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**Cardiovascular risk self-management in older people: Development and evaluation of an eHealth platform**

Beishuizen, C.R.L.

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# Chapter 1

**General introduction**

This thesis addresses how cardiovascular risk management (CVRM) could be provided to older people using eHealth. Due to global ageing, the number of people at risk of cardiovascular disease (CVD) will rise dramatically. Current CRVM programmes do not specifically address older people, although CVRM is effective until old age. In addition, effectiveness of current programmes is suboptimal, because they do not succeed in inducing long-term adherence to a healthy lifestyle and medication. It is also foreseen that the capacity of current programmes will not be sufficient to address all subjects (including older people) with elevated cardiovascular risk in the future. Novel prevention and risk management strategies are therefore urgently needed. eHealth is regarded a promising medium to provide self-management interventions. In this light, in the European study Healthy Ageing Through Internet Counselling in the Elderly (HATICE), an interactive internet-platform for CVRM in older people was developed. This platform is currently being tested in a large European RCT in Finland, France and the Netherlands.<sup>1</sup>

The aims of this thesis were to develop an internet-platform for cardiovascular risk self-management in older people (the HATICE internet-platform) and to gain better understanding on how to engage older people in new forms of cardiovascular risk management.

## **CARDIOVASCULAR RISK MANAGEMENT IN OLDER PEOPLE: CURRENT SITUATION AND PRACTICE**

### **Global ageing and cardiovascular disease: epidemiology**

Currently, we live in times of large demographic transition due to global ageing. In 2011, the percentage (%) of people older than 60 years was 22 in Europe, 19 in North-America, 6 in Africa and 10 in Asia. In 2050, these percentages are projected to rise to 34, 27, 10 and 24, respectively.<sup>2</sup> This leads to enormous relative and absolute increases in numbers of older people worldwide. Consequently, this will induce large epidemiological changes of disease prevalences, characterized by age-dependent non-communicable diseases taking the place of communicable diseases worldwide.<sup>3</sup>

At old age, cardiovascular disease is the most prevalent non-communicable disease also causing the largest burden. According to the Global Burden of Disease (GBD) figures for 2010, this burden was estimated to be 173.9 million disability adjusted life years (DALYs), representing 30.3% of the total global burden of disease of the population of people 60 years and older. In 2030, this percentage is projected to have increased to 40.6%.<sup>4</sup> In higher income countries, cardiovascular mortality rates decrease since the seventies, due to improved treatment options and implementation of primary

and secondary prevention programmes. Morbidity rates are still rising, which can be understood as an effect of ageing, reduced mortality and the pandemic of unhealthy lifestyle and diabetes. In lower income countries, both mortality and morbidity rates are rising, which can be regarded an effect of improving socio-economical standards, because communicable disease become better controlled, life expectancies rise but people also adapt the unhealthy 'Western' lifestyle.<sup>4,5</sup>

In Europe, cardiovascular mortality rates are declining: in Western and Northern Europe rates have been falling for over 30 years and since the millennium, rates are declining in the majority of European countries. Nevertheless, due to ageing there was an increase in absolute numbers of CVD cases. CVD is responsible for the largest loss of DALYs in Europe, as illustrated by a loss of 64.7 million DALYs in 2015 (23% of total burden of disease).<sup>6</sup>

Also the incidence and prevalence of dementia is expected to rise enormously with global ageing.<sup>7</sup> In 2010, the global burden of dementia in people aged 60 years and older was estimated 10.0 million DALYs, and this burden is projected to rapidly rise with 82.6% in 2030.<sup>4</sup> In Europe, in 2015, the number of people with dementia was 10.5 million, and this number is expected to increase with 28% by 2030. Even larger increases are foreseen in low- and middle income countries.<sup>8</sup>

Taking these trends together, it is expected that in the near future, the number of people at risk of cardiovascular disease or dementia will rise dramatically, also in Europe. This requires large flexibilities and unprecedented adaptations of health care systems.<sup>9</sup> Cardiovascular prevention and risk management becomes more important than ever. It can serve a dual goal in preventing both cardiovascular disease and dementia because cardiovascular disease and dementia share many risk factors.<sup>10-13</sup> Ideally prevention initiatives result in non-occurrence of the diseases, but even if diseases are merely postponed, this will already substantially reduce their respective burden.

### **CVRM at high age**

Although cardiovascular prevention is a lifelong assignment, current clinical guidelines recommend that the best time for CVRM for high-risk individuals to start is at middle age, because then modifiable cardiovascular risk factors (obesity, hypertension, diabetes mellitus, hypercholesterolemia, smoking and physical inactivity) start to become visible and elevated risk can still be minimized with lifestyle adaptations and, if indicated, medical treatment.<sup>14</sup> However, a wealth of scientific publications strengthens the hypothesis that cardiovascular risk reduction is effective until very old age. Health benefits occur within a few years after a cardiovascular risk factor has been targeted, both with regard to primary and secondary prevention.<sup>15-20</sup> These will

be relevant for many older people, if one considers that, for example, the average life expectancy in the Netherlands for a 80-year old individual is 8 years for a man and 10 years for a woman.<sup>21</sup> Effects of CVRM are not limited to the prevention of CVD and, potentially, dementia, but are beneficial for healthy ageing in general. Clinical guidelines only recently started to include recommendations for CVRM in older people.<sup>14 22</sup> Many clinical dilemmas specific for CVRM at older age are not yet fully addressed.<sup>23</sup> These dilemmas include for example ideal target values for cardiovascular risk factor control, multimorbidity, polypharmacy, adverse events of drugs, frailty, shortened life expectancy and different priorities in health. These dilemmas need to be further studied to understand how to specifically address the needs of older people in CVRM programmes.

### **Current practice of CVRM in Europe**

Most European countries have well implemented CVRM programmes following recommendations of the European guidelines on cardiovascular disease prevention, including population strategies and high-risk strategies.<sup>14</sup> Cardiac rehabilitation programmes aimed at direct rehabilitation after suffering from an acute event, are generally implemented in secondary care settings by cardiologists.<sup>24</sup> For the chronic management of these conditions, as well as for primary prevention, CVRM programmes are mostly implemented in the primary care setting.<sup>25</sup> Often, primary care nurses (or practice nurses) deliver a substantial part of these programmes.<sup>26</sup> In this thesis, we focus on CVRM in France, Finland and the Netherlands. Therefore, CVRM in these countries is described briefly.

#### *French cardiovascular risk management*

In France, CVRM is included in primary care and provided by general practitioners. National guidelines exist that address the different cardiovascular risk factors.<sup>27</sup> <sup>28</sup> National health campaigns exist to raise awareness for, for example, smoking cessation, physical activity and signs of stroke. General practitioners provide all care and monitoring themselves and do not delegate this to nurses. If indicated, patients are referred to a dietician or a psychologist (in case of smoking cessation), or to a medical specialist.

#### *Finnish cardiovascular risk management*

In Finland, cardiovascular risk management is included in primary care. In addition, a tradition of public campaigning exists to raise people's awareness. Several national primary care guidelines exist addressing the different cardiovascular risk factors, including recommendations for primary and secondary prevention.<sup>29-31</sup> In close

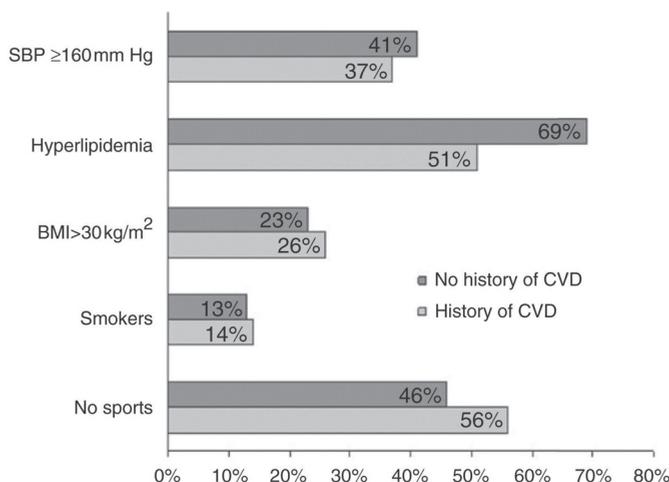
collaboration with general practitioners, practice nurses monitor patients with diabetes, hypertension and dyslipidaemia, as described in these national guidelines. In Finland, occupational health facilities are also largely developed and offer preventive health care services in parallel to the primary care system. They also work with nurses and follow the same guidelines.

#### *Dutch cardiovascular risk management*

In the Netherlands, cardiovascular risk management is included in primary care provided by general practitioners. A national comprehensive cardiovascular risk management guideline provides a tool for calculation of the individual cardiovascular risk and recommendations for both primary and secondary prevention. In case of suffering an acute cardiovascular event, patients first follow an intensive rehabilitation programme, after which they are referred back to the general practice. In the general practice, practice nurses provide a substantial part of cardiovascular risk management, under supervision of a general practitioner, including diabetes care, which has been detailed in several regional and national guidelines and work descriptions.<sup>32-35</sup>

#### **Current and future problems of CVRM programmes**

Current CVRM programmes face several problems. A big gap exists between the scientific promise and the reality of CVRM effectiveness. This is illustrated by the EUROASPIRE IV survey on therapeutic target achievements in coronary patients in Europe. At a median time (interquartile range) of 1.4 years (0.9-1.9 years) after a coronary event, 42.7% of the participants had hypertension (blood pressure  $\geq 140/90$  mmHg) and 42% had hypercholesterolaemia (low-density lipoprotein (LDL)-cholesterol  $\geq 2.5$  mmol/L).<sup>36</sup> Similar findings were obtained when evaluating Europeans at high risk of CVD.<sup>37</sup> This also holds for older people from Dutch general practice populations, as was shown in the preDIVA-study: there is ample room for improvement of the cardiovascular risk profiles of older people with and without CVD (**Figure 1**).<sup>38</sup> The preDIVA-study will be further described at the end of this introduction.



**Figure 1** Percentages of cardiovascular risk factors in people aged 70-78 participating in preDIVA.

From: Suzanne A Ligthart et al; *Eur J Prev Cardiol* 19, 1365-1372.

BMI, body mass index; CVD, cardiovascular disease; Hyperlipidaemia, total cholesterol  $\geq 5.0$  mmol/l in primary prevention group, low-density lipoprotein  $> 2.5$  mmol/l in secondary prevention group; No sports, including no recreational walking/bicycling tours; SBP, systolic blood pressure (mmHg); Smokers, current smokers.

One important patient-related factor is that lifelong adherence to a healthy lifestyle and medical treatment is difficult to achieve and requires an enduring health behaviour change. The process of health behaviour change has been studied and theorised extensively,<sup>35 39-42</sup> but in daily life, inducing and maintaining health behaviour change remains a large challenge. Another problem that current programmes face are the expanding costs of healthcare if the number of people eligible for CVRM will rise. Therefore, further research is required to study which CVRM strategies work best to stimulate enduring health behaviour change, which strategies work for older people and which strategies are fit to manage the increasing numbers of people at risk.

## NEW PERSPECTIVES ON CVRM: SELF-MANAGEMENT AND EHEALTH

### Self-management

In the last decades, new perspectives have been developed towards more optimal and ‘future-proof’ CVRM. Alongside the development towards patient-centered care, shared decision making and patient empowerment,<sup>43</sup> one strategy is to adopt patient self-management in CVRM. In self-management, the patient takes an active role in setting treatment goals and managing his health and the health care professional takes a supporting role, providing all education and tools needed to stimulate the patient’s autonomy.<sup>44 45</sup> This approach requires that patient and health care professional see each other as equals that both bring expertise essential for optimal management of the condition of the patient.<sup>46</sup> The idea is that in this way, the patient obtains self-efficacy, becomes a problem solver of his own health condition and is intrinsically motivated towards lasting health behaviour change that results in therapeutic control of his condition, because he sets his own priorities, he is in control, and makes a conscious comparative assessment of the consequences of his decisions.

Two tools that health professionals can use in supporting patient self-management and health behaviour change are the ‘Stages of Change’-model and ‘Motivational Interviewing’. The ‘Stages of Change’-model was developed by Prochaska and DiClemente in the nineties.<sup>41</sup> The model consists of five motivational stages (precontemplation, contemplation, preparation, action, maintenance and relapse) that together form the process of behaviour change. If health care professionals adapt their support to match the stage the patient is in, this will help the patient in moving towards the next stage.

‘Motivational Interviewing’ was developed by Miller and Rollnick in the nineties for supporting patients in quitting from alcoholism and was later developed for other health behaviour problems including smoking.<sup>47</sup> It is defined as “a directive, client-centered counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence”.<sup>48</sup>

Self-management has been elaborated and studied most extensively in the context of diabetes,<sup>49 50</sup> but also fits CVRM.<sup>51</sup> It has been shown effective for control of individual CV risk factors, for example the control of hypertension<sup>52</sup> and management of anti-coagulation therapy.<sup>53</sup> It has also been shown effective in cardiac rehabilitation programmes.<sup>54 55</sup> It has been less extensively studied in the context of primary prevention and in older populations. Its long-term effectiveness also needs to be further elucidated.

## **eHealth**

Concurrently, the field of eHealth is being developed and rapidly expands the possibilities of healthcare.<sup>56</sup> eHealth is a buzz word and policymakers, scientists, doctors and enterprises all have high expectations of eHealth. Large investments are being done both publicly and privately. eHealth is an umbrella term and can be very broadly defined as:

“Health services and information delivered or enhanced through the Internet and related technologies.”<sup>57</sup>

The European Commission defined eHealth in their eHealth Action Plan 2012-2020 as:

“eHealth is the use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals.”<sup>58</sup>

A few examples of applications of eHealth are: electronic health record systems, teleconsultations for tele-dermatology or tele-radiology, home tele-monitoring systems and wearable monitoring devices, educational health portals and online patients support groups. In this thesis, we focus on one particular form of eHealth, namely, patient-centered internet-platforms, that can be defined as:

“Systematic treatment/prevention programmes, usually addressing one or more determinants of health (frequent health behaviours), delivered largely via the internet (although not necessarily exclusively web-based), and interfacing with an end-user.”<sup>59</sup>

Patient-centered internet-platforms are very suitable to deliver self-management interventions because of the possibilities for education, interactivity and monitoring.<sup>59</sup>

<sup>60</sup> Once the platform has been developed, the self-management intervention could be delivered to a very large number of patients at relatively low costs.<sup>60</sup> This makes web-based platforms very attractive tools for innovative CCRM. In fact, over the last fifteen years, many internet-platforms have been developed. In the beginning, most interventions focussed on control of single cardiovascular risk factors. Meta-analyses evaluating interventions targeting smoking,<sup>61</sup> hypertension,<sup>62</sup> overweight,<sup>63</sup> and diabetes mellitus II<sup>64</sup> in adult populations found small significant effects on improvements of intermediate outcomes (control of the risk factor itself), when comparing interventions to usual care. Overall, effects of internet interventions were smaller than of face-to-face interventions. Internet interventions that targeted

multiple lifestyle components for improvement of the cardiovascular risk profile were not superior to usual care.<sup>65</sup> To date, little is known about the potential effectiveness of internet-platforms for older people, since only few platforms have been developed specifically for older people.

The research field of internet-platforms is relatively young and is still facing a number of teething problems. A common pitfall is that the interventions studied are not being described in a standardised way. This makes it difficult to compare interventions and identify the most effective components. Many internet-platforms are developed and offered on the market as health-application without robust evaluation of their effectiveness. Linked to this issue is the fact that digital developments go so fast that they can be hardly robustly tested in randomised controlled trials. Last, an often reported problem faced are high dropout rates.<sup>66</sup> To enhance effective implementation of interventions, it is important to involve the target population throughout the development process.<sup>67,68</sup> In this young field, many issues warrant further study. In this thesis we try to address the following questions: how to optimally develop an internet-platform that targets multiple cardiovascular risk factors? How to design an internet-platform specifically for older people? How can the process of self-management and health behaviour change best be supported online? How can sustained adherence to internet-platforms be stimulated?

## **OLDER PEOPLE AND INTERNET USE**

Today, internet has become part of every domain of our lives. Access to internet is almost becoming a necessary premise for successful participation in society.<sup>69</sup> For example, in 2015, the Dutch tax department aimed to work towards a complete transition from paper mail to digital communication with citizens regarding tax payment.<sup>70</sup> Worldwide, many older people are still digitally illiterate. The current generation of older people did not grow up with computers and only became familiar with the internet at relatively old age. Many people feel internet technologies are developing faster than they can keep pace with. This often puts people off in engaging with new technologies or makes them feel uncertain when using them. In the European Union, a 'digital divide' exists between younger and older generations regarding internet use. However, the percentage of people aged 55-74 using internet at least once a week increased rapidly from 32% in 2009 to 57% in 2016. Older people use the internet mostly for emailing, looking up information on goods and services and reading the news. Seeking health information is the fourth most frequent activity on the web.<sup>71</sup>

These promising numbers make it likely that, in the near future, the problem of a computer illiterate older generation will gradually disappear, and therefore, it is

not necessary to develop applications specifically for older people. Still, other age-related problems that can hamper internet use (such as sensory problems or cognitive impairment) will continue to exist. Since not many internet applications have been developed specifically for older people, research on how older people use these applications is also still in its infancy.<sup>72</sup> Studies show that older people use and understand websites and applications in a different way than young people, as illustrated with the following examples:

- older people often have sensory and motor impairments that complicate use of applications, but applications can be made more senior-friendly with rather simple 'lay-out' solutions such as using bigger font size, contrasting colours, simple navigation, and large buttons to facilitate clicking<sup>71</sup>
- older people easier get lost on websites due to limited navigation skills, but are able to navigate well with a static navigation menu<sup>73</sup>
- older people seem to have more difficulty to filter for relevant information. When a lot of information is available, they have a tendency to read everything<sup>74</sup>
- (age related) cognitive impairment can negatively affect older people's digital skills.<sup>73 75</sup>

To facilitate older people in using applications and websites, these should be designed with these specific age-related problems in mind.

## CONTEXT OF THIS THESIS

This thesis was conducted in the context of two studies:

- the Healthy Ageing through Internet Counselling in the Elderly (HATICE)-study<sup>1</sup>
- the Prevention of Dementia by Intensive Vascular Care (preDIVA)-study<sup>76</sup>

### **The Healthy Ageing through Internet Counselling in the Elderly (HATICE)-study**

The HATICE-study aims to develop and test a coach-supported interactive internet-platform for self-management of cardiovascular risk factors in older people to improve the cardiovascular risk profile and reduce the risk of cardiovascular disease and cognitive decline.<sup>1</sup> This thesis describes the development and evaluation of this platform. The HATICE consortium consists of clinical research teams of five European universities (University of Amsterdam (the Netherlands), University of Cambridge (UK), Karolinska Institutet (Sweden), University of Eastern Finland (Finland) and the University of Toulouse (France)) and two ICT companies (Vital Health Software (the Netherlands) and Novapten (France)). The platform was developed in close

collaboration with the private company Vital Health Software. Additional general objectives of the platform were:

- the platform should target older people with multiple cardiovascular risk factors and/or disease
- the platform should be implementable in different European countries, compatible with different health care systems and of added value to different health care structures.

Currently, the platform is being tested in a pragmatic, multi-national, multi-centre, prospective, randomised, open-label blinded endpoint (PROBE) trial with 18-months intervention and follow-up. The trial is being performed in the Netherlands, Finland and France. People aged 65 and older with at least two cardiovascular risk factors and/or a history of cardiovascular disease and basic Internet skills (ability to do a Google search and send an email) were eligible to participate. People were randomised to the intervention group (the interactive internet-platform with coaching) or to the control group (a static 'sham' platform). Primary outcome was defined as a composite score of the effects on systolic blood pressure, low-density-lipoprotein and body mass index. Secondary outcomes included the effect on lifestyle-related risk factors, incident cardiovascular disease, mortality, cognitive functioning, mood and cost-effectiveness. Recruitment started in March 2015. By July 2016, 2,725 people were included. Follow-up is expected to be completed in February 2018.

### **The Prevention of Dementia by Intensive Vascular Care (preDIVA)-study**

For this thesis, data from the preDIVA-trial were used to study determinants of dropout from and non-adherence to a nurse-led CVRM programme for older people. The preDIVA trial was a Dutch cluster RCT with 6-year intervention and follow-up in a primary care setting.<sup>76</sup> Briefly, the study assessed the effects of nurse-led intensive vascular care on prevention of dementia in a sample of 3,526 community-dwelling older people aged 70-78 without dementia. Participants were randomised to the intervention group (nurse-led intensive vascular care) or to the control group (usual care). The intervention consisted of 4-monthly consultations with the practice nurse at the general practice for assessment of the cardiovascular risk profile (blood pressure, LDL-cholesterol, weight, smoking habits, diet and physical activity). Based on these assessments, and following a protocol adhering to the Dutch primary care cardiovascular risk management guidelines,<sup>77</sup> the practice nurse provided individually tailored lifestyle advice and optimised cardiovascular medical treatment. Outcome assessments took place at 2-yearly intervals. Follow-up was completed in March 2015.

## OUTLINE OF THIS THESIS

This thesis is divided in two parts. Aim of **part 1** is to describe the development of an internet-platform for cardiovascular risk self-management in older people (the HATICE internet-platform). In order to create an evidence-based platform the development process included several phases. In **chapter 2**, we report the results of a systematic review and meta-analysis to answer the question whether internet-interventions for CVRM in older people are effective in reducing cardiovascular risk and disease. In **chapter 3**, we report the results of an international focus group study with Dutch and Finnish primary care nurses. In this study we discussed nurses' experiences and practices with behaviour change support for CVRM and the integration of their practices into a coach-supported internet-platform. **Chapter 4** provides a synthesis of the developmental phases of the HATICE internet-platform, its evaluation in an international pilot study and a description of the final product. Aims of **part 2** of this thesis were to gain better understanding on how to engage older people in new forms of cardiovascular risk management. In **chapter 5**, we report the outcomes of a qualitative study with Dutch participants of the HATICE trial to evaluate the internet-platform. We focussed on participants' experiences that were perceived to influence their engagement with the internet-platform and assessed participants' views on implementation of the platform in the primary care setting. In **chapter 6**, we report the outcomes of a study into engagement of older people with a CVRM programme from another angle, by quantitatively evaluating determinants of dropout and non-adherence in the preDIVA trial. In **chapter 7** we discuss the main findings of the different studies, methodological considerations, potential clinical implications and directions for future research.

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