Effectiveness of the population-based 'check your health preventive programme' conducted in a primary care setting: a pragmatic randomised controlled trial

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ABSTRACT

Background Health checks have been suggested as an early detection approach aiming at lowering the risk of chronic disease development. This study aimed to evaluate the effectiveness of a health check programme offered to the general population, aged 30–49 years.

Methods The entire population aged 30–49 years (N=26 216) living in the municipality of Randers, Denmark, was invited to a health check during 5 years. A pragmatic household cluster-randomised controlled trial was conducted in 10 505 citizens. The intervention group (IG, N=5250) included citizens randomised to the second year and reinvited in the 5th year. The comparison group (CG, N=5255) included citizens randomised to the 5th year. Outcomes were modelled cardiovascular disease (CVD) risk; self-reported physical activity (PA) and objectively measured cardio respiratory fitness (CRF); self-rated health (short-form 12 (SF-12)), self-rated mental health (SF-12_Mental Component Score (MCS)) and, registry information on sick-leave and employment. Due to low participation, we compared groups matched on propensity scores for participation when reinvited.

Results Participation in the first health check was 51% (N=2698) in the IG and 40% (N=2120) in the CG. In the IG 26% (N=1340) participated in both the first and second health checks. No intervention effects were found comparing IG and CG. Mean differences were (95% CI): modelled CVD risk: −0.052 (95% CI −0.107 to 0.003)%, PA: −0.156 (−0.331 to 0.019) days/week with 30 min moderate PA, CRF: 0.133 (−0.560 to 0.826) mL O_2/min/kg, SF-12: −0.003 (−0.032 to 0.026), SF-12_MCS: 0.355 (-0.423 to 1.132), sick leave periods ≥3 weeks: −0.004 (−0.025 to 0.017), employment: −0.004 (−0.032 to 0.024).

Conclusions Preventive health checks offered to the general population, aged 30–49 years, had no effects on a wide range of indicators of chronic disease risk.

Trial registration number NCT02028195.

INTRODUCTION

Early detection and treatment of risk factors for chronic diseases such as cardiovascular diseases (CVDs) and diabetes mellitus have been found to lower the risk of disease development and complications.[1] Preventive health examinations so-called 'health checks' are such an early detection approach. However, the value of health checks is debated.[2–7] However, evidence from large pragmatic trials evaluating the effect of preventive health checks performed in real-world settings is scarce. Despite limited evidence on the health effects of providing preventive health checks, in 2009, the UK National Health Service (NHS) implemented a programme (NHS Health Check) offering a risk assessment with tailored management strategies to all adults aged 40–74 years without known vascular disease.[8] Not long after, in 2012, the Danish municipality of Randers, decided to initiate a somewhat comparable prevention programme, offering health checks to the general population aged 30–49 years, in close collaboration with general practitioners and the municipality-led healthcare centre.[9] Results from the NHS Health Check showed modest impact on modelled risk for CVD and individual risk factors and low to modest uptake.[8] Low uptake is a well-known challenge when evaluating the effect of health checks as it may increase the risk of biased effect estimates. Furthermore, there is a social gradient in uptake, where lower uptake is seen among socioeconomically disadvantaged groups of people.[10–12] As such, evaluating the health impact of large-scale public policy changes and interventions performed in a real-world setting, while minimising biased effect estimates, are challenging. We aimed to evaluate the effectiveness of the Danish population-based 'check your health preventive programme' (CHPP), on modelled CVD risk, physical activity (PA), self-rated health and functional capacity.

METHODS

The study is registered at ClinicalTrails.gov on 7 March 2014 and Statistical Analysis Plan, 21 August 2018. The trial protocol has been published.[9] The study conforms to the Consolidated Standards of Reporting Trials, including the extension for pragmatic trials.

Study design

In order to evaluate the effectiveness of preventive health checks in a real-world setting on health and social outcomes, a pragmatic randomised controlled trial (the CHPP core trial)[9] was conducted in the municipality of Randers, Denmark (95 756 inhabitants on 1 January 2012 (Statistics Denmark, www.dst.dk)). All citizens aged 30–49 year, living in the municipality on 1 January 2012, were invited to a health check at the local healthcare centre.

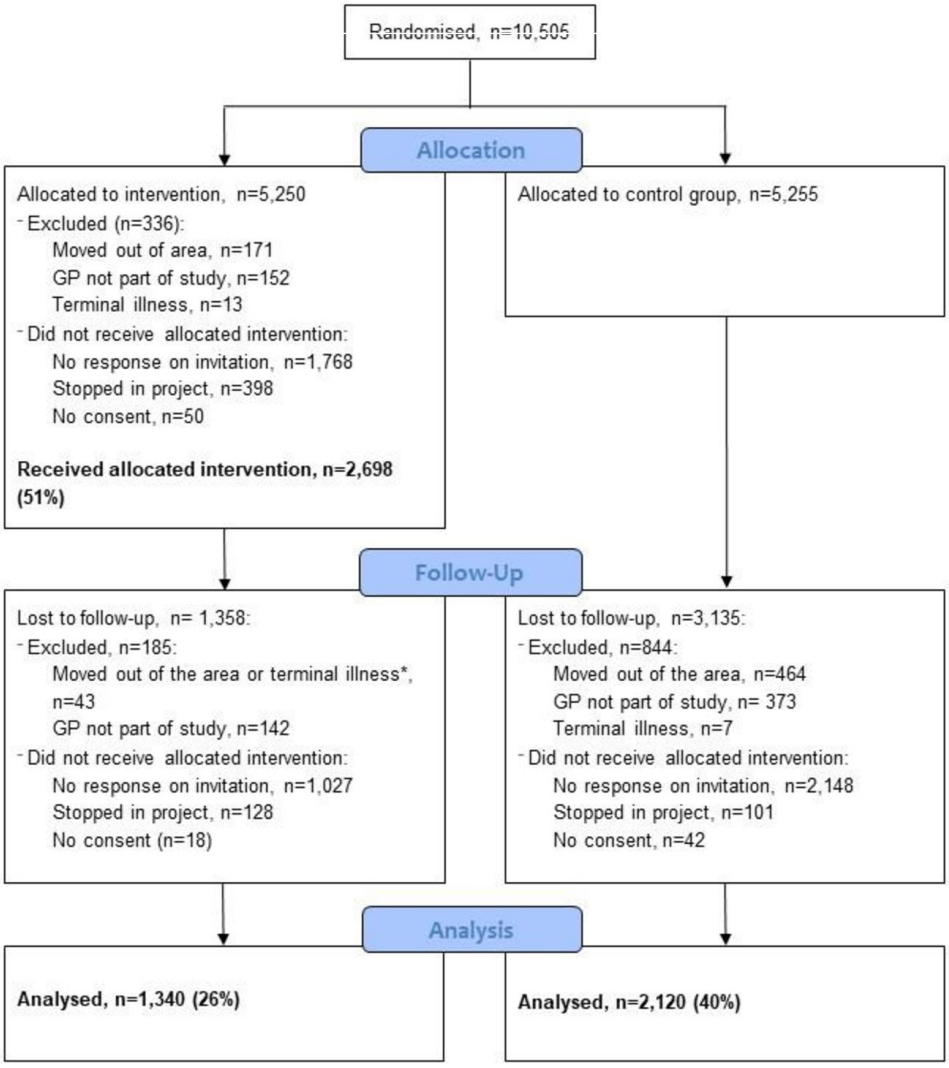

Figure 1 Flow chart of the check your health prevention programme study population. GP, general practitioner. *Terminal illness, n<5.

Subsequently, they were offered tailored health interventions based on their risk profile. The study design and setup have been described thoroughly in the trial protocol.[9]

Randomisation

The randomisation process is described in detail in the trial protocol.[9] To avoid contamination from cohabitants, the study randomised households. Cluster randomisation of invitation sequence (year 1–5) was performed on 1 January 2012 at the household level using information on residency obtained from the Danish Civil Registry. Randomisation was further balanced at the general practice level (N=38 general practices) to ensure an even workload over the 5-year programme. In total, 26 216 citizens (99.8% of the entire age group living in Randers municipality) were assigned a randomised invitation sequence for the CHPP (approximately 5200/year).

Participants

A predefined subset of 10 505 citizens was selected for the CHPP trial analyses. The Intervention group (IG) was defined as the population invited to attend the health check in year 2 (invitation period: from 2 July 2013 to 21 October 2014) and reinvited in year 5 (N=5250) (invitation period: from 6 April 2017 to 15 October 2018), and the comparison group (CG) was defined as the population invited to attend in year 5 (N=5255) (invitation period: from 6 April 2017 to 15 October 2018)[9] (figure 1).

Setting

The study was performed as an integrated part of the routine healthcare service,[9] which in Denmark is based on a tax-funded system, with the responsibility shared between local and regional health authorities. The primary entry point into the healthcare system is through general practitioners. Prior to the study health professionals at the healthcare centre received training in the measurement procedures as well as in health promotion and risk communication.[9] The general practitioners also received training including introduction to the CHPP, shared decision-making, PA promotion and the risk stratification algorithm. Health checks took place at the municipal-led healthcare centre in Randers.

Intervention

The intervention included four core components: (1) an invitation sent from general practice, (2) a health examination and a questionnaire, (3) a personalised health profile summary and (4) a risk-stratified follow-up at the healthcare centre or at the participant's own general practitioner, if needed. The intervention, including the preventive health checks, has been described in detail previously.[9]

Invitation

Invitations were sent out in collaboration with the local healthcare centre in Randers and the citizens' own general practitioner. The mailed invitations included an invitation letter, an information letter regarding access to the web-based questionnaire and a prebooked date and time for the health examination. People living together were offered an examination on the same date.

Health examinations

The health examinations included anthropometric measures (height, weight, waist circumference, BMI), blood samples (glycated haemoglobin A1c (HbA1c), total cholesterol, low-density lipoprotein cholesterol), systolic and diastolic blood pressures, lung function measurements and a submaximal bicycle test. Participants completed a web-based questionnaire including questions on PA level, smoking habits, alcohol use and alcohol risk behaviour using the Alcohol Use Disorders Identification Test (AUDIT) (eg, binge drinking and other preliminary signs of hazardous drinking and mild dependence), self-reported health and self-reported mental health.

Health profile summary

Results from the health examination were explained to participants immediately after the health examinations and they were given recommendations for follow-up.[9] Results were sent electronically to participant's general practitioner.

Risk-stratified intervention

Referral to tailored healthcare interventions was based on the individual participant's health profile. The stratification algorithm has been published previously.[9] It stratifies risk of developing chronic disease based on total cholesterol, blood pressure, HeartSCORE, HbA1c, lung function, waist circumference, BMI, self-reported health, alcohol consumption, smoking status and fitness level. Participants with low risk of disease development were encouraged to maintain their healthy lifestyle. Participants at moderate risk of developing disease (eg, with low PA levels, current smokers, high waist circumference or high BMI) were offered follow-up at the healthcare centre. Interventions consisted of health promotion programmes addressing weight, diet, alcohol, PA, smoking and mental health or disease-specific self-management programmes (online supplemental table S1). Finally, participants at high risk of disease development were recommended to make an appointment with their general practitioner.

Sociodemographic information

From the Danish National registers, the following information was obtained: age (years) at randomisation; sex (male/female); UNESCO classification of education[13] (categorised to <10, 10–15 and >15 years of education); Organisation for Economic Co-operation and Development-adjusted income level[14] (based on family income adjusted for family size and categorised into: low/middle/high); cohabitation status (cohabiting or living alone (ie, one person in household)); nationality based on country of birth (immigrants, second-generation descendants of immigrants or Danish) and occupation (employed, self-employed, unemployed/on benefits or social welfare recipients).

Ethical considerations

Since data collected for the study was considered routine data, the study did not need ethical approval according to the Scientific Ethics Committee, Central Denmark Region. The study complied with the Helsinki declaration and citizens provided written informed consent to use their data for research purposes. The Danish Data Protection Agency approved the storage of the data at the Department of Public Health, Aarhus University.[9]

Outcome measures

Outcome measures at clinical, behavioural and functional level were chosen to reflect different aspects and risk of chronic disease development.

CVD risk

CVD risk was assessed based on the European HeartSCORE 10-year-risk of a fatal cardiovascular event. The score is based on information on age, sex, smoking status, systolic blood pressure and total cholesterol[15] and was analysed as a continuous measure.

Physical activity

Self-reported PA was assessed by questionnaire. Information on the number of days/week (range 0–7 days/week) with a minimum of 30 min of moderate intensity PA was obtained. Cardiorespiratory fitness (mL O_2/kg/min) was estimated using Aastrand's submaximal cycle test.[16]

Self-rated health

Self-rated health was measured using the Short-form 12 (SF-12).[17] Self-rated health was assessed from the first question ('In general, would you say your health is: excellent, very good, good, fair or poor'), dichotomised to 1=excellent, very good and good and 0=fair and poor. Mental health was assessed by the Mental Component Score from the SF-12, ranging from 0 to 100.

Functional capacity

Functional capacity, including sick leave and affiliation to the labour market, was assessed based on the national register of social transfer payments (the Danish Register for Evaluation of Marginalization, DREAM).[18] Work participation was described as an average monthly fraction of full-time employment during the last year before the invitation date and was analysed as a continuous measure. Sick leave was reported as numbers of sick-leave periods of at least 3 weeks during the last year before invitation date.

Statistical analysis

Information obtained from health examinations was uploaded to Statistics Denmark (www.dst.dk) before merging with register data, using the unique Danish Civil Registration Number. Utilising Statistics Denmark's dedicated research server, statistical analyses were conducted in STATA (StataCorp. Stata Statistical Software: Release V.15.). Statistical significance level was set to $p<0.05$. Since the CHPP had low participation, the planned ITT analysis was modified.[9] The revised statistical analysis plan was registered at ClinicalTrials.gov (see the Methods section) prior to initiating the present evaluation.

Descriptive analysis

Intervention and CGs were characterised with respect to baseline demographics. Continuous variables were reported as means and SD. Categorical variables were reported as frequencies with corresponding percentages of the total.

Analysis of study outcome measures

We used a multiple imputation (MI) and propensity score-based analytical strategy in order to account for low participation and high dropout in evaluating the effectiveness of the CHPP.

Multiple imputations

MI was used to impute missing values only for persons participating in the health checks (ie, not for nonparticipants). MI was performed, with missing-at-random assumption, by chained equations procedure[19] using 100 imputations and adjustments according to Rubins's rule.[20] In addition to estimates of interest, we report the Fraction of Missing Information to facilitate assessment of the impact of missing data. A full description of the MI procedure is found in online supplemental material S2 in addition to results of additional analysis testing the robustness of the MAR assumptions (online supplemental table S2).

Propensity score matching

Due to the modest participation in the initial health check (51% IG and 40% CG) and the even lower participation at follow-up (26% IG), a direct comparison between the IG follow-up and CG baseline would not represent a fair comparison based on randomisation. Consequently, we used propensity score matching (PSM) to restore the comparability of the two groups. The propensity refers to the probability of IG individuals participating in their follow-up health check, given that they had participated in their baseline health check. To estimate the intervention effect, we used a matching approach as suggested and validated by Austin.[21] For a full description of the PSM, please see online supplemental material S2 including also online supplemental table S4 and online supplemental figure S1.

Effect estimates

Average treatment effects were estimated and expressed as mean differences, reported with 95% CIs. All analyses accounted for clustering at household level. Linear regression analyses were performed with the Huber-White sandwich estimator accounting for clustering at household level. Binary outcomes were analysed based on discordant values using linear regression analysis with robust variance estimation accounting for clustering at household level.

In addition to the prespecified analysis, explorative subanalyses were carried out to evaluate the participants' general practitioner utilisation pattern following the health check. The mean difference (with 95% CI) in face-to-face contacts at their general practitioner before and after the health check was reported for the IG. This was based on information on the IGs average number of face-to-face contacts to their general practitioners up to 3 months after the health check (administrative code: 0101 from the Danish national primary care registry) and on the number of contacts prior to the health check (average count per 3 months during the year before health check).

RESULTS

Population-specific characteristics

There were no differences in the population-specific characteristics of the IG and the CG at the time of randomisation (1 January 2012) (table 1). In total, 51% of the study population were men. Mean age was 40.5 years, with more participants in the older age group participating as compared with the younger age groups. Seven per cent of the participants were immigrants or descendants. Almost one-fifth of the study population was living alone, 11.5% were social welfare recipients, and one-fifth had an educational attainment of below 10 years.

Findings

Participation

Of the citizens allocated to the IG (N=5250), 2698 (51%) participated in the baseline examination. Of these, 1340 persons (26% of those allocated to IG) participated in both the baseline examination and the re-examination and completed the two corresponding questionnaires. In the CG (5255 allocated) 2120 persons (40%) participated in the examination and completed the questionnaire (figure 1). The baseline clinical and behavioural profile, including the proportion of missings in individual characteristics of the IG participants, is presented in the online supplemental table S5. The proportion of missings in individual characteristics for the control group is presented in online supplemental tables S6 and S7, which shows the proportion of missings in individual characteristics for the analytic sample, using modelled CVD as example. No variables had missing values for more than 9% of individuals participating in the study. Due to the MI and PSM strategy, information from all participants (IG: N=2698 and CG: N=2120) formed the basis for the evaluation of the intervention effect.

Likelihood of participation in the re-examination

In the IG, smoking at the time of the first health check was the strongest predictor for not participating in the re-examination (log odds=−0.490 (CI −0.712 to −0.268), p=0.000 or OR=0.61 (CI 0.491 to 0.765), p=0.000), followed by being self-employed. The strongest predictors for participating in the re-examination were (as measured or reported at the time of the first health check): having fair or excellent fitness level, having higher age, having a higher income level and being an immigrant or descendant (online supplemental table S3).

General practitioner consultations following health check

In the IG (N=2698), the mean difference in average face-to-face contacts at their general practitioner (GP) per 3 months period prior to the health check and 3 months after the health check were +0.093 (95% CI 0.042 to 0.143) contacts.

Effect estimates

After MI and PS matching, we found no statistically significant differences between IG and CG in modelled CVD risk, PA, self-rated health or functional capacity (table 2). Likewise, there were no differences in the crude outcome (before MI and PS matching) between the IG and the CG (table 3). Baseline and follow-up values of the pre-specified health outcomes among the IG are presented in online supplemental table S8.

DISCUSSION

In this large pragmatic randomised controlled trial, carried out in a real-world setting, we found no effect of offering preventive health checks to a general population aged 30–49 years old on modelled CVD risk, PA level, self-rated health or functional capacity.

Strengths and limitations

The CHPP was designed as a pragmatic randomised controlled trial, using a blended approach combining a real-world implementation setting with the structure of an RCT, inviting an entire population within a specific age group in a Danish municipality. This approach was not only a major strength but also introduced

Table 1 Characteristics of intervention and comparison group in the 'check your health preventive programme' at the time of randomisation (January 2012)

Characteristics	Intervention group	Comparison group	Total	P value
Total population, n (%)	5250 (50.0)	5255 (50.0)	10505 (100.0)	
Sex				
Women, n (%)	2565 (48.9)	2581 (49.1)	5146 (49.0)	
Men, n (%)	2685 (51.1)	2673 (50.9)	5358 (51.0)	0.78
Age at randomisation (years)				
Age, mean (SD)	40.6 (5.6)	40.5 (5.6)	40.5 (5.6)	0.25
Age groups, n (%)				
30, n (%)	1093 (20.8)	1129 (21.5)	2222 (21.2)	
35-, n (%)	1316 (25.1)	1351 (25.7)	2667 (25.4)	
40, n (%)	1340 (25.5)	1334 (25.4)	2674 (25.5)	
45, n (%)	1501 (28.6)	1440 (27.4)	2941 (28.0)	0.51
Nationality				
Danish, n (%)	4872 (92.8)	4849 (92.3)	9721 (92.6)	
Immigrants or descendants, n (%)	376 (7.2)	404 (7.7)	780 (7.4)	0.30
Living alone				
No, n (%)	4218 (80.3)	4201 (80.0)	8419 (80.2)	
Yes, n (%)	1032 (19.7)	1053 (20.0)	2085 (19.8)	0.62
Educational attainment				
<10 years, n (%)	1061 (20.6)	1051 (20.4)	2112 (20.5)	
10–15 years, n (%)	2549 (49.4)	2603 (50.4)	5152 (49.9)	
≥15 years, n (%)	1549 (30.0)	1507 (29.2)	3056 (29.6)	0.55
Income level				
Low, n (%)	1738 (33.3)	1750 (33.4)	3488 (33.3)	
Middle, n (%)	1712 (32.8)	1773 (33.9)	3485 (33.3)	
High, n (%)	1775 (34.0)	1711 (32.7)	3486 (33.3)	0.32
Income (1000 DKK), mean (SD)	233.9 (108.8)	233.2 (100.8)	233.6 (104.9)	0.71
Occupational status				
Employed, n (%)	4085 (77.8)	4032 (76.8)	8117 (77.3)	
Self-employed, n (%)	225 (4.3)	249 (4.7)	474 (4.5)	
Unemployed/benefits, n (%)	232 (4.4)	239 (4.6)	471 (4.5)	
Social welfare recipients, n (%)	599 (11.4)	610 (11.6)	1209 (11.5)	
Others, n (%)	107 (2.0)	121 (2.3)	228 (2.2)	0.62

challenges. The unique collaboration, taking its point of departure in the existing healthcare system, involved the local healthcare centre, local and regional authorities, the citizens' own GP, the local environment in general and the university. Together the stakeholders ensured that the implementation of the preventive health check programme was practically and financially feasible and acceptable to the population. This setup ensured that, had the programme demonstrated added effectiveness, it would be sustainably to implement. Even though the study had null findings, the efforts and lessons learnt during this implementation provided the local environment with important experience on how to conduct health promotion interventions in a sustainable way. Furthermore, the unique collaborative approach may have led to an unmeasured increased political and strategic focus on promoting a healthy lifestyle—from municipal politicians, opinion formers and from the local society in general. This dimension is subjected for further research.

As seen in other studies evaluating preventive health checks,[10 22 23] the CHPP had low participation and large dropout. Consequently, we could not perform the planned intention-to-treat analysis on health outcomes[9] in a nonbiased way, due to missing outcomes. Hence, we used MI and propensity score methods to minimise biased effect estimates. Our extensive model control did not give rise to validity concerns as our supplementary analyses provided almost identical results.

Still, some limitations exist: first, we cannot rule out the impact of effect dilution. Even though citizens living together were randomised and invited to participate at the same time, in order to avoid contamination, the CHPP was a real-world study carried out in a local setting. As such, the municipal focus (eg, media and political coverage) regarding the CHPP could have raised the awareness of the citizens allocated to the control group to focus on their health. The tendency that citizens with a healthier and socioeconomically advantaged profile were more likely to participate in the programme (as compared with disadvantaged citizens), which also might have induced a dilution of the effect. Second, the actual dose of stratified health intervention delivered in CHPP is unknown, since we did not have data on participation in the health promotion programmes at the Randers Health Care Centre. Indeed, information from the national registers showed that there was a small increase in number of consultations at the general practitioners following

Table 2 Treatment effect of CHPP on outcome measures*

		Estimate	95% CI (lower limit to upper limit)	FMI
CVD risk, HeartSCORE(%)	CG	0.631	0.587 to 0.675	0.266
	IG	0.580	0.546 to 0.613	0.004
	IG – CG	–0.052	–0.107 to 0.003	0.174
Moderate physical activity (days with min 30 min)	CG	3.883	3.750 to 4.016	0.259
	IG	3.727	3.611 to 3.843	0.034
	IG – CG	–0.156	–0.331 to 0.019	0.168
Cardiorespiratory fitness (mlO_2/kg/min)	CG	32.073	31.433 to 32.713	0.177
	IG	32.206	31.648 to 32.764	0.047
	IG – CG	0.133	–0.560 to 0.826	0.158
Self-rated health—SF12	CG	0.855	0.833 to 0.877	0.265
	IG	0.852	0.832 to 0.872	0.001
	IG – CG	–0.003	–0.032 to 0.026	0.151
NEMC mental health t-score—$SF12_{MCS}$	CG	50.291	49.709 to 50.873	0.273
	IG	50.646	50.116 to 51.176	0.094
	IG – CG	0.355	–0.423 to 1.132	0.191
Employment degree (fraction)	CG	0.805	0.783 to 0.826	0.240
	IG	0.800	0.781 to 0.820	0.004
	IG – CG	–0.004	–0.032 to 0.024	0.136
Sick leave periods ≥3 weeks duration (N)	CG	0.068	0.052 to 0.084	0.238
	IG	0.064	0.050 to 0.078	0.000
	IG – CG	–0.004	–0.025 to 0.017	0.139

*Mean differences or risk and risk differences with 95% CI based on imputed datasets with propensity score matching.
CG, comparison group; CHPP, check your health preventive programme; CVD, cardiovascular disease; FMI, fraction of missing information; IG, intervention group; NEMC, New England Medical Center; SF12, short-form 12.

the health check, as compared with the period before the health check. However, the actual content of these extra consultations is unknown. A recent Danish study evaluating the effect of preventive health checks in high-risk groups found that only a low proportion of high-risk participants was visiting their general practitioner following a health check,[24] and that general practitioners had several barriers towards referral to municipal behaviour change programmes.[24] Third, although performed in a real-world setting, the CHPP was designed as a health promotion intervention with focus on the individual level. Indeed, the CHPP had local media coverage; however, there were no formalised efforts to decrease disease risk at the local structural level or by explicitly targeting interindividual social connections. As such, the impact of providing multifaceted health promotion activities integrated in the socioecological environment remains to be examined.

Discussion of findings

Despite the young age group in the CHPP, the behavioural characteristics of the study population pointed towards a population that could benefit from health promotion initiatives at an early stage. In general, participants did not fulfil the PA guidelines from the Danish Health Authorities (minimum of 30 min of moderate intensity PA everyday), and maximal oxygen consumption was low to very low. Furthermore, the proportion of overweight (39%) or obese (23%) citizens, and the proportion of daily smokers (19%), left considerable room for improvement with regards to promoting a healthy lifestyle. The low CVD risk, as expressed by HeartSCORE, was most likely due to the low age of participants. However, even when extrapolated to the age of 60 years, the mean HeartSCORE was rather low (2.0%). When looking at the individual clinical risk factors of the IG at the time

Table 3 Outcome measures by randomisation group*, CHPP

Outcome	Intervention group	Missings, N (Pct)	Comparison group	Missings, N (Pct)
n (%)	5250 (100.0)	0/5250 (0.00)	5255 (100.0)	0/5255 (0.00)
Participation (complete), n (%)	1340 (25.5)	0/5250 (0.00)	2120 (40.3)	0/5255 (0.00)
CVD risk, HeartSCORE(%), mean (SD)	0.6 (0.6)	7/1340 (0.52)	0.6 (0.7)	5/2120 (0.24)
Moderate physical activity (days with min 30 min), mean (SD)	3.7 (2.1)	31/1340 (2.31)	3.8 (2.2)	47/2120 (2.22)
Cardiorespiratory fitness (mlO_2/kg/min), mean (SD)	32.6 (9.6)	115/1340 (8.58)	31.6 (10.2)	197/2120 (9.29)
Self-rated health—SF12 (good or better), n (%)	1142 (85.2)	0/1340 (0.00)	1785 (84.4)	5/2120 (0.24)
NEMC mental health t-score—SF12_MCS, mean (SD)	50.9 (9.0)	111/1340 (8.28)	50.2 (9.2)	161/2120 (7.59)
Employment degree (fraction), mean (SD)	0.8 (0.4)	0/1340 (0.00)	0.8 (0.4)	0/2120 (0.00)
Sick leave periods ≥3 weeks duration (N), mean (SD)	0.1 (0.3)	0/1340 (0.00)	0.1 (0.3)	0/2120 (0.00)

*Based on original non-imputed datasets.
CHPP, check your health preventive programme; NEMC, New England Medical Center; SF12, short-form 12.

of their first health check, they were only moderately raised, although largely at the same level as reported in, for example, the NHS Health check for a population of 40–70 years old.[25]

We found no effects of the CHPP on the prespecified health outcomes, which is in agreement with similar studies providing health checks to a general population.[2 4–6] The UK NHS Health Check programme showed significant reductions in cardiovascular risk and individual risk factors, when comparing data from attenders with nonattenders.[26] However, the reductions were modest as seen from a clinical perspective. This could indicate that preventive health checks are not useful in asymptomatic persons with no apparent risk factors. This does not mean that prevention and health promotion strategies addressed to the general population are not effective. 'Inter99', one of the largest randomised studies to date, investigating the effect of screening and lifestyle counselling on incidence of ischaemic heart disease, found a sustainable effect of targeted intervention delivered in a research environment on health behaviour[27 28]—despite no overall effect on the incidence of ischaemic heart disease[4] or diabetes.[5] It shows that it is possible to promote healthy habits with the right intervention, although one that may be difficult to implement on the population level. Likewise, the 'Västerbotten Intervention Programme', which took place in a real-world setting, found improvements in health outcomes of citizens participating in the programme.[3] In contrast, we did not find improvements in the prespecified health outcomes from baseline to follow-up among the IG participants (unadjusted comparison, online supplemental table S8), which is in line with our overall, adjusted findings. Participants in studies evaluating the impact of health checks on health outcomes tend to have a better health behaviour profile, lower disease risk and a better socioeconomic status, as compared with nonparticipants.[11] As such, there is a risk that traditional programmes providing preventive health checks and follow-up apply only to the healthiest part of the population and induce social inequity. In CHPP, lower participation was likewise associated with lower level of income, education, living alone and with higher proportion of morbidity.[12] Moreover, participation in the second examination (follow-up) among the IG was inversely associated with, for example, smoking status at the time of the first health check (~4 years earlier). This confirms that the high-risk population is less likely to participate in the follow-up intervention. This is important, since a recent study evaluating a Dutch cardiometabolic prevention programme (also performed as a RCT in primary care), which showed that an intervention aimed at high-risk participants was able to produce a significant decrease in estimated 10-year mortality CVD risk after 1 year of follow-up.[29] However, this study was also prone to low participation and high drop out. Overall, this highlights the need for interventions and evaluation procedures taking into account the challenges posed by selective participation, in order to provide nonbiased effect estimates.

Generalisability

The findings of the present study have high external generalisability. The invited study population comprised 99.8% of the entire population aged 30–49 years living in Randers municipality at the time of randomisation. Randers is Denmark's sixth largest city and is characterised by having a sociogeographical profile dominated by low-to-middle educational attainment, income level and employment status. We, therefore, expect our findings to be generalisable to wide regions and populations across Europe with similar socioeconomic profiles and universal healthcare access.

What is already known on this subject

- Contradictory results exist about whether preventive health checks can reduce the risk of chronic disease development.
- Low participation rates and high dropout are common in studies evaluating the effectiveness of preventive health checks.
- Due to missing outcomes, standard intention-to-treat analysis might be biased.

What this study adds

- This study demonstrates how to evaluate a pragmatic randomised controlled trial with missing data due to low participation and high dropout by using a multiple imputation and propensity score matching analytic strategy.
- This study found no measureable beneficial health effects of providing preventive health checks to a general population aged 30–49 years.
- Health check participants are better off in terms of social status and general health, as compared with nonparticipants, a pattern that also applies to the uptake of follow-up interventions

CONCLUSION

Our findings support those of previous studies: health check participants are better off in terms of social status and general health, as compared with nonparticipants, a pattern that also applies to the uptake of follow-up interventions. We found no effect of a pragmatic randomised controlled trial providing preventive health checks and follow-up to 30–49-year-old citizens on modelled CVD risk, PA level, self-rated health or functional capacity. Although there were no effects at a population level, the effect on high-risk subgroups of interest remains to be quantified in future studies. Moreover, future studies should focus on how to develop more sophisticated designs for real-world research. They should focus on how to recruit at-risk participants without the risk assessment causing selection and on avoiding selective participation in follow-up interventions. Furthermore, focus should be on developing and evaluating strategies to intervene in a variety of settings relevant for health promotion and prevention.

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Contributors AS and HTM set up and initiated the trial. AS, HTM, KN, E-MD, HS and A-LB were members of the steering committee responsible for the development and implementation of the CHPP. HS and DRW contributed to the evaluation design, analysis plan, and interpretation of results. N-HB and KN accessed and verified the underlying data. NHBR performed the statistical analysis. A-LB drafted the manuscript. All authors had full access to all of the data and are responsible for the integrity of the data and the accuracy of the data analysis. All authors provided critical review and final approval. A-LB is responsible for the overall content as guarantor and affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Competing interests None declared.

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