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Evaluating the use of the heart age tool in community pharmacies: a 4-week cluster-randomized controlled trial

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Background: Joint British Societies have developed a tool that utilizes information on cardiovascular disease (CVD) risk factors to estimate an individual's 'heart age'. We studied if using heart age as an add-on to conventional risk communication could enhance the motivation for adapting to a healthier lifestyle resulting in improved whole-blood cholesterol and omega-3 status after 4 weeks. **Methods:** A total of 48 community pharmacies were cluster-randomized to use heart age+conventional risk communication (intervention) or only conventional risk communication (control) in 378 subjects after CVD risk-factor assessment. Dried blood spots were obtained with a 4-week interval to assay whole-blood cholesterol and omega-3 fatty acids. We also explored pharmacy-staff's (n=27) perceived utility of the heart age tool. **Results:** Subjects in the intervention pharmacies (n=137) had mean heart age 64 years and chorological age 60 years. In these, cholesterol decreased by median (interquartile range) −0.10 (−0.40, 0.35) mmol/l. Cholesterol decreased by −0.20 (−0.70, 0.30) mmol/l (P difference =0.24) in subjects in the control pharmacies (n=120) with mean chronological age 60 years. We observed increased concentrations of omega-3 fatty acids after 4 weeks, non-differentially between groups. Pharmacy-staff (n=27) agreed that heart age was a good way to communicate CVD risk, and most (n=25) agreed that it appeared to motivate individuals to reduce elevated CVD risk factors. **Conclusions:** The heart age tool was considered a convenient and motivating communication tool by pharmacy-staff. Nevertheless, communicating CVD risk as heart age was not more effective than conventional risk communication alone in reducing whole-blood cholesterol levels and improving omega-3 status.

Introduction

Successful prevention of cardiovascular disease (CVD) includes predicting and communicating risk and tailoring preventive efforts accordingly.[1] Identifying and acting on high CVD risk factors early in life can prevent rapid accumulation of the risk-factor burden and consequently CVD.[1,2] We have previously shown that community pharmacy is a high-yield arena to detect hyperlipidemia.[3] A systematic review found that pharmacists-led interventions in general practice reduce medical risk factors of CVD.[4] However, except for smoking cessation interventions,[5] few studies have investigated effects of lifestyle-interventions in community pharmacies. Consequently, we previously conducted a randomized controlled trial (RCT) in community pharmacies [minus (−) 52-weeks RCT].[6] The aim was to study if alerting subjects to their elevated CVD risk through conventional risk communication would result in participants adopting to a healthier lifestyle and consequently present favorable risk-factor levels after 8 weeks.[6] Conventional risk communication included comparing assessed CVD risk-factor levels to predefined color-marked cut-off levels followed by risk-factor targeted diet and lifestyle advice.[6] However, this approach was not effective in reducing risk-factor levels.[6] Such numeric risk presentation can be perceived as technical and vague.[7–9] How risk is communicated and consequently understood is often vital to how risk is acted upon.[9] We hypothesized that the previous ineffective intervention could be due to misperception or unrecognition of own risk.[7] We therefore sought to overcome these probable barriers of risk communication by conveying the result of assessed CVD risk as the visual and simple context of an individual's heart age developed by Joint British Societies (JBS) based on QRISK2 lifetime risk of CVD.[1] An immediate recognizable heart age older than own chorological age is thought to motivate to preventive lifestyle behavior aiming at reducing heart age and consequently CVD risk.[1,10] Lopez-Gonzalez et al. has previously shown that conveying information on CVD risk as heart age was more effective than traditional risk score (Framingham REGICOR) in reducing risk in a primary health-care setting.[11] Hence, using a similar simplistic, real-life approach, our aim was to investigate the 4-week changes (as it is generally accepted that steady state occur after 4 weeks) in whole-blood cholesterol, fatty acids and physical activity level after using heart age + conventional risk communication (intervention) or only conventional risk communication (control) in subjects re-invited to pharmacies after attending the −52-weeks RCT.[6] In addition, pharmacy-staff's rated perceived utility of the heart age tool was investigated, in order to have multiple measures to evaluate the heart age tool for future applications.

Methods

Study design and randomization

This 4-week intervention study was initiated in unison with the 1-year follow-up of participants in the −52-weeks RCT[6] within the Vascular lifestyle-intervention and screening in pharmacies (VISA) study between September and November 2015.[3]

In total, 48 community pharmacies (carefully chosen due to their size and widespread distribution in Norway) were cluster-randomized (1:1) prior to the beginning of study visits to intervention or control. The intervention was to use heart age + conventional risk communication, whereas the control was to use conventional risk communication to convey information on CVD risk after point-of-care measurements of total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides, hemoglobin A1c (HbA1c), blood pressure, height and weight.[3,6] The randomization of pharmacies was executed in Microsoft excel version 2010, where pharmacies were sorted by size (number of subjects) in pairs, and each pair was randomized to either intervention or control. After one pharmacy with only one study participant was granted permission to change status till control, the final pharmacy assignment was 23 intervention pharmacies, and 25 control pharmacies.

Risk communication: intervention and control

In all 48 pharmacies, subjects were alerted to their assessed CVD risk in the outline of conventional risk communication, same as the −52-weeks RCT.[6] In short, each risk factor was categorized in four groups from favorable (green) to clearly unfavorable (red) following general recommendations.[12] The next step was to inform and empower subjects to make diet and lifestyle changes targeted to reduce any unfavorable risk factors. Diet and lifestyle advice was provided both verbal and as written material. The minimum advice was to choose healthy fats, increasing physical activity level and smoking cessation (Supplementary figure S1).

In the 23 intervention pharmacies, the heart age tool was used to further recognize risk and boost the motivation to comply with the diet and lifestyle advice. Pharmacy-staff plotted subject's age, gender, total- and HDL-C, blood pressure, smoking status, presence of diabetes or rheumatic disease plus living condition into the web-based JBS risk calculator (version 3, 2015).[10] This information yields an estimated heart age.[10] Subject's heart age was compared to chronological age where a higher heart age than chorological age was communicated as higher risk of CVD.[1] Within the risk calculator, there were supportive risk visualization tools available to illustrate the benefit of early (compared to later) interventions to reduce heart age.[10] Pharmacy-staff could decide whether they had time to show any of these additional risk visualizations.[10] No extra support or follow-up was provided in order to make the intervention close to a realistic pharmacy-setting (Supplementary figure S1). Intervention effects were assessed with dried blood spot (DBS) and VISA-food frequency questionnaire (FFQ). The primary outcome was 4-week change in whole-blood cholesterol concentration. Secondary outcomes were 4-week change in; eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), arachidonic acid (AA), AA/EPA ratio, omega-3 index and self-reported physical activity level, plus pharmacy-staff's rated perceived utility of the heart age tool.

Measurements and questionnaires

Background data on subject' age, sex, smoking status and educational level were obtained previously at the −52-weeks RCT.[3] Physical activity level was self-reported through the VISA-FFQ,[13] and recorded as the sum of minutes of vigorous and moderate physical activity per day as defined by Norwegian Directorate of Health and described previously.[14]

Pharmacy-staff collected an additional finger-prick blood sample using the method of DBS (Vitas Ltd, Oslo, Norway) during the pharmacy visit. The sampling method has been described.[13] Fasting samples were desired but not required. Subjects were not offered DBS sampling if they reported taking omega 3-supplements or eaten fatty fish within the last 12 h, or had late appointments (due to the ≥2 h drying time of the samples after sampling). Subjects were also instructed to self-sample DBS samples at home after 4 weeks. All completed samples were sent to the Vitas Ltd. laboratory for analysis of whole-blood cholesterol and fatty acids including EPA, DHA, AA and omega-3 index [EPA + DHA/(total fatty acids) × 100][15] using Gas Chromatography—Flame Ionization Detector.[16] Fatty acids were determined by extracting weights of fatty acid methyl esters (FAME) and thus reported as percentage of FAME (except omega-3 index).[17]

Consent was obtained before inclusion.[3,6] Additionally, all subjects were asked for written consent to DBS sampling. The study is approved by Regional Ethical Committee (2013/1660-D) in Norway, was carried out in accordance with the Helsinki Declaration and is registered at ClinicalTrials.gov (NCT02223793). Reporting of this article align with the CONSORT standards.

Study sample

The sample was obtained from the −52-week RCT, comprising 543 subjects free of CVD, including not taking any CVD-related medication (e.g. blood pressure and cholesterol lowering medication).[6] Due to limited capacity in the pharmacies, 508 participants were invited to the study visit, of whom 378 (193 randomized to intervention—and 185 to control pharmacies) attended. The final study sample consisted of 137 (intervention) and 120 (control) who completed DBS both in pharmacy and at home after 4 weeks. There was insufficient blood to analyze cholesterol concentrations in some. The corresponding numbers to analyze primary outcome whole-blood cholesterol were therefore 100 and 71 subjects, respectively (figure 1).

Pharmacy-staff and education

From 48 pharmacies, we have background information on 27 pharmacy-staff performing the study in the intervention pharmacies, and 21 pharmacy-staff from the control pharmacies. Only health-care providers staffed the study, hence the pharmacy-staff's background was pharmacy technicians ($n = 17$), pharmacists ($n = 19$) and nurses ($n = 12$).

There were 11 pharmacy technicians in intervention compared with 6 in the control pharmacies, otherwise, pharmacy-staff's background was similar across pharmacies. Almost all ($n = 44$) responded that they had also staffed the previous two visits of the VISA-study and hence had prior research experience. Pharmacy-staff had to verify completion of an e-learning course prior to study start. Staff in the intervention pharmacies also attended a mandatory 1-hour workshop with practical introduction to the heart age tool (Supplementary figure S1).

Evaluation of heart age tool by pharmacy-staff

To evaluate the utility of the heart age tool, pharmacy-staff in the intervention pharmacies were instructed to complete an evaluation form shortly after study-end. The responses from 27 pharmacy-staff were translated from Norwegian to English and presented with results in figure 2.

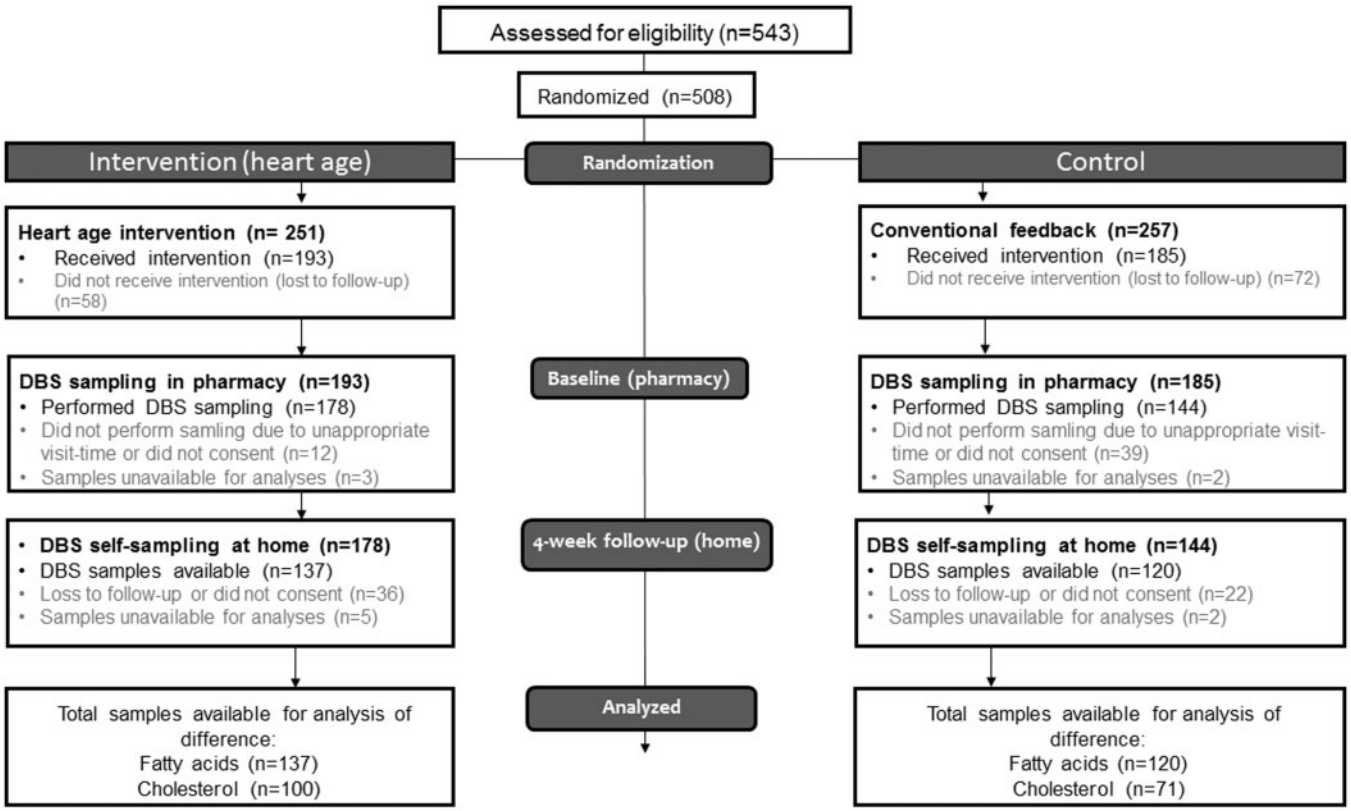

Figure 1 CONSORT flow chart of subjects randomized to either intervention or control

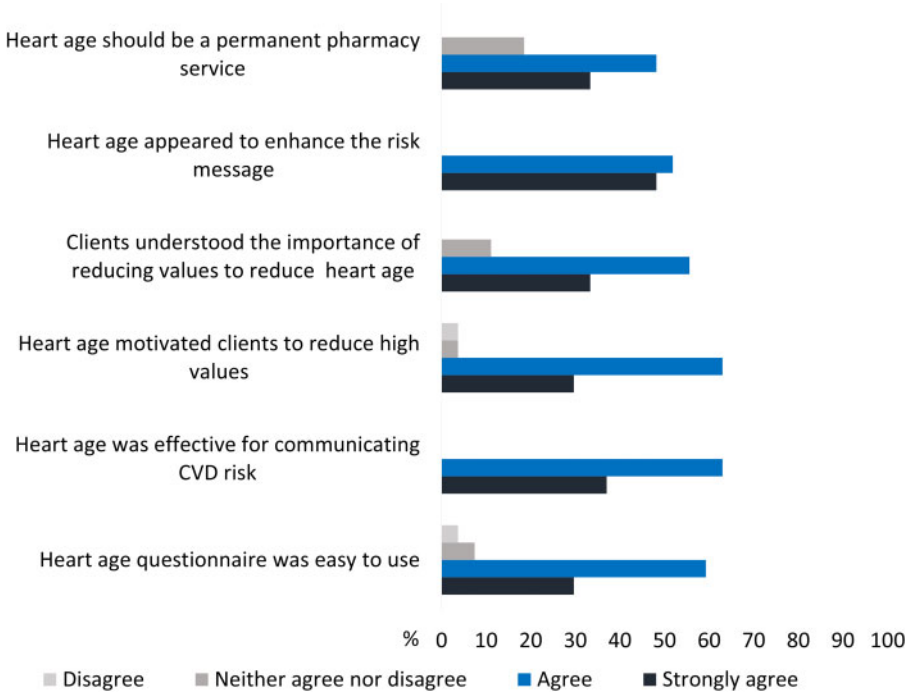

Figure 2 Health-care providers' (n=27) answers to the evaluation of the use of the heart age tool after the intervention. CVD, cardiovascular disease

Statistics

Baseline characteristics were presented as mean and standard deviation and difference between pharmacy-groups was tested using unadjusted linear regression. The primary and secondary outcomes were reported as median and interquartile range first and third quartile (Q1 and Q3, respectively). Differences between pharmacies were assessed using Wilcoxon two-sample test. Only complete cases were included in the analyses. As secondary approaches, we ran linear regression analysis and adjusted for age, sex and body mass index, and included pharmacy as a random effect in a linear mixed model to account for variance for pharmacy clustering. As the variance for pharmacy clustering was low, results from these secondary analyses were not presented. Pearson correlation coefficients (r) were also presented. SAS version 9.4 was used to execute the analyses. P-value <0.05 was set as significance level.

Results

Background characteristics

There were no differences in assessed total- and LDL-C, HbA1c, and blood pressure levels in subjects across pharmacies. Subjects in the intervention pharmacies had slightly lower HDL-C and higher share of male subjects (30% versus 19%) compared with subjects in the control pharmacies. Heart age was only calculated in the intervention pharmacies with mean 64.2 ± 13.8 years whereas chronological age was 60.1 ± 13.0 years. Chorological age in subjects in the control pharmacies was 60.5 ± 12.9 (table 1).

Cholesterol and fatty acids

Both pharmacy-groups had similar, minor decrease in blood-cholesterol concentration, with median (Q1, Q3) −0.10 (0.40, 0.35) mmol/l in subjects receiving the intervention and −0.20 (−0.70, −0.30) mmol/l in subjects in the control pharmacies (table 2). We observed a Pearson correlation of $r = -0.24$ between the disparity of chronological age minus heart age and change in blood-cholesterol concentrations.

Individuals in both pharmacy-groups improved their whole-blood fatty acid levels of EPA with median difference 0.12 (−0.12, 0.40)% of FAME in subjects in the intervention pharmacies, and 0.04 (−0.17, 0.26)% of FAME in subjects in the control pharmacies ($P = 0.12$). Improvements after four weeks were also observed for DHA and omega-3 index, whereas the median AA/EPA ratio tended to decrease in the intervention- and increase in the control pharmacies. Overall physical activity levels did not seem to change considerably after 4 weeks in any of the pharmacy-groups (table 2).

Perceived utility of the heart age tool by pharmacy-staff

As shown in figure 2, all intervention pharmacy-staff ($n = 27$) agreed or strongly agreed that estimated heart age appeared to enhance the risk message (more than just conventional risk communication that was previously used in the −52-week RCT). There was also unanimous agreement that the heart age was effective in communicating CVD risk. Most ($n = 24$) agreed that the heart age tool was easy to use, although attention should be paid to two that did not have an opinion, and one that disagreed with this assertion. A total of 22 agreed or strongly agreed that using heart age to communicated risk after CVD risk assessment should be a permanent pharmacy service, whereas five neither agreed nor disagreed with this statement (figure 2).

Discussion

We observed minor reductions in cholesterol concentration and increased concentrations of EPA, DHA and omega-3 index assayed in whole-blood 4 weeks after CVD risk assessment and communication using conventional risk communication alone or with the addition of heart age. The heart age tool was still perceived as easy and convenient to use by pharmacy-staff, and as a potential motivational risk reduction tool in a community pharmacy-setting.

Heart age quantifies lifetime risk of CVD, and has been developed as a tool to communicate and promote healthy lifestyle for risk reduction.[18] Similar easily recognizable tools have been shown to limit possible discordance between perceived- and actual risk.[19] Hence, as we had previously experienced that conventional risk communication was not effective in reducing CVD risk, our hypothesis was that the immediate recognizable message of a higher heart age than chorological age was more likely to promote immediate lifestyle changes than conventional risk communication alone. However, the results displayed similar, minor 4-week decrease in cholesterol concentration after both communication approaches. A systematic review from 2016 of studies using a varieties of vascular age,[20] identified only 2 out of 39 studies that were measuring the effect of using heart age as a communication tool to reduce risk; Bonner et al.[21] and Lopez-Gonzales et al.[11] Our results are in accordance with Bonner et al.[21] who found that using heart age to convey risk information in an online setting did not improve lifestyle behaviors compared with the use of 5-year absolute risk. In contrast, Lopez-Gonzalez et al.[11] found heart age to be more effective than a 10-year risk score in a Spanish population as part of an annual occupational health check. The overall observed minor reductions in cholesterol concentrations are in line with minor

Table 1 Background characteristics of subjects randomized to intervention (heart age+conventional risk communication, n=137) or control (conventional risk communication, n=120)

	Intervention		Control		P^a
	N	Mean±SD % (*n*)	*N*	Mean±SD % (*n*)	
Demographics					
Age, years	137	60.1±13.0	120	60.5±12.9	0.83
Heart age, years	125	64.2±13.8	–	–	–
Smoking daily or occasional (%)	137	9.4 (13)	120	13.3 (16)	0.32
Low education[b] (%)	137	53.6 (74)	120	48.3 (58)	0.36
Male (%)	137	30.4 (42)	120	19.2 (23)	0.04
Risk factors					
Total cholesterol (mmol/l)[c]	137	6.6±1.2	120	6.6±1.2	0.98
LDL-cholesterol (mmol/l)[c]	135	4.0±0.9	115	3.9±1.1	0.29
HDL-cholesterol (mmol/l)[c]	137	1.7±0.5	120	1.9±0.5	0.02
Triglycerides (mmol/l)[c]	137	1.9±1.1	120	1.9±1.1	0.82
BMI (kg/m^2)	137	27.5±4.9	120	26.1±4.0	0.02
Weight, kg	137	77.6±15.3	120	73.1±11.9	0.01
Diastolic blood pressure, mmHg	137	80.7±9.9	120	78.3±10.5	0.06
Systolic blood pressure, mmHg	137	129.0±16.2	120	125.8±18.0	0.14
HbA1c, %	137	5.5±0.3	120	5.5±0.3	0.33

a: Unadjusted linear regression was used for analyzing continuous variables and chi-square test for categorical variables.
b: ≤High school (13 years of schooling) as highest attained educational level.
c: Total cholesterol, HDL and triglycerides were measured with Alere Afinion™AS100 and LDL calculated using the Friedewald formula (only at baseline).
LDL, low-density lipoprotein; HDL, high-density lipoprotein; BMI, body mass index; HbA1c, hemoglobin A1c.

Table 2 Four-week difference in blood-cholesterol concentration and fatty acids between subjects receiving the intervention (heart age+conventional risk communication, *n*=137) and control (conventional risk communication, *n*=120)

	N	Intervention Median (Q1–Q3)	*N*	Control Median (Q1–Q3)	*P*[a]
Blood cholesterol mmol/l[b]					
Median baseline	117	4.30 (3.90, 4,80)	86	4.40 (3.90, 4.80)	0.77
4-week difference	100	−0.10 (−0.40, 0.35)	71	−0.20 (−0.70, 0.30)	0.24
AA (C204n6), % FAME					
Median baseline	138	7.42 (6.63, 8.49)	120	7.54 (6.59, 8.26)	0.90
4-week difference	138	0.49 (−0.09, 1.30)	120	0.46 (−0.15, 1.23)	0.77
EPA (C205n3), % FAME					
Median baseline	138	1.22 (0.92, 1.67)	120	1.20 (0.80, 1.88)	0.93
4-week difference	138	0.12 (−0.12, 0.40)	120	0.04 (−0.17, 0.26)	0.12
DHA (C226n3), % FAME					
Median baseline	138	3.32 (2.86, 3.83)	120	3.37 (2.79, 3.93)	0.93
4-week difference	138	0.41 (0.01, 0.79)	120	0.39 (0.03, 0.93)	0.81
AA/EPA					
Median baseline	137	6.20 (4.40, 8.90)	120	6.30 (3.85, 9.30)	0.98
4-week difference	136	−0.30 (−1.10, 1.00)	119	0.10 (−0.70, 1.20)	0.12
Omega-3 index					
Median baseline	137	6.30 (5.60, 7.10)	120	6.40 (5.50, 7.40)	0.79
4-week difference	136	0.60 (0, 1.10)	119	0.50 (−0.20, 1.30)	0.60
Daily physical activity (min)[c]					
Median baseline	135	28.73 (15.37, 51.12)	118	25.78 (14.54, 46.51)	0.80
4-week difference	122	0.60 (−8.42, 12.72)	112	0 (−19.32, 10.22)	0.40

a: *P*=data were analyzed with Wilcoxon two-sample test, *t*-approximation, two-sided *P*-values for difference between pharmacies.
b: Calculated from dried blood spot samples using regression by Lakshmy et al. (2012).
c: Physical activity was recorded in the VISA-FFQ[13] and calculated as the sum of minutes of vigorous and moderate physical activity per day following the convention of the NORDIET-FFQ[14] (based on recommendations by the Norwegian Directorate of Health of 150 min/week).
AA, arachidonic acid; EPA, eicosapentaenoic acid; DHA, docosahexaenoic acid; FAME, fatty acid methyl ester.

but favorable dietary changes.[22] In support of this, we observed improvements in blood concentrations of EPA and DHA, biomarkers of dietary intake of fatty fish. [23] We also observed increased omega-3 index that has been associated with lower risk of CVD[15] and improved metabolic health.[24] Accordingly, our results support that general CVD risk assessment and risk communication in community pharmacies can improve lifestyle habits.[6]

There is currently a high level of public interest in CVD risk self-assessments.[25]

Both communication approaches can therefore be ideal to use in various health settings by health-care providers,[11] because few people know all of the risk factors needed to calculate risk.[25] Community pharmacies also offer the benefit of attracting those who might need CVD risk assessment the most (low educated).[3] In contrast to percent risk or numeric risk-factor levels, and despite not being effective in reducing risk factors in this study, heart age may still be considered easier to understand than other risk communication approaches.[9] In support of this, the majority of pharmacy-staff felt reported that estimated heart age seemed to motivate the study subjects to improve their lifestyle, and that it appeared to enhance the risk message. Soureti et al.[26] found that the intention to change lifestyle behavior was higher in those receiving risk information as heart age compared with percent risk, and others support that heart age, compared to other risk visualization tools, positively influence risk recall and behaviors.[27] Communicating risk as heart age might however not be as effective if used in a low-risk population.[21] In line with this, we found that the average heart age barely exceeded chronological age (4.2 years), and a tendency to slightly better effect on cholesterol reduction when the disparity between heart age and chorological age increased. Contrary, ∼84% of subjects had low risk in the successful Lopez-Gonzales study.[11] Other reasons for the less effective heart age intervention could be that it was the first time the heart age tool was used in pharmacies. Since it was an add-on to the familiar conventional risk communication, it is possible that the heart age intervention could have contributed to information overload, and hence not enhanced motivation as anticipated.[7] The study sample was also likely influenced by the previous intervention (−52-week RCT).[6] This could have limited the 'surprising effect' of a heart age exceeding chronological age. These factors combined could explain why both the intervention and control communication approaches resulted in positive, yet minor effects on outcomes.[21] Going forward, as the tool had some promising outcomes; more research on the effect of using the heart age tool is needed.[20] The next study population should include unexposed subjects with high risk of CVD. In order to keep the benefits of a simplistic and time-efficient intervention, yet increase the likelihood of behavior change, the future intervention could facilitate for self-assessment, online feedback and more frequent follow-ups, as promoted for behavior change by World Health Organization and others.[28]

Strengths and limitations

A strength of this study was that it evaluated effects of a new risk communication approach for primary prevention of CVD in a large sample of subjects free of CVD and related medication in a real-life setting. Lopez-Gonzales emphasize that the simplicity of the intervention and the incorporation into a routine health check was beneficial and increased the relevance and clinical application of results in their study.[11] This also partly apply to our study. However, the simplicity of the intervention is both an advantage (easily transferred to practice) and a disadvantage (less likely to be highly effective in reducing risk).[29]

The effect of this intervention was measured by actual changes in risk markers in blood and self-reported physical activity level, in contrast to other studies reporting subject's risk perception or self-reported risk without knowing if it would transform into actual lifestyle changes.[30] Although we were aiming for immediate changes in diet and lifestyle behavior following the heart age intervention, 4 weeks might for some parameters and individuals be too little time to observe effects of lifestyle changes. The study population is probably also not representative for pharmacy costumers as they were former participants of a lifestyle intervention.[6] Systematic differences between pharmacies occurred as there were more subjects

performing DBS testing in the intervention pharmacies. Using whole-blood cholesterol and fatty acids assayed from DBS have limitations. It might poorly reflect dietary patterns.[22,31] Transport time of DBS samples could also have affected the quality of DBS analysis, in particular of the unstable EPA, DHA and AA.[32,33] As seen in Table 1 and 2, there were generally huge disparities between average total cholesterol levels and cholesterol assayed from DBS. Another limitation was that more blood was needed for analyzing cholesterol than for the fatty acids, and consequently the number of analyses of cholesterol was substantially lower. However, as change in blood concentration was the primary outcome, and because pharmacies were randomized and widespread in Norway, most limitations are likely to be similarly distributed among pharmacies independent of randomization.

In summary, the heart age tool was considered a convenient and motivating communication approach to convey CVD risk by pharmacy-staff in a simplistic, real-life setting. Nevertheless, using the heart age tool as a perceived enhancing motivational risk communication approach did not have any additional impact on improving whole-blood cholesterol, omega-3 status and physical activity level after 4 weeks compared with conventional risk communication alone.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Conflicts of interest: V.H.T.-H. was employed in Mills AS, and K.W.G. and L.T.M.R. were employees in Boots Norge AS, at time of study initiation. K.S., V.H.T.-H. and K.R. have received research grants from Mills AS. K.S. received funding for writing of this article from a pharmacy interest organization, Stiftelsen til fremme av norsk apotekfarmasi. K.R. has received honoraria for meeting in advisory boards and lectures for Amgen, Chiesi, Sanofi, MSD (Norway) and for participation in meetings for Norwegian Directorate of Health and the Norwegian Medical Association. D.R.J. and H.B.H. report no relevant conflict of interest.

Key points

- Successful prevention of cardiovascular disease (CVD) includes predicting and communicating risk and tailoring preventive efforts accordingly.
- High public interest in CVD self-assessment calls for evaluations of effective and motivational risk communication tools in community health settings.
- The heart age tool was perceived a convenient and motivating risk reduction tool by pharmacy-staff.

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