eHealth in cardiovascular risk management to prevent cognitive decline
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"How can I type a capital letter?"

(Participant in one of the platform testing sessions, November 2014)
Chapter 2

DEVELOPMENT AND VALIDATION OF AN INTERACTIVE INTERNET PLATFORM FOR OLDER PEOPLE
THE HEALTHY AGEING THROUGH INTERNET COUNSELLING IN THE ELDERLY STUDY

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ABSTRACT

Background A myriad of web-based applications on self-management have been developed, but few focus on older people. In the face of global aging, older people form an important target population for cardiovascular prevention. This article describes the full development of an interactive Internet platform for older people, which was designed for the Healthy Ageing Through Internet Counselling in the Elderly (HATICE) study. We provide recommendations to design senior-friendly Web-based applications for a new approach to multicomponent cardiovascular prevention.

Methods The development of the platform followed five phases: (1) conceptual framework; (2) platform concept and functional design; (3) platform building (software and content); (4) testing and pilot study; and (5) final product.

Results We performed a meta-analysis, reviewed guidelines for cardiovascular diseases, and consulted end users, experts, and software developers to create the platform concept and content. The software was built in iterative cycles. In the pilot study, 41 people aged ≥65 years used the platform for 8 weeks. Participants used the interactive features of the platform and appreciated the coach support. During all phases adjustments were made to incorporate all improvements from the previous phases. The final platform is a personal, secured, and interactive platform supported by a coach.

Discussion When carefully designed, an interactive Internet platform is acceptable and feasible for use by older people with basic computer skills. To improve acceptability by older people, we recommend involving the end users in the process of development, to personalize the platform and to combine the application with human support. The interactive HATICE platform will be tested for efficacy in a multinational randomized controlled trial (ISRCTN48151589).
BACKGROUND

In the last decade, the development of web-based applications has expanded dramatically(1). A concurrent development in medicine is the promotion of patient-centred care and self-management(2, 3). Web-based applications fit in this trend. They are a useful medium for patient-education, stimulation of behaviour change and enhancement of self-management. In addition, web-based interventions can be implemented on wide scale at low-cost and allow for tailoring, interactivity, interpersonal communication and provide anonymity(4, 5). This renders web-based interventions suitable to target common health care problems with high costs such as cardiovascular disease.

Web-based interventions targeting single cardiovascular risk factors in adult populations have shown to be effective(6-9). However, cardiovascular prevention guidelines recommend a comprehensive approach of the total cardiovascular risk profile(10, 11). It is currently unknown whether web-based interventions targeting multiple risk factors are also effective.

With global ageing, older people form an important target population for cardiovascular prevention. Few web-based applications for cardiovascular risk management focus specifically on older people(12, 13). The number of people aged 65-74 in the European Union using internet increased from 20% in 2009 to 42% in 2015, illustrating the high potential of web-based interventions in older populations. Since older people read, use and understand websites in a different way than young people, a thorough design process is required to ensure that a web-based application truly fits this older audience(14-16). In this paper we aim to describe the full development, from idea to piloting and implementation, of an interactive internet platform for older people to improve their cardiovascular risk profile through a multicomponent prevention strategy. We describe all development phases to facilitate others in building on our experiences and move the development of web-based applications further. In addition, we provide recommendations to design senior-friendly web-based applications for multicomponent cardiovascular prevention. This platform is especially designed for the Healthy Ageing Through Internet Counselling in the Elderly (HATICE) trial(17). This is a pragmatic, multi-national, multi-centre, prospective, randomised, open-label blinded endpoint (PROBE) trial with 18-months intervention and follow-up. The aim of the HATICE trial is to evaluate the effectiveness of the interactive internet platform to improve the cardiovascular risk profile of older people with elevated cardiovascular risk.
METHODS

The concepts of the platform were developed by the HATICE-consortium. Close interaction between academic researchers and software builders was key in the development phase. Important spearheads were to design a generic platform that is widely implementable and easily adaptable to different countries and primary care systems. Simultaneously, it should serve as the electronic database for data collection and storage, and comply with all security and privacy regulations for Good Clinical Practice(18). The platform was developed following five phases as shown in Figure 1.

![Figure 1. Phases of platform development](image)

**Phase 1: Conceptual framework**

We based the conceptual framework of the interactive internet platform on Bandura's social-cognitive theory for self-management and behavioural change and its practical elaboration in the computerized self-regulatory system(19). Successful behavioural change and its maintenance depend on self-efficacy, managing outcome expectations, setting goals and dealing with barriers. In this system, people are supported in the development of self-regulatory skills in a blended way; by a computer platform and a person serving as online coach. The computer platform can provide an environment for learning, goal setting, action planning and progress monitoring. The coach evaluates what people are doing within the platform and provides feedback.
We based the HATICE platform on this theory, by combining a web-based interactive platform for self-management with a personal coach. This coach uses motivational interviewing techniques (20) and the stages of change model (21) as tools to provide feedback and stimulate behavioural change in a cyclic manner (Figure 2). We used Michie’s taxonomy for standardized definitions of the behaviour change aspects in our intervention (22).

**Figure 2.** Cycle of self-management supported by the platform and coaching, numbers correspond with the definitions of behaviour change techniques from Michie’s taxonomy (22)

### Phase 2: Platform concept and functional design

We performed a systematic literature review and meta-analysis on the effectiveness of internet-interventions targeting cardiovascular risk factors in older people (13). In parallel, we conducted 14 four-hour brainstorm sessions with academic researchers and software developers to elaborate our concept and the functional design of the platform. We made schematic visualizations of the functionalities and architecture of the platform (wireframes). We discussed this first concept with an expert in health communication among older people, an expert in online lifestyle change, an expert in preventive cardiology and representatives of patient-organizations (Dutch Heart Foundation and the Dutch and Finnish Alzheimer Association).
Chapter 2

We organized focus groups with the target population and nurses with experience in cardiovascular risk management in the three countries where the trial will take place (the Netherlands, Finland and France). During these focus groups it was discussed how an internet platform could help people improve their lifestyle and which functions such a platform should offer. We incorporated the results of the meta-analysis, expert meetings and focus groups into the final version of the functional design.

Phase 3: Building

3a: Generating the platform content

A prerequisite for platform content was that all information had to be evidence-based. We evaluated the European, French, Finnish and Dutch clinical guidelines on cardiovascular prevention and risk management(10, 23-27) and developed generic modules for cardiovascular risk profile evaluation, lifestyle support and pharmacological recommendations. To address the complete cardiovascular risk profile, the intervention focused on seven modifiable cardiovascular risk factors (hypertension, dyslipidaemia, diabetes mellitus, overweight, lack of physical exercise, smoking and unhealthy nutrition)(10). We aimed to combine interactive modules with static information, both with a strong focus on self-management.

3b: Building the platform-software

The final version of the functional design served as the basis to build the platform-software. Software was built using Scrum, an agile software development method in which small parts of the software are built in iterations(28). We worked in semi-monthly planning cycles in which functionalities of the platform were agreed on, developed by the software developers, tested by both developers and researchers and subsequently released. A secure hosting environment was created that complied with strict Good Clinical Practice(18) privacy regulations covered within the local NEN 7510 standard(29).

3c: Building the platform for the control-condition of the HATICE-trial

In the HATICE randomised controlled trial (RCT), the interactive internet platform will be compared to a control condition. Therefore, we built a separate control-platform. This platform only contains static information modules on the seven cardiovascular risk factors and lacks all interactive features of the interactive internet platform. There will be no coach support for the control group.
Phase 4: Testing and evaluation

Prior to the pilot we performed two testing sessions with Dutch older people representative for the target population. Using the thinking aloud principle(30), assignments were given to the participants. Tasks included for example: 1) Find the website using the Uniform Resource Locator (URL) and log on. 2) Prioritize a risk factor and make a related healthy lifestyle goal. Problems discovered during the test sessions were solved and improvements were incorporated in the platform.

Pilot methodology

The pilot took place in the three countries to test acceptability and feasibility of the intervention and control platforms and the complete study logistics. Detailed study logistics and complete inclusion criteria of the HATICE trial are published elsewhere(17). Participants were aged ≥65 years, had an elevated risk of developing cardiovascular disease and had basic computer skills.

After eligibility-screening, the participants visited the research nurse. They received a welcome email with their sign in details, a short explanation of the platform and a paper manual. Randomisation took place during the visit in a 2:1 ratio. We chose to oversample the intervention group because the main aim was to test the interactive intervention platform. After randomisation, participants assigned to the intervention group, made lifestyle improvement goals and received coach-support. Participants assigned to the control group received access to the static control platform. Follow-up was eight weeks. After all participants had completed the pilot, an evaluation session was held in each participating country. Participants completed an evaluation questionnaire about logistics, usability and acceptability.

Phase 5: End product for randomised controlled trial

After incorporation of the adaptations identified during the pilot, the platform was considered ready to be used in the RCT.
RESULTS

Phase 1, 2 and 3 (development)

The results from the meta-analysis showed that only few web-based applications are specifically designed for, and tested in, older people(13). Also, web-based applications can induce small improvements in the cardiovascular risk profile, with larger effects for blended (computer/coach) interventions.

The brainstorm sessions and expert consultations yielded important insight into specific requirements for a platform for older people, including adaptation of font size and the need for a simple and consistent layout with large buttons. To easily absorb information, older people need the platform to be well-organized which can be enhanced by using basic distinctive colours and simple illustrations. Adaptation of default audio settings to people with hearing impairments is required. A concise site map and a limited number of web pages can facilitate navigation. To prevent loss of motivation, people need to be kept allied to the platform. If people do not login for approximately three weeks, their motivation might already be disappearing. The experts also advised that a memory training game and other interactive features might stimulate motivation to log on.

From all three countries, forty older people with elevated cardiovascular risk and internet skills participated in the focus group sessions. In addition, seven Dutch nurses experienced in cardiovascular risk management participated in two sessions. The focus groups with the target population indicated that older people liked to be able to ask questions to a coach via internet. They indicated that the platform should have a positive appearance, focussing on health rather than disease, and provide practical and reliable information that is often difficult to find on websites. The nurses felt that, in order to provide adequate support, some face-to-face contact would be indispensable, but also that the platform had potential added value in providing continuous support on lifestyle change (manuscript currently being prepared by the HATICE consortium).

Content of the intervention

In line with the suggestion to focus on health rather than disease, we renamed risk factors 'health factors'. The intervention starts with an evaluation of the personal cardiovascular risk profile, which is generated by the platform from information provided during the study visit. Together with the coach, the participant decides which health factor(s) will be prioritized. By doing so, the platform adapts the content of the platform to these health factors and
becomes tailored. For each health factor, participants can: (1) set and monitor lifestyle goals; (2) enter health factor-related measurements (e.g. blood pressure, weight, etcetera); (3) view informative contents. We created a step-by-step procedure that guides the participant to the process of setting a lifestyle improvement goal (Supplement 1). The participant sets a target date for the goal and can choose to receive automated reminders about this goal. The participant can write a message to the coach via a secured mailbox within the platform. Apart from the virtual presence of the coach, several other aspects of the intervention stimulate (inter)active participation such as interactive information video’s and lifestyle groups (Table 1). The lifestyle groups provide an opportunity to connect with other participants and perform healthy activities together in real life.

To keep participants allied to the platform, the coach is automatically alerted if participants refrain from logging on for more than three weeks. The coach will then contact the participant and tries to motivate the participant again.

Table 1

<table>
<thead>
<tr>
<th>Features that stimulate (inter) active platform use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interactive information video’s</td>
</tr>
<tr>
<td>Goal-setting module (Supplement 1)</td>
</tr>
<tr>
<td>Reminder messages on the goal</td>
</tr>
<tr>
<td>Reminder messages for the coach when the platform was not used for 3 weeks by a participant</td>
</tr>
<tr>
<td>Automated feedback messages on measurements with a positive, motivating tone</td>
</tr>
<tr>
<td>Lifestyle groups</td>
</tr>
<tr>
<td>Cognitive training program</td>
</tr>
</tbody>
</table>
**Phase 4 (pilot results)**

**Study Population**
Recruitment for the pilot started in September 2014 and follow-up lasted until February 2015. In total 41 participants were randomized (29 to the intervention group and 12 to the control group Figure 3). Baseline characteristics of the participants are presented in Table 2. The mean age (standard deviation) of the participants was 69 (4.6) years and 44% were male. Almost half of the participants had a history of cardiovascular disease, including myocardial infarction, stroke, transient ischemic attack, peripheral artery disease or angina pectoris. The mean number (SD) of cardiovascular risk factors was 2.4 (1.1) per participant.

![Diagram](Figure 3: Pilot flowchart)
Development and validation of an interactive internet platform

Table 2. Baseline characteristics of the pilot study population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total N=41</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (SD)</td>
<td>69 (4.6)</td>
</tr>
<tr>
<td>Male gender, N (% of total)</td>
<td>18 (44%)</td>
</tr>
<tr>
<td>Education Level&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Primary, N (% of total)</td>
<td>10 (24%)</td>
</tr>
<tr>
<td>Secondary, N (% of total)</td>
<td>17 (42%)</td>
</tr>
<tr>
<td>University, N (% of total)</td>
<td>12 (29%)</td>
</tr>
<tr>
<td>History of CVD, N (% of total)</td>
<td>20 (49%)</td>
</tr>
<tr>
<td>Hypertension&lt;sup&gt;b&lt;/sup&gt;</td>
<td>35 (85%)</td>
</tr>
<tr>
<td>Currently smoking&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>Diabetes Mellitus type 2&lt;sup&gt;d&lt;/sup&gt;</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Dyslipidaemia&lt;sup&gt;e&lt;/sup&gt;</td>
<td>25 (61%)</td>
</tr>
<tr>
<td>Overweight&lt;sup&gt;f&lt;/sup&gt;</td>
<td>20 (49%)</td>
</tr>
<tr>
<td>Lack of physical exercise&lt;sup&gt;g&lt;/sup&gt;</td>
<td>16 (39%)</td>
</tr>
<tr>
<td>No. of cardiovascular risk factors per participant, N (% of total)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>1</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>2</td>
<td>16 (39%)</td>
</tr>
<tr>
<td>3</td>
<td>14 (34%)</td>
</tr>
<tr>
<td>4</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>5</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Two missing values for this variable

<sup>b</sup> Hypertension: ≥140/90 mmHg for participants <80 years, ≥160/90 for participants ≥80 years, or on blood pressure-lowering agents

<sup>c</sup> Smoking: any kind of tobacco

<sup>d</sup> Diabetes: Diagnosed by a general practitioner/specialist or on antidiabetic medication

<sup>e</sup> Dyslipidaemia: total cholesterol ≥5.0 mmol/L, LDL-cholesterol ≥2.5 mmol/L or on lipid-lowering agents

<sup>f</sup> Overweight: body mass index ≥30 kg/m² or waist circumference men ≥102 cm, women ≥88 cm

<sup>g</sup> Lack of physical exercise: below the World Health Organisation norm of 150 min of intermediate exercise a week.

Patterns of use of the website

Number of log-ins

The characteristics of platform use are given in Table 3. Participants logged in 357 times in total, of which 282 times by the intervention group and 75 times by the control group. The coaches logged in 383 times over a total study period of 12 weeks.
Table 3. Feasibility parameters of the pilot study

<table>
<thead>
<tr>
<th>User statistics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total log-ins (N=41)</td>
<td>357</td>
</tr>
<tr>
<td>Intervention (N=29)</td>
<td>282 (79%)</td>
</tr>
<tr>
<td>Control (N=12)</td>
<td>75 (21%)</td>
</tr>
<tr>
<td>Total log-ins coach</td>
<td>383</td>
</tr>
<tr>
<td>Total N of messages send by intervention group</td>
<td>74</td>
</tr>
<tr>
<td>Total N of messages send by coach/platform</td>
<td>162</td>
</tr>
<tr>
<td>Total N of goals set</td>
<td>30</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>2</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0</td>
</tr>
<tr>
<td>Exercise</td>
<td>13</td>
</tr>
<tr>
<td>Smoking</td>
<td>0</td>
</tr>
<tr>
<td>Nutrition</td>
<td>4</td>
</tr>
<tr>
<td>Weight</td>
<td>9</td>
</tr>
<tr>
<td>Total N of measurements entered</td>
<td>212</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>78</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0</td>
</tr>
<tr>
<td>Exercise</td>
<td>68</td>
</tr>
<tr>
<td>Smoking</td>
<td>0</td>
</tr>
<tr>
<td>Nutrition</td>
<td>10</td>
</tr>
<tr>
<td>Weight</td>
<td>55</td>
</tr>
</tbody>
</table>

Number of messages
The participants sent in total 74 messages to their coach via the platform. The average content of the messages was about their personal goals and how to achieve them. Participants received a total of 162 messages, including tailored messages sent by the coaches and automatic reminders. The average content of the messages from the coaches was an answer to participants’ questions and coaching/motivating the participants in their lifestyle goal.

Number of goals and measurements
In total, 30 lifestyle improvement goals were set. The majority of the goals were related to improvement of exercise and weight.
A total number of 212 new measurements were entered, mostly pertaining to blood pressure (78), exercise (68) and weight (55). A mean (SD) number of 5.2 (10.3) measurements were entered per participant.

**Evaluation session**

All pilot participants were invited to the evaluation session and 27 (66%) participants attended. They liked the idea of the platform, but were uncertain what to expect from it. Passwords provided to login for the first time were too difficult. The majority of the participants considered an instruction video on the use of the intervention platform necessary. Setting a goal was difficult for participants, although most succeeded with guidance from the coach. Participants appreciated the interactive features of the platform, including goal setting with associated measurement entries and the interactive videos. The information about a healthy lifestyle was appreciated, but the participants felt the need to print the texts on paper, so an icon for an easy way to print would be useful. The platform did not work optimally when relatively old software and/or hardware was used. Communication with the coach was very much appreciated and felt very personal to all participants, even though there was no face-to-face contact after the study visit.

**Phase 5 (final version of the platform)**

The final version of the platform is a secured web-based platform with personalised, secured accounts, where the participant can find seven key pages and functionalities as described in Table 4. We have been simplifying the randomly generated passwords. To limit the chances of participants getting lost on the platform, the navigation structure has been kept as flat as possible. The seven key pages contain functionality that may open a pop-up (with the menu page still visible at the background), but there is no navigation deeper into the platform. The self-monitoring tools and the goal diary have also been also simplified. We have been creating an introduction video to provide more guidance on use of the platform. The platform is now accessible on all computer devices (desktop computer, laptop and tablet) with all major operating systems (Windows®, Mac OS®) and all major browser software (Internet Explorer®, Edge®, Safari®, Chrome® and Firefox®) including older versions. The final platform has a simple and consistent layout style with large font size, limited use of (different) colours, a static main menu that is visible on every page and clear 'return'-buttons. The layout of one of the pages of the platform is shown in Figure 4.
### Table 4. Key pages and functionalities of the HATICE intervention platform

<table>
<thead>
<tr>
<th>Platform page</th>
<th>Functionality</th>
</tr>
</thead>
</table>
| Home page             | Introduction video explaining how to use the platform  
                          Overview-homepage to navigate directly to the most important items of the platform: personal health priorities, goals, new messages and personal lifestyle groups  
                          Photograph of the coach                                                                                                                                 |
| My health priorities  | Overview of personal health priorities and step-by step procedure to register a measurement  
                          Overview of goals and step-by-step procedure to set new goal  
                          Overview of achieved goals  
                          Summary of personal cardiovascular health profile                                                                                                                                 |
| Lifestyle groups      | Personal lifestyle groups  
                          Overview of other available groups                                                                                                                                 |
| Messages              | Messages inbox for interaction with coach                                                                                                                                 |
| Advice and Education  | Information, advice and tips and tricks on healthy lifestyle for each health factor  
                          Educational video’s for each health factor  
                          Peer-to-peer video’s with personal stories of peers on lifestyle change                                                                                                                                 |
| News                  | Every month a new international or national news item on research highlights, facts or activities related to preventive health                                                                                                                                 |
| User support          | Help-buttons on every page explaining the users specific functionalities  
                          Help-assistance through email and phone  
                          In addition, paper instruction manual                                                                                                                                 |

**Figure 4.** Final version of platform – My health priorities/blood pressure page
DISCUSSION

In this paper we described the design, development and piloting of an internet intervention platform to improve the cardiovascular risk profile in older people using a multicomponent intervention strategy. The pilot showed that this platform is acceptable and feasible for use by older people. The entire development process took two years of preparation time and effort.

The meta-analysis learned us that blended web-based applications associated with larger treatment effects than internet-only applications(13). This was one of the reasons why we combined the platform with a coach, also, because we think that the personal touch may strengthen motivation and adherence. The expert consultations and focus groups helped us to understand the barriers older people encounter when using the internet. Some barriers, such as readability and comprehensibility of the website, and privacy concerns, were already known from previous research. Other barriers, like the fear of getting lost and the preference for a positive tone, were new. The pilot enabled us to evaluate if this platform had overcome those barriers and revealed other issues such as difficulties with the login procedure. Simplifying the login-procedure seems a triviality but, for older people, this can make a huge difference in accessibility of the platform.

Over the coming years, the platform described in this paper will be tested for efficacy in the HATICE RCT(17). It is crucial to not only design an evidence-based internet platform, but to test it in a controlled setting as well.

In this time of vast digital expansion, technical developments tend to advance faster than researchers can keep pace with. Therefore, some researchers advocate the use of adaptive trial designs to enable a more flexible form of testing(31). Although this seems appealing, we think that ultimately robust controlled study designs are required to evaluate clinical effectiveness and utility. Thorough communication between the software developers, researchers and end-users is crucial in understanding each other’s visions and needs. The final platform needs a synthesis of the three different viewpoints (clinical trial setting, software capabilities and senior-friendliness) of these groups.

To accomplish acceptability for older people, we recommend to start with a theoretical backbone, to involve the end-users in the entire process of development, to personalise the platform and to combine the application with human support.
If proven effective, the pragmatic design of the HATICE intervention, independent of existing health care structures, will facilitate easy and wide implementation throughout Europe. The tailor-made character of the platform specifically suited to the needs of older individuals fits with the current development towards a more personalised and digital approach in medicine.
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REFERENCES


SUPPLEMENT 1. STEP BY STEP PROCEDURE FOR GOAL SETTING

Step 1: Selecting a health factor

Step 2: Selecting a goal

- Choose from a list of predefined goals
- Or create your own goal

Step 3: Defining the goal

- Make an action plan
- Set a target date
- Automatic reminders