barriers in general practice.

"The pandemic may mean that you don't think fundamentally about 'what does our organization need now to face the next challenges?' Because of the burden that COVID-19 brings.
(Physician, general practice 1)

Maintenance

Due to time constraints (i.e., a fixed period of funding) we were unable to assess the long term maintenance of the intervention and its impacts. Nevertheless, the sustainability potential was evaluated using a post-intervention workshop and interviews with implementers and other

stakeholders. After the end of profiling and coaching, a discussion was held with the resonance group on the implementation process and sustainability potential. The automated profiling tool and customized feedback, risk notification cards and activity self-monitoring charts were among the tools to be used both in general practices and community settings. Some general practices requested to use the automated profiling and feedback algorithm in practice beyond the application within the project and its goals.

Nurses mentioned that the project led them to consider developing a practice level prevention policy and incorporate it as part of routine practice. The implementers' keen interest in the project activities and compatibility with the current agenda are the factors positively influencing future maintenance. In contrast, the need for restructuring primary care towards prevention and time balancing with other core activities within the general practice are potential challenges towards sustainability of the intervention components.

"Doing this project has set something in motion within our team. We have learned that it is possible within a primary care practice if you have nurses. We intend to continue preventive consultation in some form." (Physician, general practice 1)

Implementers suggested that it is possible to improve maintenance beyond the project period through strengthening nursing competencies in collaboration with education institutions and linkage of primary care with community welfare organizations. In community settings, collaboration with several smaller organizations and integrating similar projects is an important condition and facilitator to maintain the project.

"That there are also similar projects …. I think we also have to see that we don't do different things alongside each other. (...) Needless to say, it would be nice if they could merge into one another. (…) It is difficult, but would be ideal"
(Implementer – Service point of health insurance fund)

Discussion

Summary of findings

The primary aim of this paper was to evaluate the translation and adaptation potential of primary CVD prevention among vulnerable communities in primary care and community settings using the RE-AIM QuEST framework. We described the reach, effectiveness, adoption, implementation and maintenance of the intervention and explored facilitators and barriers for each dimension. Overall, our evaluation demonstrated the high potential of primary CVD prevention implementation in primary care settings, existing community organizations and the Health kiosk. However, existing legal and financial frameworks need to be adapted thereby giving more attention to prevention in those settings. Primary

care settings have a relatively better adoption rate, and participants are more likely to be enrolled in the intervention. Community settings seem preferable to reach out to vulnerable populations and probably sustainable provided that it is sufficiently funded.

Our evaluation indicated that primary care and community settings have great potential to implement CVD preventive interventions. Given the strength and limitations of each setting, we learnt that there is no single organization or setting for optimal CVD prevention. Rather, an integrated multidisciplinary team-based approach with strong referral linkage is vital, putting the community at the center with the necessary support from the primary care practice. Multiple risk factors are involved in CVD progression and a holistic approach is needed integrating community welfare organizations with the primary care system. Primary prevention guidelines strongly recommend a team-based approach involving multidisciplinary health professionals, patients and other stakeholders as an effective strategy (15, 42). Most CVD risk stratification tools, including the NL-IHRS that we employed, are easily applicable by lay people and community settings could support risk assessment, lifestyle coaching and referral of those at high risk to primary care settings for further follow-up (43). Similarly, primary care professionals could integrate primary prevention activities for patients with community organization for lifestyle intervention and psychological support. In this study, efforts to link community settings with primary care were limited and we recommend that future projects include integration as the core component. Nevertheless, a policy framework is needed to facilitate collaboration and linkage of primary care to the community; in order to move towards integrated care.

Our qualitative evaluation found that, despite a strong need of practitioners to shift towards prevention, lack of time, insufficient competency for lifestyle intervention and absence of a legal and financial framework are the major barriers for intervention in primary care. Other studies also identified the lack of sufficient funding, working procedure and resources for prevention among barriers of intervention implementation in primary care (44, 45). Furthermore, studies also found lack of time, motivation and competency of practice nurses and physicians towards health promotion programs, and insufficient financial compensation or reimbursement are the major barriers (46-48). Physicians and nurses in practice are overwhelmed with patient consultation and other curative services thus their role in prevention remains limited. Therefore, policies need to give more attention in restructuring human resource composition and financing to enhance prevention in primary care, particularly general practices.

Belgium's healthcare system performs well in curative services, however, preventable mortality is higher than in many western European countries, indicating relatively poor performance in prevention (49). In principle, primary care in Belgium mainly involves physicians, nurses and pharmacists, providing consultation and curative services (50). However, involvement of nurses and integration of

their roles in the general practice team is limited, affecting primary prevention activities in the practice. The health status assessment measures and health system performance show the need for reconsideration of policies regarding prevention (50). The legal framework for financial reimbursement and provider's competency on provision of preventive services is limited. This could be due to Belgium's governmental structure in which preventive healthcare is regional whereas curative services are federal including financing. Policy support and additional financial means are crucial to improve prevention in primary care and enhance provider's capacity and commitment towards preventive interventions (51). Furthermore, stimulating general practices to work as a multidisciplinary team and policy support could be beneficial.

Furthermore, our evaluation also emphasized challenges of reaching vulnerable groups in preventive interventions and some of the barriers were related to lack of participants' health literacy, preference of another approach such as medication, language or cultural barriers, and other competing priorities. Other studies also identified lack of knowledge, language and cultural diversities among the most important barriers of lifestyle intervention among low socioeconomic and socially disadvantaged populations (52, 53). Tailoring the intervention considering the aforementioned barriers through involving multilingual and diversified intervention teams might enhance participants' engagement. Provision of information to improve health literacy is crucial, which thereof improves participation in preventive interventions. Despite existing challenges, the potential of reaching vulnerable groups is better in community settings than general practices. Thus, strengthening the role of community welfare organizations and the health kiosk in primary prevention could be helpful to minimize the disproportionately high burden of CVD in disadvantaged groups. These settings have the potential to reach vulnerable groups and to link them to primary care settings for further services whenever necessary.

Enrollment to the coaching intervention is relatively better in primary care settings than community settings and trust-based relationship with nurses and physicians was mentioned as the main facilitator. Trust is the core component of patient-physician relationship in clinical practice and is an important determinant of engagement in healthy lifestyle intervention (54). Furthermore, it could be due to people's expectation since it is aligned with the core activities of general practices. Hence, using physician prescription/recommendation and referral linkage could improve enrollment to lifestyle intervention programs.

Although we could not assess the long term maintenance of the intervention due to time limitations, post-intervention discussions with implementers indicate the potential of sustainability of some of the activities. Improvement of the legal ground for prevention and strengthening of the competency of nurses in providing lifestyle coaching are suggested solutions to improve maintenance in general

practices. While in community settings, establishing the Health kiosk and community health workers (CHWs) with clear working procedures might be the preferred approach to sustain primary preventive interventions particularly in reaching vulnerable communities. CHWs are evidenced to play a critical role in improving health behaviors and facilitate linkage with clinical practice in both high-income and LMICs (55-57). However, the CHW program is currently on a pilot stage running in very few locations with a mission of health promotion and linking people to family doctor, psychologist, dentist, child and family care, and so on (58). Upon evaluating the cost-effectiveness of such an approach, expansion of CHWs could be one of the strategies to improve prevention in Belgium.

Limitations

Findings from this study need to be interpreted in the context of the following limitations. First, due to the low retention rate, we could not assess the evolution of healthy behavior and CVD risk levels across time. Second, the COVID-19 pandemic negatively impacted organizations' participation into the intervention due to overburdening of healthcare practice and community welfare organizations in providing other urgent services. The pandemic affected all aspects of the intervention including participant recruitment, profiling, coaching and follow-up assessment. Nevertheless, adaptation of some of the intervention activities to virtual platforms during lockdown underlined the potential and importance of such techniques for lifestyle interventions also for future use. Finally, we did not assess the cost associated with the interventions studied within this project and therefore we cannot inform the cost-effectiveness thereof. Nevertheless, the findings could help in improving preventive interventions in terms of reach, effectiveness, implementation, adoption and how to maintain the impact in the long run.

Conclusions

In general, this study showed the potential of rolling out primary preventive interventions in primary care and community settings to improve CVD risk behaviors. Community settings including the Health kiosk and local service points of health insurance fund are preferable in reaching vulnerable groups, whereas primary care settings are more likely to adopt and participants in these settings are more likely to be enrolled in the intervention. Barriers related to legal and financial frameworks for primary prevention in primary care settings need to be addressed. Further research aiming to develop, implement and evaluate integration of community settings with primary care are recommended. Furthermore, studies are needed evaluating the cost-effectiveness of the Health kiosk and its role in prevention to maximize population level impact.

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Chapter 9

General discussion and conclusion

Summary of main findings

The general objective of this thesis was to develop and implement a comprehensive intervention program for the primary prevention of cardiovascular disease (CVD), comprising of risk profiling and a multicomponent behaviour change intervention, in primary health care (PHC) and community settings in Belgium.

First, we looked into interprofessional collaboration in general practice by exploring views and experiences in relation to the shift to an interprofessional approach in general practice from the perspective of general practitioners (GP), practice nurses (PN) and people living with chronic illness **(Chapter 3)**. Integrating an interprofessional model of care in general practice improves responsiveness to patient needs and can be facilitated by a clear vision and mission, team communication, complementarity of responsibilities and trust-based professional relationships. Traditional role concepts, current legal frameworks and reimbursement schemes are limiting barriers to a more integrated interprofessional collaboration which is required by current and future challenges in PHC.

Next, **Chapter 4** gives an overview of best practice recommendations regarding interventions to promote physical activity (PA) in the adult general population for the primary prevention of CVD at PHC and community level. There is strong evidence on the benefit of regular moderate-intensity aerobic PA to reduce individual CVD risk. Multi-component interventions, consisting of education, counselling and self-management support, should be delivered by multi- and interdisciplinary teams in PHC or community settings. Person-centred care and behaviour change techniques need to have a central role in such intervention programs.

In addition, the context of PHC, including general practices and community settings in Antwerp (Belgium), was analysed through macro-, meso-, and microlevel stakeholders' engagement to identify potential implementation determinants of a comprehensive intervention program for the primary prevention of CVD **(Chapter 5)**. The project was valued as an opportunity to improve risk awareness and health behaviour in the target population, in particular among vulnerable communities. Our research highlighted contextual elements to consider when implementing a CVD prevention program in real life settings. We identified its relative advantage, evidence-based design, adaptability to the needs and resources of target communities, and the alignment with policy evolutions and local mission and vision, as important facilitators. The main barriers included legal and structural characteristics and intervention complexity.

Next, we developed and contextualized a comprehensive intervention program for the primary prevention of CVD. In addition, we documented the adjustments to the program during

implementation based on implementer and participant feedback **(Chapter 6)**. We incorporated multiple methods and techniques during four phases. The intervention program consisted of two main components: 1) a profiling component including CVD risk profiling using the Non-Laboratory INTERHEART Risk Score (NL-IHRS) tool and risk communication, and 2) a coaching component including behaviour change and motivational interviewing techniques.

Finally, we evaluated the implementation of this intervention program across the different implementation settings, including general practices and community organisations, and captured pros and cons, key factors for implementation success and sustainability, and the variation in reach, adoption, implementation, and maintenance **(Chapters 7 & 8)**. We learned that general practice has a relatively better adoption rate, and participants are more likely to be enrolled and stay engaged in a prevention program. Community organisations seem preferable to reach vulnerable populations for preventive action, yet there are many barriers to the sustainable integration of prevention programs in such settings. Actions to address barriers should be tailored to each unique situation and structurally linked to implementation strategies. Prioritization of prevention, ownership and shared responsibility of all team members, compatibility with existing work processes and systems, expanding PNs' roles and upskilling competence profiles, supportive financial and regulatory frameworks, integration of various related initiatives, and a strong PHC - community link were identified as crucial factors to increase implementation success and long-term maintenance of prevention programs.

Discussion of main findings

Prevention of cardiovascular diseases in primary health care and community settings: The Belgian context

We learned several lessons during this PhD. Foremost, our research demonstrated the crucial role that general practice plays in the primary prevention of CVD in our Belgian context **(Chapter 7)**. In addition, it showed the great potential of implementing preventive measures for CVD in community settings, in particular welfare organizations, local services centres, health insurances; and the low threshold community health literacy hub 'Health kiosk'; a grassroots innovation **(Chapter 8)**. The context of PHC is valued promising to increase equity of preventive health care access (1), and to reduce socioeconomic inequalities in health (2, 3). As indicated in the main findings section of this general discussion, our evaluation of the implementation of a comprehensive CVD prevention program showed that each setting had its own strengths and limitations. This implies that interventions related to primary prevention, and by extension health promotion, should not be targeted at one single setting to achieve maximum impact on the entire population, including vulnerable communities. On the

contrary, our results suggest that a multi-pronged effort is needed to really make a difference from the complementarity of various avenues for prevention, especially since CVD involves multiple risk factors and multilevel determinants.

General practice and the role of the practice nurse

From our implementation process evaluation in **Chapter 7**, we have learned that general practices play an important role in reducing the risks and burden of CVD and socioeconomic inequalities through the implementation of our prevention program. However, within the changing context of PHC and its and challenging and dynamic needs, the GP is currently still too centralized in our context. This study especially highlighted the essential role of nurses' support of the transition of Belgian PHC to a more people-centred model of care, in the context of disease prevention and health promotion. Indeed, several nursing practice roles have been developed worldwide, and from the outset, nurses have been delivering primary care, traditionally in underserved and vulnerable communities (4). In various contexts, nurses increasingly and most effectively manage and coordinate care for people with, or at risk of, chronic disease, including tasks related to lifestyle risk counselling (5, 6). Other evidence shows that nurses play a critical role in broadening, connecting, and coordinating primary and community care (7), by applying competencies such as patient advocacy, education and people-centred care (8). Our research activities in Belgian general practice provided the opportunity to expand the PN's scope of practice, yet upskilling their competence profiles before implementation was crucial. Limitations of relevant competences have been previously identified as a barrier to nurses' active involvement in preventive care (9). However, evidence cannot ascertain what level of nursing education leads to the best outcomes when nurses are substituted for physicians in PHC (4). Our experiences were consistent with literature describing the need for ongoing education for upskilling existing nursing profiles to a more advanced level (5, 10, 11), especially with regards to patient-centred communication (12), behaviour change counselling and motivational interviewing, optimizing nurses' effectiveness in communicating about lifestyle risk reduction and the reduction of chronic disease (13, 14). To meet these needs, we have developed various training modules and training materials in collaboration with experts, as part of our intervention development **(Chapter 6)**. These intervention components were very well received by both GP and PN and will certainly be utilized further within the participating settings together with the health care provider's (HCP) acquired competences, even beyond the scope of our CVD prevention-related intervention program. In addition, essential elements of our training modules have meanwhile been integrated into the postgraduate training for PN and the basic training for GP at the related educational institution, which structurally contributes to the long-term maintenance of our research activities and outputs.

Despite the great potential for general practice to improve prevention in Belgium, we recorded very low adoption rates even in practices with the support of a PN, and the PHC teams reported several barriers during the implementation of our intervention program. The complexity of our intervention program and its implementation strategies, including role expansion of nurses in general practice, can be partially attributed to the insufficient role description in our Belgian context. The lack of supportive financial and regulatory frameworks clarifying roles and shared responsibilities for interdisciplinary collaboration within PHC teams, were identified as main barriers to adoption. A defined scope of practice and suitable legislation may facilitate optimally shared responsibility for patient care and interprofessional collaboration within PHC teams (15, 16). Enabling nurses to work to the full extent of their scope is expected to mitigate future workforce shortages and improve patient access to care (17). However, in Belgium, their level of clinical practice is restricted to perform only a limited set of advanced clinical activities, under physician supervision, thus limiting the PN's ability to strengthen PHC (15). Although introducing protocol-based care may facilitate instrumental PN-GP collaboration in this context (15), it may also diminish opportunities for the shift from task delegation to integrated team care with shared responsibilities in general practice (18). A structural solution is therefore needed for the further professionalization of the PN profession, but also to support interdisciplinary collaboration within general practice. To this end, the job profile and task division between professionals should be reviewed. There is an urgent need to revise and update the legislation governing the exercise of the healthcare professions. The aim should be to entrust tasks to the HCP who can perform them in the most effective and qualitative manner. In addition, the preconditions such as training and team structure should also be redefined within a vision for high-quality, accessible and sustainable care. Furthermore, the development of national professional practice standards for PN working in Belgian general practice might support further professionalisation of the role of PN in Belgian PHC. Such standards could contribute to the definition of PN roles and scope; to curriculum development; and to the practical implementation of nursing skills in specific settings and its performance measurement and quality control (19, 20).

General practices are faced with the task of streamlining the financing models they use with the vision they have of healthcare. There is a need for adequate funding, along with sufficient time and resources to facilitate the uptake of preventive actions in general practice and to mitigate the role constraints practitioners experience within current health systems (9, 21). Such support is also essential to enhance the continuity of preventive care and implementers' commitment, confidence and capacity to expand their scope of practice to systematically taking up preventive tasks. The fee-for-service system, which is most common in Belgian general practice, hampers role expansion of nurses as only services delivered by physicians are reimbursed, whereas a capitation-based reimbursement system is

supportive for the role expansion of the PN (15). Moving towards financial systems that support an integrated care model will enhance interprofessional collaboration and therefore increase general practices' capacity to do more in the field of prevention and health promotion within their wider neighbourhood. An additional challenge here is to introduce population management, for example to carry out targeted preventive actions adapted to the target group. Population management, which ensures socially equitable access to care and addresses the environmental and socio-economic determinants of disease, is an essential strategy for implementing prevention and health promotion in an integrated way. The "modern" general practice plays a crucial role in identifying the needs of certain subpopulations and developing, together with other local partners, appropriate interventions that can improve the care or well-being of these groups.

Policy initiatives tailored to the needs of today's PHC, must lead to a stronger PHC system in Belgium which needs to be more successful in delivering goal-oriented care, adapted to what people need for the best possible quality of life. The recently launched 'New Deal' for general practice seems to be a promising step towards the development of a renewed and sustainable organizational and financing model for general practice. In addition, the Flemish government and the RIZIV are also making efforts to facilitate interprofessional collaboration with PN and practice assistants in general practices through financial support, both structurally and through pilot projects (22). With these initiatives, policy makers aim to protect general practice's essential role in Belgian PHC, by focusing on collaboration within the PHC teams and between the general practice and other actors in the healthcare sector (23).

It will be key for the government to closely evaluate the effect of the New Deal on the situation. Policy makers will have to continue to monitor, invest and reform their initiatives to realize the five ambitions of the Quintuple Aim[6] (24) for our health and healthcare policy.

Linking primary health care with the community

Our evaluation of the implementation of our CVD prevention program across various community settings as reported in **Chapter 8** demonstrated the need for strengthening the role of welfare organizations and the Health Kiosk in primary prevention, to minimize the disproportionately high burden of CVD in disadvantaged groups. These settings showed great potential to reach vulnerable groups and to refer them to PHC settings for future health care.

Many CVD risk stratification tools, among which the NL-IHRS are easily applicable by lay people; providing community settings the opportunity to support risk assessment and referral of those at increased risk to PHC settings for further follow-up. An integrated multidisciplinary team-based

[6] The Quintuple Aim includes: 1) improves patient experience and better outcomes and quality; 2) HCP wellbeing; 3) health and social equality; 4) lower costs and improved economy; and 5) maximum health for every citizen

approach with a strong referral strategy is therefore vital, putting the community at the centre with the necessary support from general practice. Similarly, PHC teams could integrate primary prevention activities for their patients, connecting them to community resources for appropriate lifestyle interventions and psychosocial support. In this thesis, initiatives to strengthen collaborative action between general practice and community sources for referral of participants, were hindered by the lack of a strong linkage between PHC and community settings, and lack of suitable community-led services. To improve reach in future program planning and development, other studies also recommend the integration of health and social care for vulnerable populations through multisectoral and community-based strategies (1, 25). Previous studies have shown that this has great potential to increase community engagement levels and the reach of currently under-served populations, resulting in a positive impact on CVD and its risk factors (26-28). In addition, the need for reprioritising health promotion activity within PHC systems and for shifting towards a more preventive and integrated approach to restore the health care system's resilience (29), was especially stipulated by our experiences of implementing a CVD prevention program during the COVID-19 pandemic. Although in times of COVID-19 prevention proved to be more important than ever, preventive care was compromised and chronic care was mostly postponed, raising concerns on the profound impact of the pandemic on health, and psychological and socioeconomic well-being in vulnerable populations (30).

During our research, we recorded low adoption rates in community settings because of their priority focus on social welfare rather than health. Due to contextual characteristics, welfare organizations are very protective in their policies to preserve their own activities and resources. This distrust of organizations towards each other leads to major barriers for collaboration and consequently hinders the necessary transition to integrated community care. With the Health Kiosk which was developed in the context of the SPICES[7] project, we set an innovative example of embedding CVD prevention in a broader context of integrated community care. Its low-threshold and outreaching approaches, presenting health issues in an accessible and completely different way from traditional settings, showed a lot of potential to engage vulnerable communities in their health. We learned that to achieve integrated community care, it is important to involve HCP, but also informal partners in the neighbourhood. Intersectoral collaboration between welfare and care partners together with partners from other sectors is essential in this respect. A mission of participation and inclusivity is also crucial. The community health worker (CHW) program could assist in the further translation of the concept of integrated care in our Belgian context. CHW deliver preventive services using informational as well as

[7] Scaling-up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and Sub-Saharan Africa: An implementation research

behavioural approaches in noncommunicable disease (NCD) control programs worldwide (31, 32). Although such roles are currently not supported in our Belgian context, a CHW program is currently on a pilot stage running in very few locations with a mission of health promotion and linking people to GP, psychologist, dentist, child and family care, and so on (33). Further integration of such roles into the healthcare system and existing community structures should be considered, taking into account population needs, health system requirements, and resource implications (34), since expansion of CHW could be one of the strategies to strengthen prevention and health promotion activities through integrated community care in Belgium.

Today, our health care system is too fragmented, too focused on acute care and insufficiently adapted to dynamic societal challenges such as the aging of the population, the increase in chronic diseases and multimorbidity with a growing need for chronic and complex care. This leads to issues remaining undiscovered and therefore unresolved, and inadequate delivery of goal-oriented care. Transitioning the Belgian health care system towards integrated care, guided by the Quintuple Aim (24), focusing on collaboration and integration at different levels, is therefore key. To achieve this cultural change, we need to move away from the traditional silos. Only if well-being and health care are linked, we will be able to achieve the network care that is necessary to guarantee health for everyone. In addition, strengthening each individual's health and autonomy competences, will be crucial. A major policy reform regarding prevention and health promotion in PHC is required to reach vulnerable populations, to reduce healthcare costs and also to be able to work from an integrated, holistic approach and to provide goal-oriented care. We therefore recommend that future projects include integration as one of their core components. Nevertheless, a supportive policy framework on integrated care is needed to facilitate collaboration and linkage of PHC to the community. Such a reform requires advocating for a mission and vision focused on integrated care, fostering collaboration with a focus on population care, regional multisector collaborative partnerships, and comprehensive strategies to transform health and well-being in communities (35, 36). Continued efforts to digitize healthcare will be important to guarantee optimal care by facilitating the availability and exchange of health data. Finally, efforts from network partners and primary care zones will be crucial to effectively realize this in practice and to continue to advocate 'Health in all policies' to policymakers, so that such projects also have the opportunity to be embedded in the longer term.

Prevention of cardiovascular diseases: A broader perspective

Individual strategies versus public health strategies

Current evidence points to two major categories of primary preventive strategies: 1) high-risk 'individual' strategies, to protect susceptible individuals; and 2) population 'mass' strategies, to control

the determinants of incidence (37). To date, many uncertainties remain around the (cost-) effectiveness of interventions and strategies for those at increased risk or the entire population triggering debate among research groups and policy makers on the optimal strategies for primary prevention of CVD (37, 38). Our systematic review **(Chapter 4)** stipulated that a comprehensive approach tackling multiple lifestyle risk factors should be the cornerstone for reducing the global CVD burden, both in individual and population strategies, which is supported by other studies (39-41).

In **Chapter 6**, we have extensively focused on strategies for primary prevention of CVD for individuals at increased risk. During our evaluation of the effectiveness of the intervention program, we have observed a significant improvement in risk perception, intention towards PA, and healthy diet intention **(Chapter 8)**. Moreover, a related systematic review, performed by other researchers from the SPICES consortium, showed that interventions targeting high-risk groups were even more effective in the reduction of CVD risk factors than population strategies (42). Implementation of such interventions requires a rigorous analysis of and tailoring to the context, vulnerable target population and the individual **(Chapter 6)**. If high risk 'individual' strategies for the primary prevention of CVD are to have a major impact on public health, they need to be implemented more widely than is currently the case (43). It is clear that fewer people will be reached through individual strategies, making their impact at the public health level in terms of CVD burden seemingly small. Therefore, it will be important for policymakers and practitioners to create more capacity in PHC systems, allowing effective individual strategies for disease prevention to be structurally embedded in routine practice, and in addition to be able to offer these not only to individuals at high-risk of developing CVD but also to those at intermediate or low risk. Policy support and additional financial means are crucial to improve prevention in PHC and enhance HCP's capacity and commitment towards preventive interventions (44).

On the other hand, a population-wide reduction of the major CVD risk factors is required to substantially reduce the global CVD burden (43). Other evidence emphasizes the importance of giving priority in CVD prevention strategies to reduce CVD risk factors in the whole population across the lifespan, regardless of individual CVD risk, with the focus on behavioural and lifestyle risk factors, targeting tobacco use (45), unhealthy diet (excessive salt and sugar intake, lack of fruits and vegetables and the harmful use of alcohol) (46), physical inactivity (47, 48) (49), and sedentary behavior (50). Such an integrative approach would also be an opportunity to target other major NCD, such as diabetes mellitus and cancers (51). Population strategies, however, on their turn seem to have less impact on individual risk reduction (42). Moreover, other research has found that population strategies had a greater impact especially on high-income groups, at the risk of exacerbating health inequalities, whereas high risk strategies have been shown to have greater impact on low-income groups (52). It

will therefore be important in the future to continue to focus on both categories of strategies, and to look for complementary individual and public health approaches in order to truly make a difference at both individual and population level in terms of lifestyle and cardiovascular health.

Person-centred approach

Reaching vulnerable populations for health promotion and interventions, is challenging (53, 54). Other studies identified a lack of knowledge, language barriers and cultural diversities among the most important barriers of lifestyle interventions among low socioeconomic and socially disadvantaged communities (55, 56). Giving more attention to low-threshold approaches; population empowerment; enhancing health literacy; and social determinants of health and health care access, could assist in scaling-up similar preventive programs. Furthermore, cultural and behavioural insights and participatory approaches should be used in policy design and implementation of initiatives for prevention, to involve underreached communities or their advocates (57). A person-centred approach of well-being within all policies and decision-making is fundamental in the pursuit of maximum cardiovascular health (57). People are important partners in coordinating health policy at the micro, meso and macro level and their perspective on health, well-being and the health care system should become more directional in future policies. Various efforts and initiatives are therefore needed to activate and empower them. Empowerment contributes to people's ability to be resilient to the physical, emotional and social challenges in their life, and to be in charge of their own life dimensions and change process. A holistic perception of health is valuable for HCP and policy makers, as it may bridge the gap between healthcare and the social domain and contribute to the transition of integrated care that is needed to address CVD, its burden and its risk factors (58). Creating durable person-centred health services requires a new understanding of the concept of health-related empowerment, by focusing on the individual as a co-manager with freedom to choose and focus on their own well-being (59). The main principles of empowerment are shared decision making, enabling choices, personalised care, social prescribing and community-based support; supported self-management; and personal health budgets and integrated personal budgets (60, 61). PHC services and prevention programs should be designed in a way that empowers users and supports building the trust in the available services.

Health in all policies

In our research, we mostly focused on behavioural risk factors at the individual level. However, development of CVD is not only determined by lifestyle and genetic factors, or access to care; the environment also plays an important role (62). Many factors outside the health sector indeed have influence. On the one hand, the environment can have a direct influence on the cardiovascular health of a population. A healthy environment protects our health, for example by taking measures to reduce

air pollution (63). On the other hand, the environment can also have an indirect influence on our cardiovascular health, influencing the population's lifestyle behaviour (64). A healthy environment in that sense is a supportive environment in which making healthy choices is obvious, and where thresholds are built in for making unhealthy choices (64). Examples are the redesigning public spaces to encourage exercise, or the presence of healthy food around schools. This also implicates that Belgian citizens are not equally equipped to address environmental threats to their cardiovascular health. The ability of people to protect themselves from developing CVD, and to respond to health-threatening circumstances, depends on socio-economic, educational, cultural and behavioural factors that must therefore also be taken into account in policy reforms concerning health promotion and CVD prevention. Although choosing a healthy lifestyle is not always an individual free choice, the ultimate goal should be that every person, in whatever circumstances, can make that choice for themselves. It is therefore up to the government to guarantee the possibility to maintain a healthy lifestyle and a healthy living environment for everyone (65).

A narrow focus on behavioural risks and protective factors at the individual level is insufficient to tackle health disparities in Belgium. To do so, we need broader health promotion strategies targeting community-level structures and societal structures outside health care systems (66). For example, health taxes were identified by the World Health Organization as some of the most effective policy measures, or 'best buys', to effect behavioural change in the Belgian population (67). Improving public areas and exercising facilities; improving access to healthy food; mandating nutrient profiling and food labelling; enacting and enforcing bans and restrictions; and mass media campaigns for health promotion were also highly recommended (68). The challenges we experienced during our research activities to implement an individual CVD prevention program, especially for vulnerable people of low SES **(Chapters 7 and 8)**, indeed stressed the urgency of structural and integrated intersectoral action. Adopting a 'Health in all Policies' approach is vital to address the burden of CVD among other NCD, with special attention to health equity. This cannot be achieved by a single government authority but requires shared objectives, intersectoral commitment and partnerships to prioritize and support health and well-being within all sectors, including ministries in charge of the environment, social affairs and finance, private sector engagements influencing commercial determinants of health, and the health sector. Intersectoral governance can build bridges and facilitate dialogue and collaboration between policy makers, sectors and stakeholders by leaving the traditional silo's and developing a shared understanding of the challenges ahead (69). In Belgium however, the challenge will be to concretise health policy across the highly fragmented policy areas; at federal, Flemish and local level, using a 'Whole of Government' approach (70). We need integrated plans for tobacco, alcohol, nutrition and PA with the commitment of all relevant stakeholders. These strategic plans must be

operationalized in concrete regulations and measures at prevention and, where necessary, additional help and care (57). Finally, monitoring and evaluating the impact of these policies is crucial, especially the extent to which they empower vulnerable communities to choose their health. Setting measurable health targets to pursue universal health coverage and identifying indicators that align with the broader Sustainable Development Goals, can further assist in addressing the determinants of cardiovascular health. They can also serve as a compass to implement and evaluate policy measures, considering the 'One World, One Health' perspective (71). Moreover, national and regional budget allocation must support the paradigm shift more in the future, in response to dynamic global and local care needs. In addition, international incentives and guidelines for developing a preventive health policy are crucial to make a difference.

Implications and recommendations

Reducing the burden of CVD in Belgium is complex and requires an ongoing multi-level approach. It will be important to consider the preconditions needed to embed primary prevention of CVD in a more systematic and sustainable way in the current systems, not only at the level of general practice or community settings, but also at meso-level networks and government level. We have therefore defined key implications and recommendations for planning successful and sustainable implementation that should be taken into careful consideration by research groups, policy makers, practitioners, implementation teams, managers, project leaders and all those involved in the development and implementation of CVD prevention programs in similar contexts or those addressing the challenges associated with transformations in PHC.

For practice

- Evaluating the unique context of a planned implementation is important to map potential barriers and facilitators. Implementation determinant frameworks could be useful to assist in this process.
- General practice and community settings are important avenues to consider for primary prevention of CVD, particularly when targeting vulnerable populations. Developing stakeholder interrelationships is key, and entails maintaining and extending networks between PHC and community partners. Different collaboration models must be explored, in which PN and (lay) community partners can play a critical role.
- Multi-level stakeholders, implementers, target groups and communities should be involved at all stages of an implementation project, including during project design and implementation planning. Participatory strategies are useful to obtain and maintain their engagement, since they foster buy-in of stakeholders and can empower those involved in

taking up certain roles and ownership in the implementation. These strategies may positively impact implementation outcomes such as reach, adoption, fidelity and maintenance.

- Prevention programs must be designed to be integrated in pre-existing workflows and systems. Therefore, aligning intervention purposes with local policy, resources, vision, and mission is essential.
- Those who will provide the intervention need to have the necessary competencies or have access to tailored training to acquire them.
- Stepwise implementation allows continuous adaptation the intervention program to the dynamic needs of the implementation context, implementers and target population. In addition, it is important to offer support and interactive assistance to implementers, and to develop and adjust tools and strategies to mitigate the complexity of the intervention and to address barriers.
- PHC teams need to have a clear vision on prevention and its relative priority in their context, considering challenges in general practice such as the GP shortage, acute care demands and resilience to non-plannable care.
- PHC teams are advised to develop and contextualize protocols for prevention, entailing population management; consolidation of the link with existing tools and guidelines; a fit with existing workflows; integrating roles and responsibilities; building local community networks; and available human and financial resources.
- PHC teams and local community partners should contribute to the wider community in terms of health promotion and well-being. They should undertake actions following the principles of proportionate universalism to reach all layers of the population, including vulnerable people. To achieve this, they are advised to determine in which cases it is necessary to intensify their approach and add proportionalities to the intervention.
- Professional associations related to PHC and social care have an important role in creating an intersectoral learning community for sharing knowledge, expertise and best practices. PN are also encouraged to unite in a professional association to contribute to the further development and professionalization of the PN profession. This could contribute to a growing awareness among policy makers of the need to further align the financial and legal frameworks with the needs and opportunities associated with the integration of nurses in general practice and the transition to integrated community care.

For education

- Interprofessional training of HCP is needed to improve future collaboration.
- Educational institutions have a great responsibility in empowering their students in the context of the current evolutions regarding care substitution and role expansion in PHC.
- In future, health and social care professionals will be deployed more within the broad spectrum of health and well-being. Educational institutions should therefore contribute to building bridges between sectors.
- Current societal challenges catalyse the development of entirely new functions or innovative interpretations of existing roles, such as of community nurses or CHW. In addition, informal caregivers, lay people and peers, will increasingly be engaged structurally in care processes. Consequently, educational institutions are urged to reinvent themselves and to continuously adapt to the need for a more integrated approach.

For policy

- Belgium urgently needs a shift from curation to prevention, both in health care policy and financing. The burden associated with lifestyle-related risk factors will take up a large part of the budget for cure in the near future. In addition, the current reimbursement framework for preventive care is insufficient to cover expenditures in comparison to curative care, which threatens to widen health disparities even further. A revision of funding and reimbursement is necessary to make all aspects of preventive care accessible to the wider public.
- A strong policy framework for prevention is needed. Policymakers must set common goals and define, support and drive the strategic transformations that are needed to proactively improve public health. Belgium therefore needs a better collaboration between different policy levels at the federal and Flemish level by better coordinating policy across the different levels and trusted partners, including networking organisations (e.g. Loco Regional Health Consultation and Organization), centres for expertise (e.g. Vlaams Instituut Gezond Leven) and organizations responsible for the fieldwork on preventive health policies.
- The link between research and policy needs strengthening to catalyse the sustainability and scaling-up of the impact of action research related to prevention projects.
- Policy makers should focus on ‘Health in All Policies’, which is the key to a healthier wider public. The media could contribute through its educational function, and health literacy could be included educational institutions’ curricula. But, also communities, schools, workplaces health insurances, and industry play a crucial role in creating a healthy environment across a variety of settings. It is therefore critical for policymakers to provide a comprehensive

framework, to map out a broad, layered strategy and to provide the necessary resources for Health in All Policies; so that all aspects of health can be connected across different sectors and organisations.

- Primary care zones are urged to make concrete efforts to link PHC, welfare and community initiatives at the micro level with tangible impact in daily practice. Their activities are aimed at taking into account the needs of the local population, aligning PHC accordingly, exchanging knowledge and information, and coordinating their activities. They could contribute to the collaboration between SPICES with linked projects such as Zipster (https://www.zipster.care/ a digital referral platform to local community actors) and BOV (exercise on prescription).
- We urge the government to further invest in unambiguous Information and Communication Technologies to further consolidate the link between PHC and community services, by strengthening the information flow, communication, referral and interprofessional and intersectoral collaboration.
- A mentality shift is needed from the current culture of patronizing or blaming to empowering the public and involving communities to take responsibility for their health. Involving the wider public more closely in the development and execution of policy measures through participatory and bottom-up approaches, could create the support base that is needed.
- De-professionalisation of (primary) health care in our context by allocating more resources to further explore community-oriented care and caring neighbourhoods could be the key to link professionals with neighbourhoods, to increase participation and inclusion, to connect formal and informal care, and to generate intersectoral collaboration.
- Investing in goal-oriented care may offer a way to enable person-centred integrated care delivery that is needed to also reach and empower vulnerable populations for their health.
- Policy makers are urged to thoroughly review legal and financial frameworks to formally support new forms of collaboration and preventive care initiatives, including the development of new functions or innovative interpretations of existing roles and the integration of informal care in the context of integrated health care. Piloting organizational and financing models (such as the New Deal) for general practice will need close monitoring to follow-up on the extent to which is meets the dynamic contextual needs.
- Introducing practice standards for nurses in PHC teams, linked with performance reimbursement, may support ongoing professionalization, unambiguous articulation of roles and scope, and the development of formal educational and career pathways.
- Introducing a pay for quality system, based on quality indicators, could act as an incentive for PHC teams to focus more on activities aimed at health promotion and disease prevention.

For future research

- More research is needed on the role of lifestyle behaviour change interventions in the primary prevention of CVD, especially to further define the active ingredients or core elements that should be integrated in prevention programs.
- Researchers should further investigate how intervention characteristics such as content, form and intensity can be diversified to different contexts, settings and target populations including vulnerable groups.
- Similar intervention programs should put more emphasis on the broad range of determinants for cardiovascular health, rather than merely focusing on health outcomes and lifestyle behaviour.
- To involve under-served and sub-reached populations more in future research, researchers should apply participatory approaches and create conducive research contexts in order to increase the involvement and engagement of vulnerable populations and communities from the outset of research projects. Introducing a community think tank involving community members and researchers could support collaborative action through structured dialogue.
- Innovative recruitment strategies, tailored to various cultures and languages, should be further explored to enhance the reach and participation of vulnerable target groups in preventive interventions, without stigmatizing or allocating resources disproportionately.
- Further exploration of the role of nurses and community members, peers and CHW, as well as thorough cost-benefit analysis of such interprofessional collaboration frameworks will provide the systematic guidance practitioners are urging for and will lay the groundwork for the sustainable change that is much needed.
- More efforts are needed to (cost-) effectively and sustainably implement evidenced and tailored interventions for primary CVD prevention into routine practice by integrating strategies related to action research, dissemination, knowledge valorisation and health economics.
- Research funding bodies should allocate sufficient funding for research projects aiming at linking their (action) research to policy and practice and creating beneficial impact and value for society, by transforming evidence into sustainable products and insights.

General conclusion

Our research demonstrates the potential of implementing a prevention program in both PHC and community settings to reduce the individual CVD risk. Involving macro-, meso-, and microlevel stakeholders from the outset is important to elicit the different contextual dimensions to consider, so that actions and strategies can be tailored to the needs and preferences of the target population and setting. Continuous stakeholder involvement and contextualization of interventions also increase implementation success and sustainability. Participatory strategies allow for continuous adaptation, which enhances the uptake of preventive intervention programs in practice. The complementary use of implementation frameworks is useful to guide the qualitative implementation process evaluation of prevention programs and has the potential to clarify how the complex interplay of dynamic determinants influences the outcomes and process of the implementation of CVD prevention programs in real life settings. Adaptation to the context; development of stakeholder interrelationships; and training and educating implementers, are crucial to address barriers. Community settings are preferred for reaching vulnerable populations, while prevention programs are more likely to be adopted in general practice and the target population is more likely to engage in the intervention. Interprofessional collaboration and expanding practice nurses' roles has great potential to build the capacity needed for scale-up and sustainability of preventive action in a person-centred model of care in general practice. Supportive legal and financial frameworks and a strong integrated community health model are needed to engage vulnerable populations and to increase long-term maintenance of prevention programs. When planning and rolling out a preventive health policy, all stakeholders should keep in mind maximum health for the entire population as a shared goal, including vulnerable groups. Health systems must therefore be designed to provide people with the care they need in an accessible way. Prioritizing the increase of our health care system's resilience and capacity is urgently needed, so that actions related to health promotion and disease prevention can be structurally embedded. Finally, our findings reinforce the urgency of health care systems connect the dots through integrated community care.

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Supplementary materials

Supplementary materials for each chapter are available through the following links.

Chapter 3

https://onlinelibrary.wiley.com/action/downloadSupplement?doi=10.1111%2Fjocn.15092&file=jocn15092-sup-0001-Supinfo.pdf

Chapter 4

https://figshare.com/articles/journal_contribution/Additional_file_1_of_Systematic_review_of_international_clinical_guidelines_for_the_promotion_of_physical_activity_for_the_primary_prevention_of_cardiovascular_diseases/14623198

https://figshare.com/articles/journal_contribution/Additional_file_2_of_Systematic_review_of_international_clinical_guidelines_for_the_promotion_of_physical_activity_for_the_primary_prevention_of_cardiovascular_diseases/14623201

https://figshare.com/articles/journal_contribution/Additional_file_3_of_Systematic_review_of_international_clinical_guidelines_for_the_promotion_of_physical_activity_for_the_primary_prevention_of_cardiovascular_diseases/14623204

https://figshare.com/articles/dataset/Additional_file_4_of_Systematic_review_of_international_clinical_guidelines_for_the_promotion_of_physical_activity_for_the_primary_prevention_of_cardiovascular_diseases/14623207

https://figshare.com/articles/journal_contribution/Additional_file_5_of_Systematic_review_of_international_clinical_guidelines_for_the_promotion_of_physical_activity_for_the_primary_prevention_of_cardiovascular_diseases/14623210

Chapter 5

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Chapter 7

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Curriculum Vitae

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PROFESSIONAL EXPERIENCE

GZA-ZAS

Staff member prevention, safety and environment — 10/2023 - current

University of Antwerp

Teaching assistant — 10/2022 - 09/2023

Predoctoral researcher — 03/2017 – 07/2023

AZ Sint-Maarten

Emergency nurse — 09/2009 – 02/2017

EDUCATION

University of Antwerp

Doctor of Medical Sciences 2017 - current

Master of Science in Nursing and Midwifery 2012 - 2016

Grade: Magna cum laude

Thesis: "Integratie van een verpleegkundige in de huisartsenpraktijk: een kwalitatief, verkennend onderzoek naar de visie van patiënten met een chronische aandoening"
Winner of the honorary prize Gerebern 'Benny' Laenen

Lessius Hogeschool Mechelen

Second Bachelor in Emergency and Intensive Care nursing 2009-2011

Grade: Summa cum laude

Katholieke Hogeschool Kempen

Bachelor in Nursing 2006-2009

Grade: Magna cum laude

ADDITIONAL COURSES AND WORKSHOPS

The EIE2023 pre-event online workshop 'Grappling with the Updated Consolidated Framework for Implementation Research (CFIR)', April 2023.

'Implementation science' lecture series given by Prof Sabina De Geest, laureate of the Belgian Collen-Francqui Chair, 2018-2019.

EGPRN Preconference workshop 'Writing for publication', May 2017.

Doctoral School, University of Antwerp

Grow your future career (2020)

Optimizing cooperation in international research groups (2019)

Personal effectiveness (2019)

Writing academic papers (2018)

English for PhD - Linguapolis (2017)

OTHER ACTIVITIES

MaVVerAnt

Board member (secretary) alumni association 2017 - 2023

SCIENTIFIC ACTIVITIES

Published articles in peer reviewed international journals

- Hassen HY, Abrams S, Musinguzi G, Rogers I, Dusabimana A, Mphekgwana PM, Bastiaens H; Scaling-up Packages of Interventions for Cardiovascular diseases in Europe and Sub-Saharan Africa (SPICES) study investigators. Disparities in the non-laboratory INTERHEART risk score and its components in selected countries of Europe and sub-Saharan Africa: analysis from the SPICES multi-country project. European Heart Journal Open. 2023;3(6):oead131.
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- Aerts N, Van Bogaert P, Bastiaens H, Peremans L. Integration of nurses in general practice: A thematic synthesis of the perspectives of general practitioners, practice nurses and patients living with chronic illness. Journal of clinical nursing. 2020;29(1-2):251-64.
- Odorico M, Le Goff D, Aerts N, Bastiaens H, Le Reste JY. How To Support Smoking Cessation In Primary Care And The Community: A Systematic Review Of Interventions For The Prevention Of Cardiovascular Diseases. Vascular health and risk management. 2019;15:485-502.

Master thesis supervision

- Implementatie van gezondheidscommunicatie en –coaching rond leefstijlverandering in het kader van primaire preventie van hart- en vaatziekten binnen de eerstelijnszorg
  (Advanced master of Family Medicine, University of Antwerp, 2021-2022)
- Implementatie van een cardiovasculair preventieprogramma in community en eerstelijnssettings: een kwalitatief onderzoek naar de perspectieven van de doelgroep
  (Advanced master of Family Medicine, University of Antwerp, 2021-2022)
- De ervaring van huisartsen en praktijkverpleegkundigen bij de implementatie van systemische profiling en coaching van leefstijlgedrag binnen de primaire cardiovasculaire preventie: een descriptief kwalitatief onderzoek
  (Advanced master of Family Medicine, University of Antwerp, 2020-2021)
- Profiling en communicatie van het cardiovasculair risico bij kwetsbare populaties door welzijnswerkers: Een context-analyse van een kwetsbare regio in Antwerpen
  (Master of Nursing and Midwifery, University of Antwerp, 2018-2019)
- De rol van de interprofessionele eerstelijnspraktijk bij ondersteuning van gedragsverandering naar een gezonde levensstijl bij kwetsbare patiëntengroepen, een multiple case study
  (Master of Nursing and Midwifery, University of Antwerp, 2018-2019)
- De rol van de verpleegkundige in de huisartsenpraktijk omtrent primaire cardiovasculaire preventie: een descriptief kwalitatief onderzoek
  (Advanced master of Family Medicine, University of Antwerp, 2018-2019)
- Het FLOREO-project en de zoektocht naar online mHealth informatie-architectuur voor zelfmanagement ondersteuning na een beroerte: Een kwalitatieve descriptieve exploratie over de ervaring en visie van de patiënt en mantelzorgers
  (Master of Nursing and Midwifery, University of Antwerp, 2017-2018)

- Griepvaccinatie in het ziekenhuis: een kwalitatief onderzoek naar de motivatie van verpleegkundigen en vroedvrouwen
  (Master of Nursing and Midwifery, University of Antwerp, 2017-2018)

International conferences

- EGPRN-meeting Split, Croatia (European General Practice Research Network), May 2023.
  Maltreatment of older people: Challenges for patient-centred care in general practice. (Oral presentation)
- SPICES consortium scientific and work meeting Kampala, Uganda, March 2022.
  Developing and tailoring a comprehensive program for prevention of cardiovascular disease prior to its implementation in general practices in Belgium. (Oral presentation)
  Implementation of a comprehensive intervention program for prevention of cardiovascular diseases in general practices in Belgium: a qualitative evaluation using the RE-AIM (Poster presentation)
- EGPRN-meeting Virtual (European General Practice Research Network), May 2021.
  Developing and tailoring a complex intervention for the primary prevention of cardiovascular disease prior to its implementation in general practices in Belgium. (Oral presentation)
- EFPC Nanterre, France (European Forum for primary care), September 2019.
  Contextual analysis prior to the implementation of an evidence-based complex intervention for the primary prevention of CVD at primary health care and community level: A descriptive qualitative study using adaptive framework analysis. (Oral presentation)
- CARE4 Leuven, Belgium (International Scientific Nursing and Midwifery Conference), February 2019.
  Integration of nurses in general practice: A qualitative study from the perspective of general practitioners, practice nurses and chronic patients. (Oral presentation)
- EGPRN-meeting Lille, France (European General Practice Research Network), May 2018.
  Integration of nurses in general practice: A qualitative, exploratory study from the perspective of general practitioners, practice nurses and patients with chronic disease as key stakeholders. (Oral presentation)
- EGPRN-meeting Riga, Latvia (European General Practice Research Network), May 2017.
  Integration of nurses in general practice: a qualitative, exploratory study from the perspective of patients with chronic disease. (Oral presentation)

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Practice nurse assessing cardiovascular risk in general practice