Practice examples of international digital products for cardiovascular risk assessment and management
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1. Introduction

The NHS Health Check is a national prevention programme in England which seeks to reduce the chance of adults aged 40-74 years having a heart attack, stroke or developing some types of dementia. The programme does this through the early awareness raising, assessment, and management of the major risk factors and health conditions driving premature death, disability and health inequalities.

The report identifies and describes:
• five digital products used internationally to assess, communicate and support users to take action to reduce their cardiovascular disease (CVD) risk
• how the products were used
• the outcomes they achieved

Learnings from these examples are described in the context of England’s NHS Health Check. This report will be of interest to policy makers as well as local authorities which have responsibility for commissioning the NHS Health Check programme, and organisations delivering the NHS Health Check.

2. Methods

Public Health England (PHE) undertook a search of online databases in November 2020 to identify scientific papers featuring international digital products delivering a comparable intervention to the NHS Health Check. Following the database searches, reviewers sifted the identified papers based on agreed inclusion and exclusion criteria. Further information about the method is provided in appendices A, B and C.

From the sifted papers, five digital examples were selected because they met all of the following criteria:
• targeted adult populations
• assessed multiple cardiovascular disease (CVD) risk factors
• communicated results and supported users to take action to manage their risk of CVD

The Template for Intervention Description and Replication\(^1\) (appendix D) was used to identify the information needed to describe each example. This information was then presented for each digital example using the structure of introduction, purpose, implementation, outcomes and learning. The description of the digital product was extracted from published sources and communication was initiated with all authors where information was incomplete.
This piece of work was limited by the availability of information describing digital products in published scientific papers. While we did invite authors to provide supplementary information, we were only able to engage with two authors. It is likely that the identification and description of these products is limited as a result.

A further limitation of the method is that there may be other similar products in existence which have not been included as examples because there is an absence of published scientific literature evaluating or describing them. Additionally, we did not critically appraise the quality of the studies evaluating these products, we have only summarised their findings.

3. Key messages

This work identified five examples of digital products used to some degree to assess and communicate CVD risk and/or provide onward support to reduce that risk. The five digital examples identified indicate that:

- it is feasible to use digital products to complete CVD risk assessments, communicate risk scores, and set and monitor behaviour change goals
- a digital CVD risk assessment, communication and management product is acceptable to some adults, including those at higher than average risk of CVD
- a greater proportion of users of these digital products tend to be from affluent groups
- overall, they were only able to reach a small proportion of those invited to use them and marketing of the product, and provision of support and guidance to use the products, seems to help improve take-up
- completion of the digital risk assessment can be supported by facilitating their use in the workplace and automatically providing on site biometric testing
- requiring users to order home biometric testing kits, rather than automatically issuing one, seem to result in fewer completions
- these digital products seem to be acceptable to health care practitioners
- they can be used with a health care professional to engage with individuals in community outreach settings
- they may be associated with favourable changes in behaviour and CVD risk. However, the quality of evidence on outcomes was mixed ranging from observational to randomised controlled trials

Together these five examples show the potential benefits that could be realised in terms of CVD risk assessment, behaviour change and CVD risk reduction. They also provide some insights into who might be more likely to use them and how they might be implemented in order to maximise their impact.
4. Examples

Five international examples of digital CVD risk assessment, communication and management products were identified and summarised.

Dutch CVD health risk assessment and intervention product

Introduction

This digital example, from the Netherlands, draws on information from two scientific papers. It describes a digital product which aligns with the following components of the NHS Health Check pathway (appendix E): risk factor measurement, CVD risk calculation, communication of risk and supporting individuals to make behavioural changes and access to clinical care which supports them to reduce their risk of CVD.

Purpose

The product aims to calculate and communicate CVD risk to adults, and support users to reduce their risk of CVD and underlying risk factors by:

- assessing CVD risk to identify individuals within the general population at increased risk of CVD
- providing feedback that motivates individuals at higher risk of CVD to make behavioural changes
- providing a personalised action plan to enable behaviour change which will reduce their risk of CVD

Product

Through this web-based product, users complete a CVD-risk-assessment questionnaire on their personal and family medical history, sociodemographic characteristics, stress, physical activity, alcohol, tobacco, depression and anxiety, burnout and self-efficacy. The questions were derived from validated instruments including the International Physical Activity Questionnaire, the five-shot questionnaire for alcohol abuse, the Dutch Expert Centre on Tobacco Control questionnaire, INTERHEART stress questions, the extended K10 for depression, the Utrecht Burnout Scale, and constructs from the transtheoretical model, protection motivation theory and social cognitive theory.

Depending on how the product is deployed, after self-completing the questionnaire, users can be provided with feedback on their results. Alternatively, those identified as being at greater risk of CVD can be invited to order a home testing pack or attend an
appointment with a trained professional for biometric measurements including: waist circumference, blood pressure, total cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides, glucose and HbA1C. The additional information is entered into the product and used to calculate the users’ 10-year CVD risk, based on Dutch CVD-management guidelines.

The product communicates to the user the result for each individual risk factor as well as their composite CVD risk using traffic lights (green: normal; orange: moderately elevated; or red: seriously elevated risk profile). An explanation of the associated health risks and potential gains of preventive action is also provided. The results are used in conjunction with information on the individual's motivation, self-efficacy and preferences to produce a tailored health action plan to support behaviour change. The action plan provides links to local behavioural services, referral suggestions, and recommendations for starting preventive drug treatment for lipid or blood-pressure lowering.

Implementation

Two different approaches to the application of the product have been evaluated in the Netherlands:

1. A community-based approach was evaluated using a prospective intervention study design with no control group. Individuals aged 45-70 years without pre-identified CVD or diabetes were invited, by their GP, to use the product. Users that were identified as high risk after completing the questionnaire were invited to order a home testing pack so that they could take and enter the biometric measurements.

2. A workplace approach was evaluated using a prospective follow-up study, where employees, were invited to participate as part of a worksite health management programme. All invited users had access to the biometric tests by making an appointment with a nurse in the workplace. Individuals were invited in two groups 6 months apart. Follow-up measurements were recorded for users in the first workplace group seven months after using the product, to allow any change in CVD risk to be assessed. No follow-up was carried out for the second workplace group.

Outcomes

In the community-based approach GPs invited 800 people to take part in the study. Of those invited, 43.4% (347 of 800) were male, with an average age of 51.9 years. Data on ethnicity and deprivation characteristics of invitees was not reported.

Around a third (29%, 230 of 800) of individuals invited by their GP took up the offer and completed the CVD-risk assessment questionnaire. The average age of participants was 52.2 years, with a similar percentage of males and females (47.8% vs 52.2% respectively). Of those participating, 46.1% were identified as having a high educational
level compared with 26.1% at mid-level and 26.1% at low level. The extent to which this was representative of the community was not reported, but the number of people with low educational attainment, smokers, and overweight were identified by the authors as being slightly underrepresented compared with the national average. Conversely, those not meeting the Dutch guidelines for physical activity levels were slightly over represented.

Of the users completing the CVD risk assessment questionnaire, 38% (89 of 230) were identified as being at increased CVD risk and invited to complete biometric assessments by ordering a home testing kit. Half of those eligible for a home testing kit went on to order one, with women ordering significantly more often than men, and 73% (32 of 44) of those who received a home testing kit going on to complete the biometric assessments.

Six months after they had received their tailored advice through the product, users were sent an electronic survey to assess satisfaction and changes in behaviour. In this community-led approach a third of survey respondents (40 of 129) reported acting on behaviour change advice. Authors concluded that the product led to self-reported behavioural change among users. However, using self-reported outcomes is subject to bias and there may be other explanations for the outcomes of this observational study beyond the digital product.

In the workplace study, the product was tested predominantly with well-educated men (80% men vs 20% women), with an average age of 45. No assessment was made in the paper of whether this was representative of the proportion of male and female employees at the organisation. Of the 1108 employees invited as the first group of users, a third (368 of 1108) completed the web-based CVD risk assessment questionnaire and biometric assessments, of whom about 80% were men. Among the second group of users the take-up rate rose slightly to 39%, with again, around 80% being men.

Follow-up measurements were recorded for only 176 (48%) of the 368 users in the first workplace group seven months after using the product (mean age 46, 81% male) of which 12.4% (21 of 170) were classified as being at high risk of CVD (defined as Framingham 10-year CVD risk of 20% or greater). Those identified at high risk of CVD reported reducing that risk by an average of 18% at follow-up. No follow-up was carried out for the second workplace group.

The reduction in CVD risk was attributed by the authors to improvements in systolic blood pressure and a concurrent increase in high-density lipoprotein cholesterol. Authors concluded that the observed beneficial changes were not accounted for by additional health counselling, referral to primary care physicians, or medication, but instead that behavioural changes driven by the provision of individualised advice via the product.
were responsible for the effect. Authors reported that the higher the user’s CVD risk, the greater the reduction at follow-up.²

Learning

Delivery of a web-based health risk assessment with tailored behavioural advice in a community and workplace setting is feasible. Between the two implementation settings, there appears to be little difference in the initial take-up with around a third of people invited using the product. However, it seems that the product may be more acceptable among men given their higher take-up rates in a community setting. Additionally, adopting a phased implementation approach in a workplace setting may increase take-up as the intervention becomes established.

The product is acceptable among certain groups, namely educated middle-aged men. Automating the arrangements for biometric testing results in a greater proportion of people completing it. The requirement to order home testing kits was less popular, resulting in greater levels of drop out.

Among users, the product was associated with favourable changes in behaviour and CVD risk; however, the findings are limited by the observational nature of the evaluations.
Healthy Ageing Through Internet Counselling in the Elderly (HATICE)\textsuperscript{11,12,13}

Introduction

This digital example, which has been used in Finland, France and the Netherlands, draws on information from three scientific papers.\textsuperscript{11,12,13} It describes a digital product which aligns with the following components of the NHS Health Check pathway (appendix E) by supporting behaviour change following a CVD risk assessment.

Purpose

- The product aims to prevent CVD and cognitive decline in people over 65 years with existing CVD risk factors by providing users with web-based coaching and enabling them to self-manage their CVD risk

Product

The product is an interactive web-based platform specifically designed for use by older people and to be accessed via a desktop computer. Once logged in, users can see their CVD results including: blood pressure, waist and hip circumference, weight and height, which were previously measured and recorded by trained professionals.

Through the product, users can set behavioural goals on up to three of the following CVD risk factors: smoking, blood pressure, nutrition, cholesterol, diabetes, weight and physical activity, with the aim of improving their results. Once participants set their own personal goal or goals for behaviour change and build a corresponding action plan, they can monitor their progress by self-entering data, such as blood pressure readings or a food diary. The layout of the homepage then becomes tailored to the participant, an example of which is shown in figure 1.
Use of the product is underpinned by expert support from coaches trained in motivational interviewing. Coaches provide users with guidance on goal setting based on the three priority areas identified by the user. Coaches motivate users to achieve their goals via a digital messaging system, encourage them to interact with the product, set additional goals over time, and provided motivating feedback. This system also alerts coaches if their allocated users have not accessed the platform for a certain period so that they can also ‘nudge’ the user.

Users decide how frequently to interact with the product and can use the messaging system to engage with their coach. The product also provides users with access to behaviour change groups and information on what their CVD risk might mean for them. Additionally, through the product users have access to static and interactive education-modules, health information, peer videos on behaviour change, and a programme for cognitive training. They can also access suggestions from other users and perform group activities together with other users that share similar goals or interests.

Users receive a 3-monthly online questionnaire about the occurrence of adverse events and clinical outcomes. At 12 months, users are contacted by telephone to discuss self-
reported outcomes and have a motivational conversation around further changes required to enhance the achievement of their behaviour change goals.

**Implementation**

Using a randomised controlled trial the implementation of the product has been evaluated in France, Netherlands and Finland. In all three countries, the product was tested with people over the age of 65, living in the community and with two or more CVD risk factors or a history of CVD or diabetes. All participants completed an in-person initial assessment of CVD risk factors. This included: blood pressure, hip and waist circumference, weight and height, blood tests for assessment of lipids, glucose, and glycosylated haemoglobin HbA1c, as well as physical and cognitive function tests. Follow-up measurements were recorded for users 18 months after using the product. The same measurements taken at baseline were repeated in person.

Study participants randomised to the intervention had access to HATICE in their own language. After secure login, users could view their own results from the initial assessment. They also set a personal goal for behaviour change to self-manage their risk factors, made a corresponding action plan, and were able to monitor goals by entering data (e.g. blood pressure or a food diary). They could also join behaviour change activity groups and correspond with their coach, whom they met in person at the initial assessment.

Participants in the control group had access to general static (not interactive) web-based information on cardiovascular risk, without any coach support.

**Outcomes**

In France, 10,229 potential participants were invited primarily through mass mailing campaigns using commercially available mailing lists. From these invitations 375 people were recruited. In the Netherlands 24,845 individuals were identified and invited by their GP to participate and, of those, 1,524 people were recruited. In Finland, 10,392 individuals were identified via a national population registry, based on area of residence and age, and invited by the researchers. Of those, 898 were recruited. Of the 2,797 who were recruited, 72 declined to participate further and one requested for the data to be withdrawn, leaving 2,724 participants.

Across all three countries, participants were evenly split between men and women and were of an average age of 69 years. Around 40% of participants had completed tertiary education. Almost all participants were of White ethnicity, with only around 2% recorded as “Other” ethnicity, which was not defined in the study. Approximately 30% of study participants reported a history of CVD. Around two thirds were on antihypertensive medication, just over half on lipid-modifying medication, around a third on antithrombotic medication and one in five on blood glucose-lowering medication.
There was a high completion rate among participants (88%) after 18 months. Authors noted that a small proportion of participants had died but those who withdrew were largely older and had a lower level of education. The characteristics and proportion (approximately 10%) of those that dropped out was similar across both the intervention and control groups suggesting that drop out was unlikely to be related to the intervention, but could have been related to the digital nature of both the intervention and control provision. The proportion who completed and withdrew from the study were not reported according to ethnicity or sex. Authors reported that individuals most in need and hardest to reach were likely to be under-represented.

The RCT showed that product users logged in more often than the control group. The total number of logins was 59,441 in the intervention group versus 17,014 in the control group. The median number of logins was 1.8 times per month for product users compared with 0.7 times in the control group (interquartile range 1.1–2.9 vs 0.5–0.9). Average use of the product was twice a month, with a wide range and a substantial number of users completing more than five logins a month. More than 90% (1,075 of 1,189) of users in the intervention group messaged their coach every month, with more than half (56.5%, 672) sending six or more messages to their coach per month and less than 10% (114) of users not sending any messages.

The primary study outcome measure was a composite CVD score consisting of systolic blood pressure, low-density lipoprotein cholesterol, and body-mass index. A modest improvement (of -0.05 (0.09 vs 0.04)) in composite CVD score and risk profile occurred among people using the product compared with the control group over 18 months. Consistent improvements in individual risk factors were also seen in the intervention group, with the effect driven by a significant reduction in body-mass index. Analysis showed that 65–70-year-olds and those with the lowest educational attainment might benefit most from access to HATICE.

**Learning**

As a digital behaviour change intervention to be used after a cardiovascular health assessment, this coach-supported digital product is feasible to deliver. It is acceptable to both men and women aged 65 years and over, but it is not known how well used it would be among individuals with existing dementia or very low levels of digital literacy as these individuals were excluded from the RCT.

The recruitment approaches used in the RCT show that only about 3% of those invited are eligible and interested in participating when a mass mailing recruitment approach is used. The product has the potential to engage a greater proportion of invitees when a more targeted approach is adopted and when the messenger extending the invitation is a trusted and known source, such as a GP.
Among users, the product resulted in favourable changes in behaviour with statistically significant reductions in body-mass index and modest reductions in the composite measure of CVD risk compared with the control group.
HealthNavigator\textsuperscript{14}

Introduction

This digital example, from Australia, draws on information from one scientific paper.\textsuperscript{14} It describes a digital product which aligns with the following components of the NHS Health Check pathway (appendix E): risk factor measurement; CVD, diabetes and kidney disease risk calculations; and communication of risk to the patient.

Purpose

The product aims to identify a user’s risk of heart attack, stroke, diabetes and kidney disease and provides support to help the user manage and reduce that risk. It does this by:

- enabling adult users to self-assess their risk of CVD, diabetes and kidney disease
- providing links to local behavioural and medical services on the basis of the users results
- providing the opportunity for users to engage with the product independently or as part of a community health screening programme

Product

This web-based product takes users through a screening questionnaire to collect self-reported information on their demographics, diet, physical activity, medical history, medications, waist circumference, height and weight. The user is also asked to self-report information on blood pressure, blood glucose, and cholesterol or, if left unpopulated, the product defaults to using national population averages.

Users are then presented with a report (figure 2) containing their three calculated risk indices using traffic lights: Framingham CVD risk score,\textsuperscript{15} diabetes risk based on the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)\textsuperscript{16}, and kidney disease risk based on chronic kidney disease risk score\textsuperscript{17} along with results of the individual risk factor measures. The report can be printed or emailed as a PDF attachment, for example, to be shared with a healthcare practitioner in primary care for follow-up medical care.

A list of services, ranked to align with the users results, are also provided through the product. The directory underpinning this list of services is maintained by the local primary-care organisation and can provide information on the cost, location and contact details of local services. This includes GPs, a range of lifestyle programmes, such as exercise programmes, psychological support groups and culturally specific outreach programmes. For listed services that are supported by the local primary care network, users can self-refer via the product by leaving their contact details and requesting more information.
Using an observational prospective cohort design, two approaches to the implementation of the product were evaluated in Australia:  
- self-guided – the product was promoted through a marketing campaign using local media and was freely accessible to any adult for self-completion  
- community-facilitator guided – the product was made available on tablets at 14 community centres as part of five existing community outreach programmes, where health workers supported individuals to use the product. Of the five programmes, one provided general health screening, two targeted socially disadvantaged groups, one was specifically for culturally and linguistically diverse groups, and one for Aboriginal and Torres Strait Islander communities.

Outcomes

In total, 2,013 completed questionnaires and self-reported measures were recorded during the year-long evaluation. The average age of users was 46.9 years, and 61.5% were women. Based on self-reported postcodes, 74.1% of users (1,492 of 2,013) were Queensland residents. All the data reported related to the 1,492 Queensland-based users. Users were from across socioeconomic groups with 40% of completed
questionnaires and self-reported measures from users from the most affluent quartile, 24% from the second most affluent quartile, 11% from the third most affluent, and 26% from the least affluent quartile. The authors did not compare these figures with the general population of Queensland. Just over 41% of users reported a birthplace outside Australia, with most of those born in Asia and Latin America. Around 10% of users identified as Aboriginal or Torres Strait Islander, and 5% as Maori or Pacific Islander. The extent to which users were representative of the community was not reported, with the exception of age distribution for those using the product aged over 25 years, which was similar to the distribution in Queensland Census data.

There was no significant difference in socioeconomic status among those who engaged with the product via the community-facilitator guided approach compared with those who used the self-guided approach. When compared with self-guided users, those who used the community-facilitator guided approach were significantly more likely to be: born outside Australia (80.5 vs 33.2%); in the high CVD risk group (19.8 vs 13.7%); and in the high diabetes risk group (58.0 vs 40.1%).

Combined results were presented for the two implementation approaches. Overall, most users accessed the product via a desktop computer (78%), with the remaining 22% using a tablet device (13%) or a smartphone (9%). Usage characteristics were markedly different for tablet users (most of whom used the community-facilitator guided approach) compared with other devices in terms of mean session duration (12 vs 3 minutes), page views per session (7.0 vs 3.5 views) and instances where the product was closed within seconds of opening it (19.4% vs 43.6%). The authors concluded that this showed that the community facilitator-guided approach resulted in a greater depth of user engagement. Anecdotal feedback from the facilitators suggested that supporting users with the product often led to a conversation between them and users on the recommendations.

Two in five users (610 of 1,492, 40.9%) had three or more risk factors at abnormal levels. Over half (853 of 1,492, 57.2%) of users were identified as being at increased risk of chronic kidney disease based on Australian guidelines, 37.0% were identified as not being at increased risk, 2.8% reported having a pre-existing diagnosis of the disease and for 3.0% their risk could not be assessed because of missing information.

Around one in five users (293 of 1,492, 19.6%) were supported by a health professional to use the product as part of the community-facilitator guided programme. For those using this approach, there was the option to request a follow-up behaviour change service. Despite the longer duration of interaction with the product by users of the community-facilitator guided approach only 4% (13 of 293) did so.
However, the lack of integration between the application and other data sources, including available referral programmes and GP records, means the trial is likely to have underestimated user follow-up.

Uptake of the product among the general population was low (at less than one percent of the estimated adult population), although the risk factor profile of users was broadly representative of the general population, with the exception of physical inactivity and smoking status which were higher. User engagement increased during periods when the product was promoted in local media.

**Learning**

The evaluation of this product shows that it is feasible to use digital products to deliver community CVD risk questionnaires to large numbers of individuals using a combination of a self-guided approach, and a community-facilitator guided approach. To drive use of a publicly available product, a marketing campaign is crucial. Although in this example it did mean that about a quarter of users were residents outside of the geography of interest. Through digital interventions, it is possible to reach individuals at higher than average risk of CVD, such as those with lower physical activity levels and higher rates of smoking, although overall a greater proportion of users were from more affluent groups.

When given face-to-face support to access and engage with a digital health product, individuals born outside their country of residence, and those at high CVD and diabetes risk are more likely to use it.
Consumer Navigation of Electronic Cardiovascular Tools (CONNECT)\textsuperscript{19,20,21,22,23}

Introduction

This digital example, from Australia, draws on information from five scientific papers.\textsuperscript{19, 20, 21, 22, 23} It describes a digital product which aligns with the following components of the NHS Health Check pathway (appendix E): risk factor measurement, calculating CVD risk, communication of risk and supporting individuals to make behavioural changes and access clinical care which supports them to reduce their risk of CVD.

Purpose

The purpose of the digital product is to communicate CVD risk and promote CVD risk management among people known to be at high risk of or with an existing diagnosis of CVD. It does this by:

- linking to the user’s electronic health record to enable the user to view their CVD risk score and individual risk factor results
- visually presenting to the user the impact of managing their risk factors on their absolute CVD risk
- improving adherence to blood pressure lowering and lipid lowering (statin) medication
- managing risk and modifying behaviours including healthy eating, smoking cessation, and physical activity

Product

The product is a web-based application accessible on any internet-enabled device including desktop, tablet, and smartphone. It was developed in a multi-stage iterative process involving clinicians, academics, software developers and proposed end users.\textsuperscript{19}

Each user’s electronic health record data is automatically uploaded to the product once authorised by the user’s GP. The information uploaded includes current medical conditions, prescribed medications, weight, waist circumference, blood pressure, cholesterol, and HbA1c for individuals with diabetes. The product then synchronises with the electronic health record to allow relevant changes to be uploaded to the product.

The product presents users with a personalised 5-year CVD-risk score calculated from the risk factor data recorded in the user’s electronic health record (figure 3). The personalised risk score can be modified by the user to see how changing their risk factor profile can influence their overall score. Users are encouraged to set goals on diet, exercise, smoking cessation, and emotional wellbeing. Through the product they can track these goals and are incentivised to achieve them through virtual rewards.
Users can enter their own data between visits to the GP, including weight and blood pressure, to track their progress. Although user-entered data is used for goal tracking and other functionality within the product, it does not upload into the patient's electronic health record. Additionally, this data does not update the user’s personalised CVD-risk score, which draws on data from the electronic health record alone.

The product also provides interactive goal-setting support; where automated tailored messages about prevention and motivation, including those related to behaviour and medication can be sent to users via email, SMS or both. This functionality can be switched on and off according to user preference. The product includes a social media component allowing users to read or write comments and ask questions. This is moderated by a clinician. Calendar links within the product also allow users to record dates for tests and appointments.

Figure 3: Screenshot from CONNECT app

Implementation
The product has been evaluated as part of a randomised controlled trial (RCT)\textsuperscript{20} and a qualitative study\textsuperscript{21} among users with moderate to high CVD risk (defined as a five-year CVD risk of 10\% or greater using the Framingham risk score\textsuperscript{23} a clinically high-risk condition based on Australian Guidelines,\textsuperscript{24} or an existing CVD diagnosis) from 23 GP practices and one Aboriginal Community Controlled Health Service.

Eligible patients were identified from electronic medical records and invited, by letter, to participate by their GP and followed up with a telephone call from the research team.\textsuperscript{22} Participants in the intervention arm of the study were shown how to use the product and were provided with four sessions of telephone and/or email support over a 26-week period, and a follow-up at 12 months. The control group were offered usual care which did not include any digital products, followed by 12 months access to CONNECT at the end of the study.

Research assistants visited participants at baseline, 12 and 24 months to ensure clinical and survey data had been recorded onto an online database. At the 12-month and 24-month assessments, access to CVD management services by both groups was assessed, including the frequency of GP and specialist visits (self-report), access to allied health services (e.g. dietitians and psychologists) and community groups or activities (e.g. local walking group, online smoking cessation programme). Data from CONNECT was extracted monthly to determine usage patterns.

**Outcomes**

Of the 3552 individuals invited to take part in the RCT, about a quarter (26.3\%, 934 of 3552) were recruited to the study. This consisted of 77\% men, with a mean age of 67.6 years, 85.9\% white ethnicity, 21.6\% with the lowest weekly household income, 28\% with 12 or less years of education, and 41\% with existing CVD.\textsuperscript{20} Of those recruited, 486 were allocated to the intervention group and 448 to the control group. Overall, 93\% (451 of 486) of people in the intervention group used the product in some way.\textsuperscript{20} Characteristics of those invited to participate were not described beyond the eligibility criteria.\textsuperscript{20} At the 12-month follow-up 26 and 17 participants had dropped out from the intervention and control groups respectively.\textsuperscript{20} This was identified by ‘did not consent to prescription data linkage’ and ‘withdrawn’.

During the 12-month period, each participant logged on to the product an average of 18 times, with the goal tracking/progress function being the most visited interactive screen.\textsuperscript{21} The chat forum was the least visited.\textsuperscript{21} Additionally, 69\% (274 of 397) of users engaged with the self-monitoring components of the product, updateable risk factors and the medication input functions. Of these, 52\% (143 of 274) reported it was helpful to be able to add personal measurements in this way.\textsuperscript{21} Of users who reported using the optional email message format (322 of 397), 55\% found the emails helpful.\textsuperscript{21} Of users
who reported using the optional SMS format (267 or 397), 54% reported the messages as helpful.\textsuperscript{21}

The product did not improve medication adherence.\textsuperscript{20} Adherence was defined as the patient being dispensed 80% or more of their prescribed medication, which was one blood-pressure lowering drug and a statin, in line with Australian guidelines, over the course of 12 months. There was borderline improvement in risk factor control; achieving blood pressure and fasting low-density lipoprotein (LDL) cholesterol (as defined by Australian guideline targets as: ≤130/80 mmHg for CVD, diabetes, or albuminuria or ≤140/90 mmHg for all others) between users of the product and the control group (17.1% vs 12.1%).\textsuperscript{20} The RCT also showed a significant difference in meeting physical activity recommendations\textsuperscript{25} between users of the product compared with the control group (87.0% vs 79.7%).\textsuperscript{20} However, authors recognised that the study was limited by the small sample size.\textsuperscript{20}

Interoperability between the product and the electronic health record was largely seen as advantageous and GPs reported the following benefits:
- improvement in CVD knowledge and risk awareness among users
- improved health related behaviour of patients
- modified attitude of patients to their health care
- facilitated positive experience of the product\textsuperscript{21}

Both GPs and patients were, in principle, in favour of further interoperability between the product and the electronic health record with a genuine two-way interface in future.\textsuperscript{23} The concerns expressed, by both groups, were primarily about the security risk to personal data.\textsuperscript{20} Although most GPs were in favour of further interoperability, they raised additional implementation concerns including questions around equitable consumer access to the product and workflow effects.\textsuperscript{21}

**Learning**

This example shows that it is feasible to deliver a digital product which is interoperable with electronic health records and able to use that data, rather than rely on self-reporting, in order to assess an individual’s CVD risk.

Users of CONNECT can be largely characterised as men in their mid-60s from more affluent socio-economic groups, of a White ethnicity and with higher levels of education.

About a quarter of people invited by their GP to use CONNECT engaged in some way. Furthermore, those who access the product do so repeatedly over a 12-month period suggesting a high level of acceptability among users.

The product did help users achieve favourable improvements in physical activity, to guideline levels,\textsuperscript{20} although it did not seem to improve users’ adherence to prescribed antihypertensive and cholesterol-lowering medication.\textsuperscript{20,21}
Both users and GPs valued the interoperability of the product with the user’s electronic health record. Concerns for security of personal information were identified particularly in relation to allowing the product to update data in the user’s electronic medical record.

The product was developed using an iterative process and user feedback was integral to the product’s design. For example, conflicting user feedback regarding receipt of automated tailored messaging via SMS and email led to the product design incorporating the functionality to switch tailored messaging on and off. A survey of users of the product in the RCT who opted to use the message function found the majority reported the messages to be helpful, highlighting the importance of user insight as a component of product design.
Engaging and Motivating Patients Online With Enhanced Resources (EMPOWER)\textsuperscript{26,27}

Introduction

This digital example, from the United States of America (US), draws on information from two scientific papers.\textsuperscript{26,27} It describes a digital product which aligns with the following components of the NHS Health Check pathway (appendix E): risk factor measurement, ongoing behavioural risk management, supporting individuals to make behavioural changes, and recording of patient information directly into the electronic health record.

Purpose

The product aims to provide a personalised approach to remotely support behavioural changes, that lead to direct improvements to a user’s blood pressure outcomes by:

- supporting direct communication between user and clinician
- providing personalised user-input data to the clinician
- providing personalised feedback to the user based on their own user generated health data in conjunction with data from the user’s electronic health record

The product is designed to be adaptable to any chronic condition where behaviour change can improve health outcomes.

Product

The product is a web-based disease management system, EMPOWER-H, which is an enhanced version of EMPOWER-DIABETES (EMPOWER-D).\textsuperscript{26,27} EMPOWER-H consists of a user (patient) interface as well as a separate practitioner interface. The user interface allows an individual to update their data, view a summary, monitor their health status over time, and communicate with their health care professional. A web-based interface can be accessed by the user's health care professional to monitor user input data and communicate with them. The product also includes the use of a wireless blood-pressure monitor and a pedometer. Both the user and the health care provider have access to the user-uploaded information, via the different interfaces, to allow tracking of progress.

This product uses a range of sources to collect user health data on:

- blood pressure - EMPOWER-H includes a wireless blood pressure monitor that directly transmits home blood pressure readings to the user's electronic health record and the EMPOWER system via a smartphone app. Users are unable to modify the data transmitted from the home blood pressure monitor to the EMPOWER-H system. Users can also have blood pressure measured in the clinical setting with a health care professional and then uploaded into the system
by the clinician. However, this is ad hoc and users primarily or exclusively self-report.

- **physical activity** - a pedometer is provided to allow users to track their physical activity, users are encouraged to upload their daily step count.
- **weight** - there is also the capability to use scales to wirelessly upload their weight. Alternatively, users self-report.
- **diet** - fruit and vegetable consumption, consumption of high-salt and high-fat foods. This is self-reported by answering questions derived from Block food questionnaires\(^{28,29}\)
- **smoking status** – self-reported

Users are monitored daily by their health care professional using the provider dashboard which uses both a 14-day average of home blood pressure data and frequency of blood pressure uploading (as a measure of engagement) to prioritise users’ level of risk from high to low. Users are asked to upload blood pressure readings twice a day on three days a week. Alerts are sent to the health care professional when users report critically high blood pressure. The product includes a two-way messaging service, allowing continued contact and support from the health care professional assigned to monitor their progress. Using the data in EMPOWER-H, the health care professional can provide tailored support using a library of web-based education handouts and feedback messages, which can be sent directly to the user as a secure message.

In addition to submitting measurements the product also invites users to participate in healthy shopping tours and cooking classes, webinars on behavioural change, pedometer challenges and healthy recipe challenges.

**Implementation**

The product’s impact on blood pressure control has been evaluated in the US, using a pre-post design.\(^{26}\) Adults aged 35-75 years with an existing diagnosis of hypertension and uncontrolled hypertension were identified through the electronic health record systems of two health care sites. Eligible individuals were invited to use EMPOWER-H over a six-month period by their primary care physician, either via a pre-existing web-based patient portal (My Health Online) or letter. Six months constituted the end point of the study at which point changes in clinical blood pressure, home-monitored blood pressure, body mass index, and behavioural outcomes were assessed.

The product was introduced during an initial face to face meeting between a health care professional and user, after the user had undertaken seven days of home blood pressure measurements. The health care professional would address questions, educate about CVD risks, provide support on using the product and the associated devices (including smartphone apps, blood pressure monitor, and pedometer), setting attainable goals, reviewing the products data dashboard, and developing a personalised
blood pressure plan. Users were also encouraged to meet with a registered dietitian to discuss their diet and recommended changes. Users were then contacted a week later through the in-app messaging service or by phone to check their progress in using the product.

Outcomes

Of the 1467 individuals invited to take part, 149 enrolled and 147 were assessed at the end of six months. The mean age of participants was 62.2 years, a third (33.3%) were retired, 76% were non-Hispanic white, and participants had a relatively high level of education with 96.6% having post high school education.

At six months, 55.9% of users achieved the primary outcome measure of clinical blood pressure goals (defined as <140 mm Hg for systolic blood pressure and <90 mm Hg for diastolic blood pressure), compared with 30% receiving the usual care alone. 86% of users achieved clinically meaningful reduction of blood pressure (defined as reduction in systolic blood pressure ≥5 mm Hg or reduction in diastolic blood pressure ≥3 mm Hg). All users were monitoring blood pressure at home and the success rate, as measured at home, correlates to the clinical outcome measure. For home monitored blood pressure goals (<135 mm Hg for systolic blood pressure and <85 mm Hg for diastolic blood pressure), success increased from 25.2% to 71.4%.

Authors reported that users significantly decreased their body weight, increased their consumption of fruit and vegetables, reduced consumption of foods high in salt and fat, and increased their aerobic exercise. Users also significantly increased their hypertension knowledge. However, there were limited effects on their smoking status. Given the design of the evaluation these outcomes can’t be attributed directly to the product.

However, there was an association between the increased number of interventions taken up (behavioural, pharmaceutical, and patient initiated contacts) and improved outcomes for clinical blood pressure. For home blood pressure, more data uploads were also associated with improved outcomes, but the odds of achieving these outcomes were reduced as the number of interventions increased.

Health care professionals reported that regularly home recorded and updated blood pressure levels helped them to make day-to-day clinical management decisions. Multiple recording times and regular uploads showing patterns of blood pressure changes, including insights into blood pressure variability by time-of-day that presented new opportunities for personalised management. The health care practitioners’ confidence in this data was also supported by users being unable to modify the blood pressure recordings, which were wirelessly uploaded to the product.
A potential limitation of the paper is that one of the authors, also the corresponding author, owns a significant financial interest in EMPOWER.\textsuperscript{26}

**Learning**

The high completion rate suggests that EMPOWER-H seems to be acceptable to both men and women aged between 52 and 72 years with uncontrolled blood pressure. Individuals with serious medical conditions (e.g. diabetes or stroke), and severe mental health issues, however, were excluded.

High levels of acceptability existed among health care professionals who recognised that EMPOWER-H helped them to make day-to-day clinical management decisions.\textsuperscript{26} In doing so, use of the product appeared to contribute to improvements in users’ clinical and home measured blood pressure, weight, and behaviours; however, the strength of this finding is limited by the study design.

EMPOWER-H is not fully automated and requires additional resource commitments from the health care professional to support the users, to monitor blood pressure readings, and communicate with them in order to provide a personalised intervention. However, it may provide a form of behaviour intervention which is less intensive than standard face-to-face formats.
References


International examples of digital cardiovascular risk assessment and management


randomized controlled trial. Npj Digital Medicine. 3. 117. DOI: 10.1038/s41746-020-00325-z.


Appendix A: Method

To maximise the identification of examples PHE undertook a search for scientific papers. A search of the online databases Web of Science, Embase and Medline was undertaken to identify relevant papers featuring digital interventions. The search strategy used is shown in appendix C. For all searches, limits were applied to include only English language articles published in the past 10 years (2010-2020).

- Digital examples of interest were those that: targeted adult populations, assessed multiple health risk factors, communicated results and supported users to access follow-on services where the results indicated high risk of ill health.

The database search with exclusion criteria generated 10,828 records. Duplicates were removed, leaving 6,398 records. To identify papers potentially suitable for inclusion, an initial sift of the abstracts was done using the following criteria:

- digital intervention
- measurement of two or more of the following risk factors: CVD risk, smoking, body-mass index (BMI) or obesity, blood pressure, pulse rhythm, cholesterol, blood glucose, alcohol, physical activity, mental health, musculoskeletal (MSK) health
- participants aged 25 years and over

The 1,410 identified articles were sifted based on the inclusion and exclusion criteria set out in table 1. Eppi-Reviewer was used to generate the random sample and Rayyan to support blind screening by reviewers.

Table 1: Inclusion and exclusion criteria of search

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papers must have been published in the past 10 years (i.e. 2010-present)</td>
<td>Papers published pre 2010</td>
</tr>
<tr>
<td>English language only</td>
<td>Non-English language</td>
</tr>
<tr>
<td>Digital intervention</td>
<td>Exclude non-digital interventions</td>
</tr>
<tr>
<td></td>
<td>Exclude telemedicine only</td>
</tr>
<tr>
<td></td>
<td>Exclude interventions in which texts/emails as mode of communication only</td>
</tr>
<tr>
<td>Measurement of two or more of the following risk factors: CVD risk, smoking, BMI/obesity, blood pressure, pulse rhythm, cholesterol, blood glucose, alcohol, physical activity, mental health, MSK</td>
<td>Exclude interventions which use twitter/ social media only</td>
</tr>
<tr>
<td></td>
<td>Studies that measure one or none of the following risk factors: CVD risk, smoking, BMI/obesity, blood pressure, pulse rhythm, cholesterol, blood glucose, alcohol, physical activity, mental health, MSK</td>
</tr>
</tbody>
</table>
Several reviewers participated in each stage of the sifting process. To ensure consistency in approach, the reviewers first sifted a 5% (71 of 1,410) random sample of the papers, the results of which were cross compared, and decisions discussed to ensure a consistent approach was used for the remainder of the papers.

An additional three reviewers were then included in the process. A second 5% (71) blinded random sample of retained references was assessed with one of the first four reviewers present to ensure consistency in interpretation. The remaining 90% (1,267 papers) were screened across six reviewers. 214 papers remained after this stage was completed.

From the 214 papers remaining, the final examples were included by the reviewers if the products that the papers evaluated met one or more of the following criteria:
- assessed CVD risk
- collected/recorded personal metrics as specified by the core requirements of the NHS Health Check
- provided tailored feedback to users e.g. communication of risk, targeted behavioural advice

As a result, five products were identified as practice examples, see appendix C for the literature search flow diagram.

The report includes limitations of each of the products and the studies they were tested in as part of each example. However, the report purposefully does not offer a full critical appraisal of the papers and is a limitation of this descriptive piece of work.

The Template for Intervention Description and Replication¹ (appendix D) was used to identify the information for each example. This information was then presented under the following structure: introduction, purpose, implementation, outcomes and learning. Where possible, information was extracted from other published sources and communication was initiated with authors to fill in gaps.
Appendix B: Literature search flow diagram

Records identified through database searches
(n = 10,838)

Records screened after duplicates removed
(n = 6,398)

Records screened in second sift
(n = 1,410)

Records excluded
(n = 1,196)

Records excluded
(n = 4,988)

Full-text articles assessed for eligibility
(n = 214)

Final Examples
5
based on n = 8 papers

Additional records identified through other sources
(n = 14)

The above is adapted from the PRISMA flow diagram\textsuperscript{30}
Appendix C: Embase search strategy

Database: Embase <1974 to 2020 November 03>
Search Strategy:
--------------------------------------------------------------------------------
1 (primary adj3 prevention).tw. (37953)
2 ((intervention* or program* or coach*) adj3 (behavior* or lifestyle* or life style* or risk*)).tw. (73036)
3 (prevent* adj3 intervention*).tw. (54869)
4 (multiple adj3 (factor* or domain* or risk*)).tw. (66905)
5 ((multifactorial* or multi factorial*) adj3 (prevent* or intervention* or program*)).tw. (1755)
6 ((multidomain* or multi domain*) adj3 (prevent* or intervention* or program*)).tw. (344)
7 ((multimodal* or multi modal*) adj3 (prevent* or intervention* or program*)).tw. (3607)
8 ((Multidimension* or multi-dimension*) adj3 (prevent* or intervention* or program*)).tw. (1085)
9 (Multiple adj3 (prevent* or intervention* or program*)).tw. (13259)
10 intervention*.ti. (207616)
11 or/1-10 (415563)
12 exp *Health promotion/ (38324)
13 exp *prevention/ (454487)
14 exp *Health education/ (113700)
15 risk reduction/ (106286)
16 or/11-15 (1039832)
17 exp *mental health/ (46696)
18 mental health.tw. (187289)
19 exp *musculoskeletal disease/ (1384849)
20 musculoskeletal.tw. (71894)
21 exp *cardiovascular disease/ (2506532)
22 metabolic syndrome X/ (85265)
23 (cardiovascular or cardiometabolic).tw. (669145)
24 exp *lifestyle/ or *lifestyle modification/ (30282)
25 ((life style* or lifestyle*) adj3 (choice* or habit* or behavior* or risk*)).tw. (22807)
26 (behavior* or risk* adj3 intervention*).tw. (56424)
27 (life style* or lifestyle*).ti. (23887)
28 or/17-27 (4538266)
29 (web based or (internet adj3 (intervention* or deliver*)) or (online adj3 (intervention* or deliver*)) or website or web app* or health app* or lifestyle app* or life style app*).tw. (86560)
30 (mobile or smart phone* or smartphone* or text message*).tw. (151743)
International examples of digital cardiovascular risk assessment and management

31 (mhealth or ehealth or m-health or e-health).tw. (9478)
32 digital*.ab. /freq=2 (40276)
33 digital*.ti. (49707)
34 *internet/ or *web-based intervention/ or *social media/ (44281)
35 online.ti. (26537)
36 exp *mobile phone/ (12817)
37 *telemedicine/ or *telehealth/ or *teleconsultation/ or *teletherapy/ (21833)
38 exp *mobile application/ (6821)
39 *web browser/ (1619)
40 *information technology/ (2795)
41 *text messaging/ (2247)
42 or/29-41 (377195)
43 16 and 28 and 42 (5250)
44 limit 43 to (english language and yr="2010 -Current") (4614)
Appendix D: TIDieR Framework

Brief name
1 Provide the name or a phrase that describes the intervention [what is it?]

Purpose
2 What was the aim and objectives of the digital tool and its application?

What
3 Digital tool: Describe the digital tool used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)

Procedures:
4 Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities

Who provided
5 For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given. In this case the provider is the digital product. If there are any individuals that support the patient with using the digital product then do describe their role, background and any specific training given.

How
6 Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. The primary mode is going to be digital but clearly that can be wrapped in to care pathways in different ways so important to capture how the technology was used or could be used here.

Where
7 Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features

When and How Much
8 Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose

Tailoring
9 If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how

Modifications
10 If the intervention was modified during the study, describe the changes (what, why, when, and how)

How well
11 Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12 Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned
Appendix E: NHS Health Check pathway

NHS Health Check

Identification and invite eligible population
Age range 40 – 74 years

Body Mass Index
Blood Pressure
Ethnicity
Gender
Age
Use
Smoking Status
Physical activity
Family history
Cholesterol

Recall in five years

NHS Health Check
Primary Care follow up

Results must be recorded on the primary care record
What is good for your heart is good for your brain
Stop smoking services
Alcohol brief intervention or referral
Physical activity intervention

Weight management services
Pre-diabetes service
65 or over: Dementia awareness & signposting

Results recorded on the primary care record. Exit the programme if exclusions apply

Diabetes filter:
Use validated diabetes risk assessment tool. If a person is identified as being at high risk of type 2 diabetes, offer HbA1c or fasting glucose test.

Chronic Kidney Disease filter:
If BP >140/90 assess for Chronic Kidney Disease and offer Serum Creatinine.

If blood pressure high also need HbA1c or FPG, offer Serum Creatinine.

Diabetes
Hypertension
Chronic Kidney Disease
Cirrhosis
Medication
Lifestyle advice
If CVD risk >10% consider statins
Signposting and/or referral

Start

Risk assessment
CVD risk communication

Clinical assessment

Risk management

Lifestyle risk management
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PHE gateway number: GW-8673

www.gov.uk/phe
Twitter: @PHEuk
www.facebook.com/PublicHealthEngland

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