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The effectiveness of general practice-based health checks on health behaviour and incidence on non-communicable diseases in individuals with low socioeconomic position: a randomized controlled trial

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Manuscripts

The effectiveness of general practice-based health checks on health behaviour and incidence on non-communicable diseases in individuals with low socioeconomic position: a randomized controlled trial

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Abstract

Background The effectiveness of health checks aimed at the general population is disputable. However, health checks aimed at certain groups at high risk may reduce adverse health behaviour and identify persons with metabolic risk factors and non-communicable diseases (NCDs).

Objectives To assess the effect of general practice-based health checks on health behaviour and incidence on NCDs in individuals with low socioeconomic position.

Methods Individuals with no formal education beyond lower secondary school and aged 45-64 years were randomly assigned to the intervention group of a preventive health check or to control group of usual care in a 1:1 allocation. Randomization was stratified by gender and 5-year age group. Due to the real-life setting, blinding of participants was only possible in the control group. Effects were analysed as intention-to-treat and per protocol. The trial was undertaken in 32 general practice units in Copenhagen, Denmark.

Intervention Invitation to a prescheduled preventive health check from the general practitioner followed by a health consultation and an offer of follow-up with health risk behaviour change or preventive medical treatment, if necessary.

Primary outcome measures Smoking status at 12-month follow-up. Secondary outcomes included status in other health behaviours such as alcohol consumption, physical activity and body mass index (measured by self-administered questionnaire), as well as incidence of metabolic risk factors and NCDs such as hypertension, hypercholesterolemia, chronic obstructive pulmonary disease, type-2 diabetes mellitus, hypothyroidism, hyperthyroidism and depression drawn from national health care registries.

Results 1,104 participants were included in the study. For the primary outcome, 710 participants were included in the per protocol analysis, excluding individuals who did not attend the health check, and 1,104 participants were included in the intention to treat analysis. At 12-month follow-up 37% were daily smokers in the intervention group and 37% in the control group (OR 0.99, 95% CI 0.76 to 1.30). No difference in health behaviour nor in the incidence of metabolic risk factors and NCDs between the intervention and control group were found. Side effects were comparable across the two groups.

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Conclusion: The lack of effectiveness may be due to low intensity of intervention, a high prevalence of metabolic risk factors and NCDs among the participants at baseline as well as a high number of contacts with the general practitioners in general or to the fact that general practices are not an effective setting for prevention.

Trial registration Clinical Trials NCT01979107.

Strengths and limitations of this study

- A major strength of this study is that it is a large-scale community-based health check intervention implemented in 32 general practice clinics and evaluated with long follow-up (1 year) and in a randomized controlled design.
- The study targets both health behavior changes and detection of non-communicable diseases and combines both patient-reported and register-based outcomes.
- The patient-reported data were linked at the individual level with national health register and obtained information on non-communicable diseases, which ensured no loss to follow-up regarding this outcome.
- The study focuses on individuals with low socioeconomic – an under-studied group in health check interventions.
- The limitations of this study include the lack of data on smoking status in non-respondents and no access to primary care medical records with details on any condition not leading to hospital contact.

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Introduction

There is a large body of evidence that developing non-communicable diseases (NCDs) is closely linked with modifiable health behaviours such as smoking, alcohol consumption, poor diet and physical inactivity as well as metabolic risk factors such as hypertension, lipid levels and blood glucose, and obesity (1). Health checks may identify individuals with adverse health behaviour and detect metabolic risk factors and NCDs at an early stage (2). To prevent NCDs or limit future harms from NCDs, health checks may provide an opportunity to motivate for behavioural change or to initiate appropriate preventive medical treatment. Benefits of general preventive health checks are, however, disputed. One Cochrane review, which included 14 trials on general health checks (N=533-57,460), concluded that health checks offered to the general population did not reduce morbidity or mortality beyond that of usual care (3). Most of the included trials, however, took place 20-30 years ago, prior to the introduction of much of the preventive medication in current use (4). A more recent meta-analysis, including six trials conducted in general practice (N=1442-7229) showed improvements in blood pressure, total cholesterol and body mass index (BMI), and reduced the proportion of patients remaining at high risk for NCDs (5). Amongst others, low socioeconomic position (SEP) has been shown to be associated with non-participation in health checks (3, 6-9). Because of the lower participation among individuals of low SEP (8) and a social gradient in modifiable adverse health behaviours and NCDs (1, 10, 11) it has been suggested that further research in the field of health check should put an extra effort into recruiting especially socioeconomically disadvantaged individuals (3, 8).

In Denmark, general practice and municipalities have a shared responsibility for preventive services aimed at the individual. General practitioners (GP) assess patient health and implement disease-specific secondary prevention, the municipalities are tasked with primary prevention such as smoking cessation, alcohol treatment, and other lifestyle related services (12). GPs collaborate closely with municipal services and can refer to some services, for instance, lifestyle change programs at the municipality health centre (13). Visiting the GP is free of charge, and around 98% of the population is assigned to one specific GP (14).

The Check-In randomised controlled trial (RCT) was developed to test the effectiveness of a preventive health check at the general practice offered to individuals with low SEP as measured by short education.

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We set out to test if Check-In results in lower prevalence of adverse health behaviour such as smoking, excessive alcohol consumption, physical inactivity and obesity, and to test if Check-In results in more new hospital contacts and prescription medication for metabolic risk factors and NCDs such as hypertension, hypercholesterolemia, COPD, T2DM, hypothyroidism, hyperthyroidism and depression. In this article we report on the effects of Check-In at 12-month follow-up.

Method and material

Trial design

Check-In was a two-arm 1:1 randomized controlled trial conducted in Copenhagen, Denmark from January 2014 to September 2016. The trial was notified to the Danish Data Protection Agency (J.nr. 16/100534) and a notification regarding the project was made to The National Committee on Health Research Ethics. However, according to the Act on Research Ethics Review of Health Research Projects (section 14,2) projects like Check-In does not need ethical approval from a Research Ethics Board (Protocol no.: H-1-2013-FSP). The trial is registered at ClinicalTrials.gov (ID NCT01979107; October 25, 2013).

Recruitment and participants

All 126 general practices in four different suburbs of Copenhagen, Denmark, were invited by letter and phone to participate in the study.

GPs do not systematically register their patients' educational level. Therefore, to identify the study population baseline questionnaires in Danish (including questions about educational level) were sent out to all individuals aged 45-64 years, who lived in Copenhagen and who were on the participating GPs' patient lists. The questionnaire was accompanied by a short letter from the GP and the research team describing that the questionnaire information would be entered into the electronic patient record at the GP, and thus could be used in future visits. Furthermore, it was explained that the questionnaire was part of a larger

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research project and that participation was voluntary and without negative consequences for the continuing doctor-patient relationship. At the end of the questionnaire, individuals were asked to indicate if they would consent to be contacted for participation in a future research project.

Inclusion criteria were no formal education beyond lower secondary school and consent to be contacted for research purpose. No exclusion criteria were implied.

Randomization

Eligible patients were randomized in SAS by a data manager to either Check-In or usual care in a 1:1 allocation. The randomization was stratified by gender and 5-year age group. Couples living together were allocated to the same group to avoid contamination.

Due to the real-life setting, blinding of participants was only possible in the control group.

Interventions

Check-In group (intervention)

The intervention included I) an invitation to a prescheduled health check, II) a health check at the GP, III) a health consultation at the GP and an offer of further action if necessary.

I) Invitation

All participants allocated to the intervention group received a postal invitation to a prescheduled health check from their GP and the research team. Included with the invitation was a written description of the project. Furthermore, it was clarified that study participation was voluntary and that withdrawal could occur at any time. Three days before the prescheduled appointment, participants in the intervention group were reminded by phone by a member of the research team.

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II) Health check

Before the health check the GPs received results from the patient-reported questionnaire in the GPs electronic patient record in the form of an electronic data interchange (EDI) message including summed scores and categorization of items from the baseline questionnaire (see supplementary). The health check took place at the general practice clinic to which the patient was registered and was conducted by either the GP or other health staff at the clinic as per usual clinical practice. The health check consisted of measurements of weight and height, hip and waist circumference, cholesterol, glycated haemoglobin, thyroidal status and spirometry for smokers or former smokers. The health consultation with the purpose of review of results was scheduled at the health checks.

III) Health consultation

At the health consultation the GP reviewed the results from the health check in combination with the summarized results of the questionnaire. Participants with abnormal screens, or health behaviour amenable to intervention at the health check, either follow the medical standards for general practice on procedures for diagnostics and treatment or received the offer of a referral to the municipality health centre for a lifestyle change program. Furthermore, these participants were offered an additional health check scheduled six months after the first health check. Decisions and reasons for referral or not were indicated by the GP in a project specified form.

Usual care (control)

Participants allocated to the control group received unrestricted usual care during the intervention period. The results from the questionnaires were entered in the GPs electronic patient record, however, no feedback was provided to the patients.

Measurement of health behaviour

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Health behaviour was measured from a self-administrated questionnaire at baseline and at 12-month follow-up. The questionnaire contained information about sociodemographic characteristics (education level, cohabitation status), health related quality of life (12-Item Short Form Health Survey) (15, 16), height and weight, smoking status, alcohol consumption, physical activity, diet, pulmonary symptoms, family dispositions of chronic diseases, general self-efficacy (17, 18) and stress (measured by Cohen's 10-items Perceived Stress Scale) (19).

The primary outcome was self-reported smoking status at 12-month follow-up. Questions included "Do you smoke?", with the response categories "yes, daily", "yes, I smoke occasional", "no, I stopped less than six months ago", "no, I stopped more than six months age", "no, I have never smoked"; dichotomized into 'daily smokers' vs 'not daily smokers', and "How much do you approximately smoke each day?" used as continuous outcome.

Secondary outcomes included self-reported alcohol consumption, physical activity, BMI, self-efficacy and perceived stress. Alcohol consumption was measured as binge drinking (five or more units of alcohol on the same occasion) dichotomized into 'weekly or more frequent' vs 'less than weekly', and units of alcohol each day during the week used as a continuous outcome. Physical activity was measured from two questions on hours spend on exercise "making you short of breath" during the week and everyday exercise, dichotomized into physical inactivity (yes, no), 'yes' defined as less than 150 minutes of moderate-intensity physical activity throughout the week, less than 75 minutes of vigorous-intensity physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity and 'no' defined as more, as defined by WHO (20). BMI was generated from questions about height and weight and analysed as a dichotomized outcome into obese yes/no, 'yes' defined as BMI≥30 and 'no' defined as BMI<30 (21) and as a continuous outcome (see supplementary).

Measurement of metabolic risk factors and NCDs

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Metabolic risk factors and NCDs were measured as any hospital contact and/or prescription medication for hypertension, hypercholesterolemia, chronic obstructive pulmonary disease (COPD), type-2 diabetes mellitus (T2DM), thyroid disease and depression in the follow-up period. ICD-10 codes and ATC-codes were specified for each of the conditions. The algorithm in supplementary give an overview of the used definitions (Appendix 3).

All citizens with a permanent residence In Denmark have a unique personal identification number (CPR-number), which makes it possible to link individual information from surveys to nation-wide administrative registries (22). For information about hospital contacts and discharge diagnoses we linked to the Danish National Patient Register (23). The Danish National Prescription Registry (24) was used to obtain information on dispensed prescription medications.

To ensure that only new contacts and/or prescription medication of metabolic risk factors and NCDs were included in the incidence analysis, register-based data on metabolic risk factors and NCDs were collected for a period of 15 years for diagnosis and 2 years for prescription medication before the baseline questionnaire were sent.

Furthermore, information on date of death was extracted from the Danish Register of Causes of Death (25). The Danish National Health Services Register was used for information on contacts with the general practice (14).

Sample size consideration

The number of individuals to include in the Check-In and usual care group were determined prior to data collection. Sample size calculation was performed to test the difference between two proportions (26). We expected a participation rate of 75% for the health check. Based on prevalence from the Danish National Health Survey from 2010, a daily smoking prevalence of 41% was assumed in the 45-64-year-old individuals with basic education; of these we expected that 50% were motivated to quit smoking (27). High-standard smoking cessation courses have been shown to yield a cessation prevalence of 20-30% (28). In the usual

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care group, we expected a cessation prevalence of 5%. Thus, we needed 150 daily smokers in each arm to detect a difference in quit rates of 15% with 80% power.

Statistical analysis

To compare health behaviour at 12-month follow-up in the Check-In and usual care group logistic regression modelling estimated intervention effectiveness on the binary outcomes daily smoking, binge drinking, obesity and physical inactivity. The model included the condition variable (Check-In versus usual care). For the continuous outcomes, cigarettes per day (among daily smokers), drinks per week (among those who drink alcohol) and BMI, median regression were conducted, and interquartile range (IQR) were estimated.

The analyses were performed i) per protocol, excluding individuals who did not attend the health check and ii) intention-to-treat (ITT). ITT analyses are recommended in the CONSORT statement (29) and implies that all randomized individuals are included in the analysis regardless of whether they attended the prescheduled health check or not. For the ITT analyses, we estimated missing data using multiple imputation (30). The imputation process for each outcome utilized participant's sex, age, ethnicity, cohabitant and employment status, condition variable and baseline specific variable. Twenty imputations were undertaken for each imputation, estimate and pooled results from these were used. In general, missing at specific item responses were low at baseline (less than 5%) – except for *drinks per week* (7% missing) and *self-efficacy* (6% missing) (data not shown). Final levels of missing data on primary outcome were 1% at baseline and 25% at 12-month follow-up. Missing at follow-up was primary due to non-response.

To compare metabolic risk factors and NCDs at 12-month follow-up in the Check-In and usual care group logistics regression were conducted for each of the outcomes hypertension, hypercholesterolemia, COPD, diabetes, hypothyroidism and hyperthyroidism. Furthermore, the analyses were conducted for *Any new chronic condition*, defined as 'yes' if any new metabolic or NCDs were found in the follow-up period.

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The analyses were performed both regarding *all* contacts/prescription medication (prevalence) and *first* contacts/prescriptions for metabolic risk factors and NCDs (incidence). The prevalence analysis included all individuals who had contact with the hospital and/or prescription medication for the metabolic risk factors and NCDs in the 12-month follow-up period. The incidence analyses excluded individuals who already had the specific metabolic risk factor or NCD at baseline. Information on metabolic risk factors and NCDs were obtained from registers and no missing occurred in these variables.

To evaluate the stability of our results an Interclass Coefficient (ICC) was estimated within a two-level model with patients (level 1) nested within general practices (level 2), and all estimates were calculated in the model including the condition variable and general practices as random intercept, allowing for correlation between patients from the same general practice (31). Furthermore, sensitivity analysis including age and sex in the logistic regression were carried out.

Patient and public involvement

Patients were not formally involved in the development of the trial. The Check-In intervention was, however, developed in close integration with general practitioners. Before Check-In was rolled out in the bigger scale the feasibility of the intervention was tested in a pilot study. In the pilot study the questionnaire was tested among the target group by interviewing them after they filled it in and non-responders were contacted by phone to include their experiences and reasons to not answer. Participants will not be directly contacted with results. All findings, including null findings will be communicated to the public by use of press releases and a report in lay-language.

Results

Participant flow

Of the 126 general practices invited, 32 clinics, including 56 GPs, agreed to participate (clinic level participation 25%). Figure 1 shows the flow diagram of Check-In. In total, 17,063 patients were mailed a

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baseline questionnaire. Of the 9,790 who responded to the baseline questionnaire, 1,104 met the inclusion criteria regarding level of education and marked that they could be contacted again. Of the 1,104 participants, 549 were randomized to the Check-In group and invited to the prescheduled health check, which 364 attended (attendance rate of 66%). Of the 1,104 participants, 850 completed the follow-up questionnaire at 12 months (response rate of 77%). The number analysed for the 'per protocol' depended on the specific outcome – for the primary outcome daily smoking this was 710, 303 for the Check-In group and 407 for the usual care group. For the ITT analyses, the number of analysed equal the number allocated to Check-In and usual care group, respectively (Figure 1).

Baseline characteristics

Table 1 shows the baseline characteristics for the Check-In and usual care group. The average age was 54 years, about half were men and more than 40% were unemployed or on social security. About 41% reported daily smoking and 17% in the check-In group and 20% in the usual care group reported 'binge drinking at least weekly'. Median BMI was 26, with 20% obese in check-In group and 23% in usual care group at baseline. Overall, 61% in the Check-In and 64% in the usual care group, respectively, had at least one NCD and 18% had ≥3 NCDs in the two groups. Around 88% had had contact with their GP within the last year. The baseline characteristics were well balanced between the Check-In and usual care group (Table 1).

Effectiveness of Check-In on daily smoking and other health behaviour

After 12 months of follow-up no statistical significant difference was found between the Check-In and usual care group on daily smoking, binge drinking, physical inactivity or obesity (Table 2) – this was seen in both the per protocol and ITT analysis. All tests for comparison of number of cigarettes/day, units of alcohol/day and BMI were statistically insignificant (Table 3) indicating no effect of Check-In on daily smoking or other health behaviour.

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Effectiveness of Check-In on detection of metabolic risk factors and NCDs

After 12 months of follow-up, we found a tendency towards higher incidence of hospital contacts and prescription medication in the Check-In group compared to the usual care group – for COPD and depression, however, only the results for depression were statistically significant in the ITT analysis (OR 2.90 (95% CI: 1.34-6.29)) (Table 4).

We found no statistically significant differences between the Check-In and the usual care group in prevalence of hypertension, hypercholesterolemia, COPD, T2DM, hypothyroidism, hyperthyroidism or depression (supplementary) – this was seen in both the per protocol and ITT analysis.

Stability of our results and sensitivity analysis

The ICC was low (ICC=0.008) indicating that patients within the same general practice were not clustered, and all estimates from multi-level analyses (data not shown) showed no different in estimates compared with estimates from logistics regression. The adjusted sensitivity analysis did not affect the estimates (data not shown).

Potential side effects

To evaluate potential side effects of Check-In we analysed perceived level of stress for the Check-In and usual care group at 12-month follow-up. We found no difference between the two groups; both groups had a median at 16 on the perceived level of stress scale (IQR for Check-In 11,20; IQR for usual care 11,21) (data not shown).

Discussion

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In this randomized controlled trial, we found no effect of an intervention of GPs invited individuals with low SEP to a prescheduled preventive health check. We found no differences in smoking status, alcohol consumption, physical inactivity, BMI or in the prevalence of metabolic risk factors and NCDs at 12-month follow-up between the Check-In group and usual care group. We did, however, find a statistically significant difference in incidence of depression, as measured by first prescription of antidepressant medication between the Check-In and the usual care group at 12-month follow-up.

The baseline characteristics showed that more than 40% of the participants were daily smokers (Table 1) as compared to 17% in the general Danish population (32). This indicated that we did reach a group with a more adverse health behaviour profile than the general population. However, the intensity of the intervention might have been too low to achieve sufficient change of adverse health behaviour among individuals with low socioeconomic position, which may have contributed to the lack of measurable behavioural change in Check-In. In a previous Danish study of health checks a significant higher smoking abstinence rate were found in a high intensity intervention group compared to usual care (33). The high intensity intervention included a consultation based on motivational interviewing, complementary samples of nicotine products, a self-help pamphlet, and the offer of participation in six smoking cessation group counselling sessions over a period of 5 months (33). Moreover, higher socioeconomic position was a predictor of successful smoking cessation (33). In contrast, Check-In relied on the behaviour change services offered by the municipality since 2007 (13, 34). The idea in Check-In was that patients with adverse health behaviour amenable to intervention at the health check should be offered a referral to the municipality health centre for a free lifestyle change program. However, project data indicated that the opportunity of a referral may have been under-utilized as some of the patients rejected a referral to the municipality, and in some cases, the GP considered a referral to be irrelevant. The result was a low level of intensity of the part of the intervention targeting adverse health behaviour.

Our results are, however, in line with the results from another study focusing at patients with high risk of cardiovascular disease, as they found no differences in the proportion of non-smoking among patients in the intervention compared with usual-care group (35).

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The lack of effectiveness of Check-In regarding more new hospital contacts and prescription medication for metabolic risk factors and NCDs can be ascribed to the fact that more than 70% of individuals included in the study were known with one or more NCDs at baseline. Most had visited their GP within the last year with a median number of contacts to the GP of 7 and 8 in the Check-In and usual care group respectively (Table 1). Patients with a known NCD may, as such most likely, already be in some kind of scheduled treatment at their GP. This illustrate that in terms of health, it is indeed a high-risk group participating in Check-In, but the intervention may not in absolute numbers have picked up many individuals undiagnosed with metabolic risk factors or NCDs, although we did see that there were more persons who initiated treatment with antidepressants in the Check-In group compared to the usual care group. This is in line with another Danish study (36).

Strengths and weaknesses

One strength of the study was that the randomization resulted in two balanced groups at baseline and minimized the influence of known and unknown confounding in the comparison of the Check-In and the usual care group. Another strength was the use of both patient-reported-outcomes and register-based outcomes, where the use of register-based data allowed us to follow all individuals in the study independent of attendance and respond to follow-up questionnaire. A third strength in Check-In was the real-life setting, where the health checks were carried out at the general practice clinics to which the patients were registered. Previous trials testing the effectiveness of preventive health check have been criticized for designing a special unit to deliver the health check (4). In Check-In it was an assumption that GPs, may be in a better position to deliver preventive health services than other health professionals and can offer professional advice accounting for the patients' state of health in order to encourage compliance (37).

A potential limitation in the study was contamination between groups, which potentially occurred if patients in the usual care group had treatment beyond usual care, e.g. a health check in the intervention

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period or if GPs because of the project had more awareness of the preventive work such as smoking cessation when seeing patients allocated to usual care regarding other health issues. However, the risk of contamination is low because GPs did not know who were allocated to the usual care group and couples living together were allocated to same group. If contamination had occurred the observed effectiveness of the intervention is most likely conservative. Another limitation is the lack of data on smoking status in non-respondents and that we had no access to GP chart notes – any condition not leading to hospital contact are not registered. However, our inclusion of prescription medication should ensure the capture of conditions only managed in general practice.

It can be argued that the GPs who participated in Check-In were especially motivated, hence, if no effect on health behaviour and detection of metabolic risk factors and NCDs are found with these GPs it is plausible to say that no effect will be found if the intervention were rolled out to all GPs. However, further studies are needed to understand non-participants and to understand the process after a preventive health at the GP.

Conclusion

This study suggests that a systematic offer of a preventive health check at the general practice aimed at individuals with low SEP have no effect on adverse health behaviour or incidence on metabolic risk factors or NCDs compared to usual care. The explanations can be low intensity of intervention, a high prevalence of metabolic risk factors and NCDs among the participants at baseline, a high number of contacts with the GP in general or that general practices are not an effective setting for primary prevention.

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List of abbreviations

95% CI = 95% confidence interval

BMI = body mass index

COPD = chronic obstructive pulmonary disease

EDI = electronic data interchange

GP = general practitioner

ITT = intention-to-treat

IQR = interquartile range

NCD = non-communicable disease

OR = odds ratio

RCT = randomised controlled trial

SEP = socioeconomic position

T2DM = type-2 diabetes mellitus

Declarations

Ethics approval and consent to participate

Check-In was developed to examine primary prevention aspects beyond existing standard clinical practice, thus no persons were refused access to standard clinical care. Participation was voluntary, and our information material highlighted the option to withdraw without further explanation and without consequences for any treatment or other contact with the GP. Personal identification is encrypted, and data is kept in accordance with the requirements of the Danish Data Protection Agency.

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The trial was notified to the Danish Data Protection Agency (permission 2015-57-0008, Acadre no. 16/100534) and the National Committee on Health Research Ethics was notified of the project. However, according to the Act on Research Ethics Review of Health Research Projects (section 14.2), projects like Check-In do not need ethical approval from a Research Ethics Board (Protocol no.: H-1-2013-FSP). The trial is registered at ClinicalTrials.gov (Early detection of and intervention towards chronic diseases; ID NCT01979107; October 25, 2013).

Consent for publication

Not applicable.

Data sharing statement

The data that support the findings of this study is located at Statistics Denmark and is only available under licence and are therefore not publicly available.

Competing interests

All authors declare that they have no competing interests.

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organization for the submitted work [or describe if any]; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

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Authors' contributions

NKL participated in the design of the study and its coordination and drafted the manuscript. JST participated in the design of the study. NKL and JST performed the statistical analysis. MBJ participated in the design of the study and its coordination. JLT participated in the design of the study. LBL participated in the design of the study. MG participated in the design of the study. CJ participated in the design of the study. SOD participated in the design of the study and its coordination and supervised the statistical analysis. All authors read and approved the final manuscript.

NKL affirms that the 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 (and, if relevant, registered) have been explained.

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Table 1: Baseline characteristics for participants with low socioeconomic position allocated to a preventive health check at the general practitioner (Check-In) or to usual care. Values are number (percentages) unless stated otherwise.

	Check-In group (n=549)	Usual care group (n=555)
Demographic and socioeconomic characteristics		
Age, years [median (IQR[#])]	54 (49;59)	54 (49;59)
Men	282 (51)	293 (53)
Danish/other Western ethnic background	437 (79)	446 (81)
Married/cohabitant	279 (51)	270 (49)
Children living at home	137 (25)	134 (24)
Employment status		
Employed	269 (49)	266 (48)
Unemployed/social security	224 (41)	239 (43)
Retired/other	56 (10)	49 (9)
Health behaviour		
Cigarette smoking		
Daily smoker	228 (42)	225 (41)
Occasional and ex-smoker	156 (28)	163 (29)
Never smoker	156 (29)	163 (30)
Cigarettes/day[*], [median (IQR[#])]	18 (10;20)	20 (10;20)
Current non-drinkers	171 (32)	174 (32)
Drinks/week[¤], [median (IQR[#])]	6 (3; 15)	6 (2; 16)
Binge drinking at least weekly	94 (17)	110 (20)
Physical inactivity[§]	268 (49)	286 (52)
BMI (kg/m^2), [median (IQR[#])]	25.9 (23.1;29.1)	26.2 (23.4;29.7)
Obese (BMI ≥ 30 kg/m^2)	104 (20)	124 (23)
Self-rated bad to very bad health	213 (39)	225 (41)
Self-efficacy, [median (IQR[#])]	29 (24;33)	29 (24;33)
Morbidity and contact with GP		
Non-communicable diseases		
Any chronic condition	337 (61)	359 (65)
Hypertension	118 (22)	133 (24)
Hypercholesterolemia	97 (18)	99 (18)
COPD	124 (23)	127 (23)
Diabetes	175 (32)	191 (34)
Hypothyroidism	55 (10)	44 (8)
Hyperthyroidism	24 (4)	22 (4)
Depression	79 (15)	81 (15)
Number of non-communicable diseases		
0	212 (39)	196 (35)
1	147 (27)	149 (27)
2	93 (17)	112 (20)
≥3	97 (18)	98 (18)
Contact with GP within the last year	495 (90)	480 (87)
Number of contacts with the GP within the last year[&], [median (IQR[#])]	7 (4;13)	8 (4;14)

[#]Interquartile range; [*]among daily smokers; [¤]among those who drink alcohol; [&]among those who visit their GP within the last year; [§]less than 150 minutes of moderate-intensity physical activity.

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Table 2: Effectiveness of Check-In on smoking status (primary outcome) and other health behaviour at 12-months follow-up measured as dichotomized outcomes. Values are number (percentages), ORs and *p* values for the intervention effectiveness. The analyses are performed as per protocol and ITT with multiple imputation.

	n (%)		**Effectiveness (Check-In vs Usual care)**	
Dichotomies outcomes	**Check-In group (n=549)**	**Usual care group (n=555)**	***OR* (95% CI)**	***P* value**
Primary outcome				
Daily smokers				
Per protocol, n=710	94 (31)	147 (36)	0.80 (0.58-1.09)	0.16
ITT; multiple imputation	203 (37)	205 (37)	0.99 (0.76-1.30)	0.95
Secondary outcomes				
Binge drinking ≥ weekly				
Per protocol, n=718	55 (18)	84 (20)	0.87 (0.60-1.27)	0.48
ITT; multiple imputation	98 (18)	116 (21)	0.82 (0.59-1.14)	0.24
Physical inactivity (<150 min/week)				
Per protocol, n=721	132 (43)	186 (45)	0.92 (0.68-1.23)	0.56
ITT; multiple imputation	252 (46)	260 (47)	0.97 (0.74-1.27)	0.84
Obese (BMI ≥ 30 kg/m^2)				
Per protocol, n=684	68 (23)	90 (23)	1.01 (0.71-1.45)	0.95
ITT; multiple imputation	131 (24)	122 (22)	0.90 (0.67-1.21)	0.93

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Table 3: Effectiveness of Check-In on health behaviour measured as continuous outcomes at 12-months follow-up measured as continuous outcomes. Values are medians for Check-In and usual care group and *p* values for the Rank-sum test. The analyses are performed as per protocol and ITT with multiple imputation.

Continuous outcomes	**Median (IQR)**		***P* value**
	Check-In group (n=549)	**Usual care group (n=555)**	**Median regression**
Cigarettes/day[#]			
Per protocol, n=239	17 (14;20)	15 (10;20)	0.35
ITT; multiple imputation	15 (7;20)	15 (7;20)	0.99
Drinks/week[&]			
Per protocol, n=419	7 (4;19)	8 (4;17)	0.38
ITT; multiple imputation	7 (4;17)	7 (4;15)	0.95
BMI			
Per protocol, n=684	25.9 (23.5;29.7)	26.4 (23.8;29.6)	0.19
ITT; multiple imputation	25.9 (23.2;29.4)	26.4 (23.6:29.8)	0.11

[#]Among daily smokers; [&]among those who drink alcohol

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Table 4: Effectiveness of Check-In on incidence of chronic obstructive pulmonary disease, diabetes, disorder of the thyroid gland, hypertension and hypercholesterolemia. The analyses are performed per protocol and as ITT.

	n (%)		**Effectiveness (Check-In vs Usual care)**	
	Check-In group	**Usual care group**	***OR* (95% CI)**	***p* value**
Any new chronic condition[#]				
Per protocol, n=919	82 (23)	120 (22)	1.05 (0.77-1.45)	0.75
ITT, n=1104	125 (23)	120 (22)	1.07 (0.80-1.42)	0.65
Hypertension				
Per protocol, n=704	40 (14)	60 (14)	1.01 (0.66-1.56)	0.96
ITT, n=856	55 (13)	60 (14)	0.88 (0.60-1.31)	0.54
Hypercholesterolemia				
Per protocol, n=752	13 (4)	20 (4)	1.00 (0.49-2.05)	0.99
ITT, n=908	18 (4)	20 (4)	0.90 (0.47-1.73)	0.76
Chronic Obstructive Pulmonary Disease				
Per protocol, n=711	19 (7)	23 (5)	1.24 (0.66-2.31)	0.51
ITT, n=844	32 (8)	23 (5)	1.44 (0.83-2.50)	0.20
Diabetes mellitus				
Per protocol, n=604	8 (3)	15 (4)	0.74 (0.31-1.76)	0.49
ITT, n=720	14 (4)	15 (4)	0.89 (0.42-1.87)	0.76
Hypothyroidism[¤]				
Per protocol, n=919	-	-	-	-
ITT, n=840	-	-	-	-
Hyperthyroidism[¤]				
Per protocol, n=878	-	-	-	-
ITT, n=1051	-	-	-	-
Depression				
Per protocol, n=789	12 (4)	9 (2)	2.05 (0.85-4.91)	0.11
ITT, n=944	25 (5)	9 (2)	2.90 (1.34-6.29)	0.007

[#]Hypertension if no hypertension at baseline, hypercholesterolemia if no hypercholesterolemia at baseline, COPD if no COPD at baseline, diabetes if no diabetes at baseline, hypothyroidism if no hypothyroidism at baseline, hyperthyroidism if no hyperthyroidism at baseline or depression if no depression at baseline

[¤]Too few in each group to report for ethical reasons

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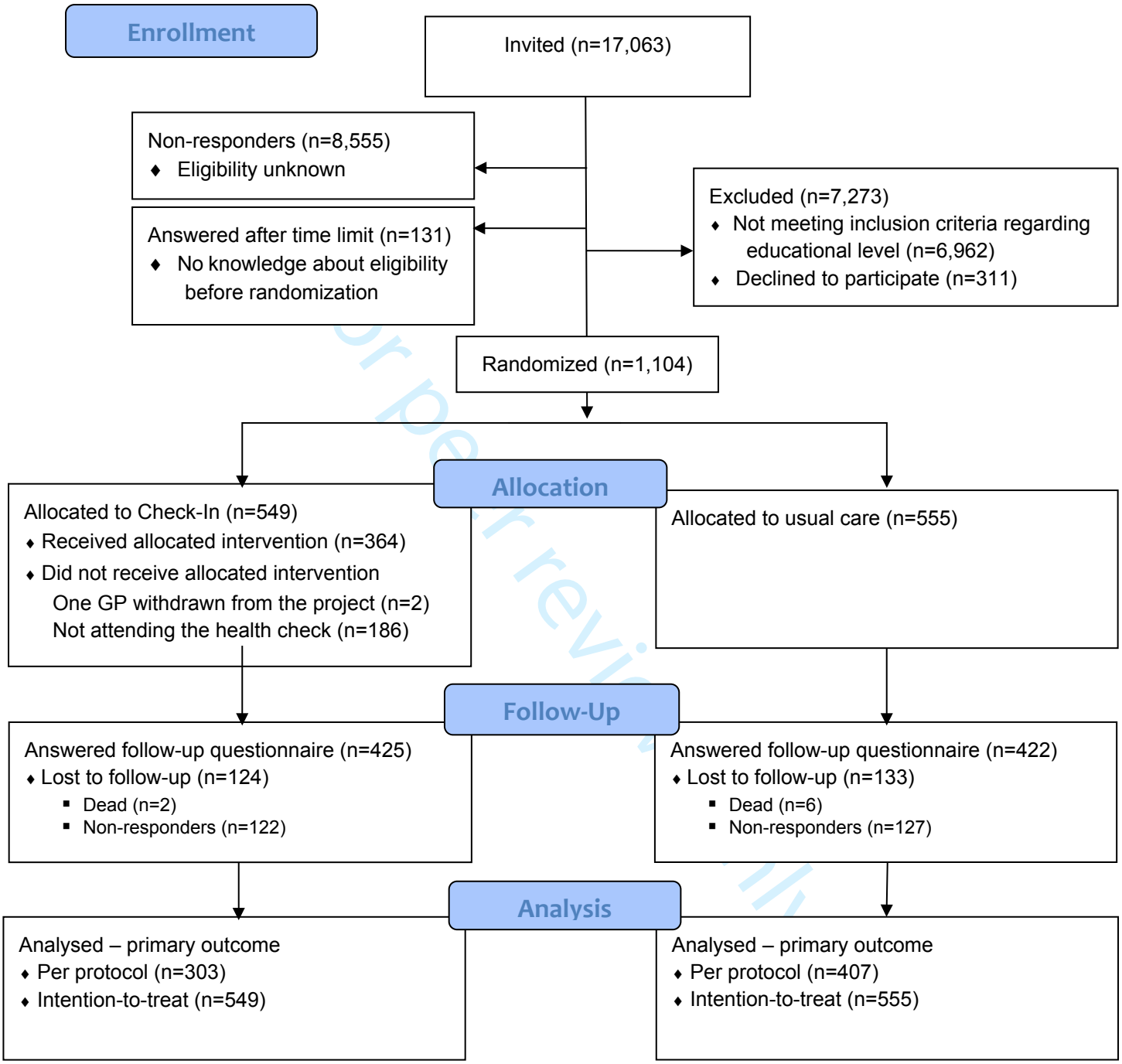
Figure 1: CONSORT flow diagram of recruitment and participation in Check-In



Example of the study-specific electronic data interchange (EDI) message to the GP, computed based on the patient-reported questionnaire, including summarized scores and categorization of items – and showing the different options. Translated from the Danish version used in the intervention

Sender: DAK-E

Headline: Results from patient-reported factors

Overall result: the patient has an overall increased risk of developing a chronic disease / the patient is at no risk of a chronic disease
School and educational level: the patient has basic/upper secondary school level and no education/special worker/vocational education/short education/medium education/long/other/missing.

Social: The patient lives alone/with partner; with children living at home/without children living at home
Weight (kilograms):
BMI: < 18.5 underweight / 18.5-24.9 normal weight / 25-30 overweight / >30 obese

Smoker status: Daily smoker/occasional smoker/ex-smoker/never
Cigarettes per day:
COPD risk score: Score 0-4 dyspnoea is not caused by COPD / score 5-10 dyspnoea is probably caused by COPD

Alcohol consumption per week (number of units):
Frequency of binge-drinking: daily/weekly/monthly/rarely/never
Follows the Danish Health Authority recommendations for alcohol consumption: yes/no

Diet score: 0-4 unhealthy dietary habits / 5-8 dietary habits can be improved / 9-12 healthy dietary habits
Specification of diet: high intake of sugar/low intake of fruit and berries/low intake of vegetables and root crops/low intake of fish and seafood.

Physical activity (minutes per week):
Follows the Danish Health Authority recommendations of 150 minutes of physical activity per week: yes/no
Specification: low physical training/low everyday exercise
Diseases in the near family: hypertension/hypercholesterolemia/blood clots in the heart/blood clots in the brain/blood clots in the lungs or legs/type-1 diabetes mellitus/T2DM/COPD/don't know/none

Self-rated health: excellent/very good/good/bad/very bad
Confidence in own ability to act (self-efficacy): the patient has under/over average confidence in own ability to act

Stress level: not high stress level/high stress level (high stress level = stress level ≥15 for men and stress level ≥17 for women)

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Assessment specification of primary outcome (smoking status) and secondary outcomes (other patient-reported health behaviour)

Outcome	Items	Response categories
Smoking (primary outcome)	*"Do you smoke?"*	1. *"Yes, daily"* 2. *"Yes, I smoke occasionally"* 3. *"No, I stopped less than six months ago"* 4. *"No, I stopped more than six months ago"* 5. *"No, I have never smoked"*
	"How much do you approximately smoke each day? / How much did you approximately smoke at the time you smoked?"	*Number of cigarettes per day: ____* *Number of cheroots per day: ____* *Number of cigars per day: ____* *Number of pipe stops per day: ____*
Alcohol	*"Do you drink alcohol?"*	1. *"Yes"* 2. *"No, never"*
	"How many units of alcohol do you typically drink each day during the week?"	*For each day in the week note:* *Units of beer:* *Units of wine:* *Units of liquor:*
	"How often do you drink more than five units of alcohol on the same occasion?"	1. *"Daily or almost daily"* 2. *"Weekly"* 3. *"Monthly"* 4. *"Rarely"* 5. *"Never"*
Physical activity	*"For how many hours during a week do you perform exercise that makes you short of breath (e.g. running, soccer, aerobics, tennis, jogging or similar)?"*	1. *"0 minutes"* 2. *"Less than 30 minutes"* 3. *"30-60 minutes (½-1 hour)"* 4. *"60-120 minutes (1-2 hours)"* 5. *"More than 120 minutes (more than 2 hours)"*
	"For how many hours during a week do you perform light exercise? / How much time during the week do you spend on everyday exercise (e.g. a walk, easy gardening, cleaning, biking to and from work or similar)?"	1. *"0 minutes"* 2. *"Less than 30 minutes"* 3. *"30-60 minutes (½-1 hour)"* 4. *"60-90 minutes (1-1½ hours)"* 5. *"90-150 minutes (1½-2½ hours)"* 6. *"150-300 minutes (2½-5 hours)"* 7. *"More than 300 minutes (more than 5 hours)"*
BMI	BMI is generated from these two items: *"What is your height? (in centimetres)"* *"What is your weight? (in kilos)"*	$BMI = \frac{weight\ in\ kilos}{(height\ in\ metres)^2}$

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Algorithms used to define the metabolic risk factors and NCDs

Condition	ICD-10 codes from the Danish National Patient Register	ATC-codes from the Danish National Prescription Registry	Definition
Hypertension	I11, I12, I13, I15	C07B, C03A, C03B, C03E, C03X; or C03C, C03D, C07A, C09 if person does not have ICD I20, I21, I25.1, I50; or C08 if person does not have ICD I20-25#	Diagnosis and/or medicine C07B, C03A, C03B, C03E, C03X; or C03C, C03D, C07A, C09 if person does not have ICD I20, I21, I25.1, I50; or C08 if person does not have ICD I20-25[#]
Hypercholesterolemia		C10	Medicine
Chronic Obstructive Pulmonary Disease	J44	R03	Diagnose and/or medicine
Diabetes mellitus	E10, E11, E12, E13, E14	A10	Diagnosis and/or medicine
Hypothyroidism	E02, E03, E063	H03AA01	Diagnosis and/or medicine
Hyperthyroidism	E05, E062	H03B	Diagnosis and/or medicine
Depression	F32, F33	N06A	Diagnosis and/or medicine

[#] to exclude treatment for underlying heart disease

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Effectiveness of Check-In on prevalence of non-communicable diseases at 12-month follow-up. The analyses are performed per protocol and as ITT

	n (%)		Effectiveness (Check-In vs Usual care)	
	Check-In group	**Usual care group**	***OR* (95% CI)**	***p* value**
Any chronic condition[#]				
Per protocol, n=919	202 (56)	306 (55)	1.01 (0.78-1.32)	0.92
ITT, n=1104	296 (54)	306 (55)	0.93 (0.75-1.21)	0.68
Hypertension				
Per protocol, n=919	111 (30)	172 (31)	0.98 (0.73-1.30)	0.87
ITT, n=1104	154 (28)	172 (31)	0.87 (0.67-1.12)	0.28
Hypercholesterolemia				
Per protocol, n=919	77 (21)	113 (20)	1.05 (0.76-1.45)	0.77
ITT, n=1104	106 (19)	113 (20)	0.94 (0.70-1.26)	0.66
Chronic Obstructive Pulmonary Disease				
Per protocol, n=919	59 (16)	81 (15)	1.13 (0.79-1.63)	0.51
ITT, n=1104	91 (17)	81 (15)	1.16 (0.84-1.61)	0.36
Diabetes mellitus				
Per protocol, n=919	57 (16)	83 (15)	1.06 (0.73-1.52)	0.77
ITT, n=1104	87 (16)	83 (15)	1.07 (0.77-1.49)	0.68
Hypothyroidism				
Per protocol, n=919	19 (5)	26 (5)	1.12 (0.61-2.06)	0.71
ITT, n=1104	29 (5)	26 (5)	1.13 (0.65-1.95)	0.65
Hyperthyroidism[¤]				
Per protocol, n=919	-	-	-	-
ITT, n=1104	-	-	-	-
Depression				
Per protocol, n=919	48 (13)	71 (13)	1.04 (0.70-1.53)	0.86
ITT, n=1104	80 (15)	71 (13)	1.16 (0.82-1.64)	0.39

[#]Hypertension, hypercholesterolemia, COPD, diabetes, hypothyroidism, hyperthyroidism or depression
[¤]Too few in each group to report for ethical reasons

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2, 3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4, 5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	None
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5, 7, 8, 9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6, 7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8, 9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	None
Sample size	7a	How sample size was determined	9, 10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	None
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6, 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	Not relevant
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10, 11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2-4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2, 4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13 and supplementary
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15, 16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14, 16
Other information			
Registration	23	Registration number and name of trial registry	18
Protocol	24	Where the full trial protocol can be accessed, if available	Not published
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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The effectiveness of general practice-based health checks on health behaviour and incidence on non-communicable diseases in individuals with low socioeconomic position: a randomised controlled trial in Denmark

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The effectiveness of general practice-based health checks on health behaviour and incidence on non-communicable diseases in individuals with low socioeconomic position: a randomised controlled trial in Denmark

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Abstract

Background The effectiveness of health checks aimed at the general population is disputable. However, it is not clear whether health checks aimed at certain groups at high risk may reduce adverse health behaviour and identify persons with metabolic risk factors and non-communicable diseases (NCDs).

Objectives To assess the effect of general practice-based health checks on health behaviour and incidence on NCDs in individuals with low socioeconomic position.

Methods Individuals with no formal education beyond lower secondary school and aged 45-64 years were randomly assigned to the intervention group of a preventive health check or to control group of usual care in a 1:1 allocation. Randomisation was stratified by gender and 5-year age group. Due to the real-life setting, blinding of participants was only possible in the control group. Effects were analysed as intention-to-treat and per protocol. The trial was undertaken in 32 general practice units in Copenhagen, Denmark.

Intervention Invitation to a prescheduled preventive health check from the general practitioner followed by a health consultation and an offer of follow-up with health risk behaviour change or preventive medical treatment, if necessary.

Primary outcome measures Smoking status at 12-month follow-up. Secondary outcomes included status in other health behaviours such as alcohol consumption, physical activity and body mass index (measured by self-administered questionnaire), as well as incidence of metabolic risk factors and NCDs such as hypertension, hypercholesterolemia, chronic obstructive pulmonary disease, type-2 diabetes mellitus, hypothyroidism, hyperthyroidism and depression drawn from national health care registries.

Results 1,104 participants were included in the study. For the primary outcome, 710 participants were included in the per protocol analysis, excluding individuals who did not attend the health check, and 1,104 participants were included in the intention to treat analysis. At 12-month follow-up 37% were daily smokers in the intervention group and 37% in the control group (odds ratio 0.99, 95% confidence interval

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0.76 to 1.30). No difference in health behaviour nor in the incidence of metabolic risk factors and NCDs between the intervention and control group were found. Side effects were comparable across the two groups.

Conclusion: The lack of effectiveness may be due to low intensity of intervention, a high prevalence of metabolic risk factors and NCDs among the participants at baseline as well as a high number of contacts with the general practitioners in general or to the fact that general practices are not an effective setting for prevention.

Trial registration Clinical Trials NCT01979107.

Strengths and limitations of this study

- A major strength of this study is that it is a large-scale community-based health check intervention implemented in 32 general practice clinics and evaluated with long follow-up (1 year) and in a randomised controlled design.
- The study targets both health behaviour changes and detection of non-communicable diseases and combines both patient-reported and register-based outcomes.
- The patient-reported data were linked at the individual level with national health register and obtained information on non-communicable diseases, which ensured no loss to follow-up regarding this outcome.
- The study focuses on individuals with low socioeconomic – an under-studied group in health check interventions.
- The limitations of this study include the lack of data on smoking status in non-respondents and no access to primary care medical records with details on any condition not leading to hospital contact.

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Introduction

There is a large body of evidence that developing non-communicable diseases (NCDs) is closely linked with modifiable health behaviours such as smoking, alcohol consumption, poor diet and physical inactivity as well as metabolic risk factors such as hypertension, lipid levels and blood glucose, and obesity (1). Furthermore, the occurrence of multiple of these adverse health behaviours are strongly associated with mortality (2) but are difficult to modify (3). Health checks may identify individuals with adverse health behaviour and detect metabolic risk factors and NCDs at an early stage (4). To prevent NCDs or limit future harms from NCDs, health checks may provide an opportunity to motivate for behavioural change or to initiate appropriate preventive medical treatment. Benefits of general preventive health checks are, however, disputed. One Cochrane review, which included 14 trials on general health checks (N=533-57,460), concluded that health checks offered to the general population did not reduce morbidity or mortality beyond that of usual care (5). Most of the included trials, however, took place 20-30 years ago, prior to the introduction of much of the preventive medication in current use (6). A more recent meta-analysis, including six trials conducted in general practice (N=1442-7229) showed improvements in blood pressure, total cholesterol and body mass index (BMI), and reduced the proportion of patients remaining at high risk for NCDs (7). Amongst others, low socioeconomic position (SEP) has been shown to be associated with non-participation in health checks (5, 8-11). Because of the lower participation among individuals of low SEP (10) and a social gradient in modifiable adverse health behaviours and NCDs (1, 12, 13) it has been suggested that further research in the field of health check should put an extra effort into recruiting especially socioeconomically disadvantaged individuals (5, 10).

In Denmark, general practice and municipalities have a shared responsibility for preventive services aimed at the individual. General practitioners (GP) assess patient health and implement disease-specific secondary prevention, the municipalities are tasked with primary prevention such as smoking cessation, alcohol treatment, and other lifestyle related services (14). GPs collaborate closely with municipal services and can

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refer to some services, for instance, lifestyle change programs at the municipality health centre (15). Visiting the GP is free of charge, and around 98% of the population is assigned to one specific GP (16).

The 'Check-In' intervention was developed to test the effectiveness of a preventive health check in a randomised controlled trial (RCT) at general practice offered to individuals with low SEP as measured by short education. It was developed in response to health-behaviour models in which increased awareness about the causes, consequences and cures for a particular health behaviour or health problem is expected to increase the likelihood for change (17) and in which knowledge is expected to lead to action (18). A preventive health check at the GP has the potential to confront the patient with a problem and provide feedback about both adverse health behaviour and the consequences of continuing the injurious behaviour. For example, poor lung function measure can demonstrate the health consequences of smoking and lead to a discussion about the adverse effects of smoking which may increase the chance for smoking cessation.

Short education was used as measure for low SEP as educational level captures the influence of resources on health and the knowledge and skills attained through education may affect an individual's cognitive functioning, make individuals more receptive to health education messages, or more able to communicate with and access appropriate health services (19).

We set out to test if 'Check-In' results in lower prevalence of adverse health behaviour such as smoking, excessive alcohol consumption, physical inactivity and obesity, and to test if 'Check-In' results in more new hospital contacts and prescription medication for metabolic risk factors and NCDs such as hypertension, hypercholesterolemia, chronic obstructive pulmonary disease (COPD), type-2-diabetes mellitus (T2DM), hypothyroidism, hyperthyroidism and depression. In this article we report on the effects of 'Check-In' at 12-month follow-up.

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Method and material

Trial design

'Check-In' was a two-arm 1:1 randomised controlled trial conducted in Copenhagen, Denmark from January 2014 to September 2016. The trial was notified to the Danish Data Protection Agency (J.nr. 16/100534) and a notification regarding the project was made to The National Committee on Health Research Ethics. However, according to the Act on Research Ethics Review of Health Research Projects (section 14,2) projects like 'Check-In' does not need ethical approval from a Research Ethics Board (Protocol no.: H-1-2013-FSP). The trial is registered at ClinicalTrials.gov (ID NCT01979107; October 25, 2013).

Identification of the study population

All 126 general practices in four different suburbs of Copenhagen, Denmark, were invited by letter and phone to participate in the study. The recruitment of the GPs was, however, challenged due to a break down in the collective bargaining between the Danish Regions Salary and Rate Board (RTLN) and the Organisation of General Practitioners (PLO) in late 2012 (20). In all, 'Check-In' ended up having five rounds between January 2014 to September 2016.

GPs do not systematically register their patients' educational level. Therefore, to identify the study population baseline questionnaires in Danish (including items about sex, date of birth, cohabitation status, highest educational level achieved, height and weight, smoking status, alcohol consumption, physical activity, diet, general self-efficacy, perceived stress and family disposition of NCDs) were sent out to all individuals aged 45-64 years, who lived in Copenhagen and who were on the participating GPs' patient lists. The questionnaire was accompanied by a short letter from the GP and the research team describing that the questionnaire information would be entered into the electronic patient record at the GP, and thus could be used in future visits. Furthermore, it was explained that the questionnaire was part of a larger research project and that participation was voluntary and without negative consequences for the

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continuing doctor-patient relationship. At the end of the questionnaire, individuals were asked to indicate if they would consent to be contacted for participation in a future research project.

Eligible patients met the inclusion criteria which were no formal education beyond lower secondary school and consent to be contacted for research purpose. No exclusion criteria were implied.

Randomisation

Eligible patients were randomised in SAS by a data manager at the National Institute of Public Health to either 'Check-In' or usual care in a 1:1 allocation. The randomisation was stratified by gender and 5-year age group. Couples living together were allocated to the same group to avoid contamination.

Double-blinded, meaning that both patients and GPs were blinded to the allocation of group, would have been ideal (21) nevertheless, due to real-life setting, blinding of participants was only possible in the control group and not in the intervention group and among GPs.

Interventions

'Check-In' group (intervention)

The intervention included I) an invitation to a prescheduled health check, II) a health check at the GP, III) a health consultation at the GP which included an offer of further action if necessary.

I) Invitation

All participants allocated to the intervention group received a postal invitation to a prescheduled health check from their GP and the research team. Included with the invitation was a written description of the project. Furthermore, it was clarified that study participation was voluntary and that withdrawal could

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occur at any time. Three days before the prescheduled appointment, participants in the intervention group were reminded by phone by a member of the research team.

II) Health check

Before the health check the GPs received results from the patient-reported questionnaire in the GPs electronic patient record in the form of an electronic data interchange (EDI) message including summed scores and categorisation of items from the baseline questionnaire (Supplementary file 1). The health check was free of charge and took place during the opening hour of the general practice clinic to which the patient was registered and was conducted by either the GP or other health staff at the clinic as per usual clinical practice. The health check consisted of measurements of weight and height, hip and waist circumference, cholesterol, glycated haemoglobin, thyroidal status and spirometry for smokers or former smokers. The health consultation with the purpose of review of results was scheduled at the health checks.

III) Health consultation

At the health consultation the GP reviewed the results from the health check in combination with the summarised results of the questionnaire. Participants with abnormal screens, or health behaviour amenable to intervention at the health check, either follow the medical standards for general practice on procedures for diagnostics and treatment or received the offer of a referral to the municipality health centre for a lifestyle change program. Furthermore, these participants were offered an additional health check scheduled six months after the first health check. Decisions for further action and reasons for referral or not were indicated by the GP in a project specified form.

Usual care (control)

Participants allocated to the control group received unrestricted usual care during the intervention period. The results from the questionnaires were entered in the GPs electronic patient record, however, no feedback was provided to the patients.

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Measurement of health behaviour

Health behaviour was measured from a self-administrated questionnaire at baseline and at 12-month follow-up. The questionnaire contained information about sociodemographic characteristics (education level, cohabitation status), health related quality of life (12-Item Short Form Health Survey) (22, 23), height and weight, smoking status, alcohol consumption, physical activity, diet, pulmonary symptoms, family dispositions of chronic diseases, general self-efficacy (24, 25) and stress (measured by Cohen's 10-items Perceived Stress Scale (PSS)) (26).

The primary outcome was self-reported smoking status at 12-month follow-up. Questions included "Do you smoke?", with the response categories "yes, daily", "yes, I smoke occasional", "no, I stopped less than six months ago", "no, I stopped more than six months ago", "no, I have never smoked"; dichotomised into 'daily smokers' vs 'not daily smokers', and "How much do you approximately smoke each day?" used as continuous outcome.

Secondary outcomes included self-reported alcohol consumption, physical activity, BMI, self-efficacy and perceived stress. Alcohol consumption was measured as binge drinking (five or more units of alcohol on the same occasion) dichotomised into 'weekly or more frequent' vs 'less than weekly', and units of alcohol each day during the week used as a continuous outcome. Physical activity was measured from two questions on hours spend on exercise "making you short of breath" during the week and everyday exercise, dichotomised into physical inactivity (yes, no), 'yes' defined as less than 150 minutes of moderate-intensity physical activity throughout the week, less than 75 minutes of vigorous-intensity physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity and 'no' defined as more, as defined by WHO (27). BMI was generated from questions about height and weight and analysed as a dichotomised outcome into obese yes/no, 'yes' defined as BMI≥30 and 'no' defined as BMI<30 (28) and as a continuous outcome (Supplementary file 2). Stress during the past month was

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assessed by the PSS (score range 0-40) (26). The person's belief in their innate ability to achieve goals was assessed using general self-efficacy (score range 10-40) (25, 29).

Measurement of metabolic risk factors and NCDs

Metabolic risk factors and NCDs were measured as any hospital contact and/or prescription medication for hypertension, hypercholesterolemia, COPD, T2DM, thyroid disease and depression in the follow-up period. International Classification of Diseases (ICD-10) codes and Anatomical Therapeutic Chemical Classification (ATC) codes were specified for each of the conditions. The algorithm in the supplementary files give an overview of the used definitions (Supplementary file 3).

All citizens with a permanent residence In Denmark have a unique personal identification number (CPR-number), which makes it possible to link individual information from surveys to nation-wide administrative registries (30). For information about hospital contacts and discharge diagnoses we linked to the Danish National Patient Register (31). The Danish National Prescription Registry (32) was used to obtain information on dispensed prescription medications.

To ensure that only new contacts and/or prescription medication of metabolic risk factors and NCDs were included in the incidence analysis, register-based data on metabolic risk factors and NCDs were collected for a period of 15 years for diagnosis and 2 years for prescription medication before the baseline questionnaire were sent.

Furthermore, information on date of death was extracted from the Danish Register of Causes of Death (33). The Danish National Health Services Register was used for information on contacts with the general practice (16).

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Sample size consideration

The number of individuals to include in the 'Check-In' and usual care group were determined prior to data collection. Sample size calculation was performed to test the difference between two proportions (34). We expected a participation rate of 75% for the health check. Based on prevalence from the Danish National Health Survey from 2010, a daily smoking prevalence of 41% was assumed in the 45-64-year-old individuals with basic education; of these we expected that 50% were motivated to quit smoking (35). High-standard smoking cessation courses have been shown to yield a cessation prevalence of 20-30% (36). In the usual care group, we expected a cessation prevalence of 5%. Thus, we needed 150 daily smokers in each arm to detect a difference in quit rates of 15% with 80% power.

Statistical analysis

To compare health behaviour at 12-month follow-up in the 'Check-In' and usual care group logistic regression modelling estimated intervention effectiveness on the binary outcomes daily smoking, binge drinking, obesity and physical inactivity. The model included the condition variable ('Check-In' versus usual care). For the continuous outcomes, cigarettes per day (among daily smokers), drinks per week (among those who drink alcohol) and BMI, median and interquartile range (IQR) were estimated.

The analyses were performed i) per protocol, excluding individuals who did not attend the health check and ii) intention-to-treat (ITT). ITT analyses are recommended in the CONSORT statement (37) and implies that all randomised individuals are included in the analysis regardless of whether they attended the prescheduled health check or not. For the ITT analyses, we estimated missing data using multiple imputation (38). The imputation process for each outcome utilized participant's sex, age, ethnicity, cohabitant and employment status, condition variable and baseline specific variable. Twenty imputations were undertaken for each imputation, estimate and pooled results from these were used. In general, missing at specific item responses were low at baseline (less than 5%) – except for *drinks per week* (7%

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missing) and *self-efficacy* (6% missing) (data not shown). Final levels of missing data on primary outcome were 1% at baseline and 25% at 12-month follow-up. Missing at follow-up was primary due to non-response.

To compare metabolic risk factors and NCDs at 12-month follow-up in the 'Check-In' and usual care group logistics regression were conducted for each of the outcomes hypertension, hypercholesterolemia, COPD, diabetes, hypothyroidism and hyperthyroidism. Furthermore, the analyses were conducted for *Any new chronic condition*, defined as 'yes' if any new metabolic or NCDs were found in the follow-up period.

The analyses were performed both regarding *all* contacts/prescription medication (prevalence) and *first* contacts/prescriptions for metabolic risk factors and NCDs (incidence). The prevalence analysis included all individuals who had contact with the hospital and/or prescription medication for the metabolic risk factors and NCDs in the 12-month follow-up period. The incidence analyses excluded individuals who already had the specific metabolic risk factor or NCD at baseline. Information on metabolic risk factors and NCDs were obtained from registers and no missing occurred in these variables.

To evaluate the stability of our results an Interclass Coefficient (ICC) was estimated within a two-level model with patients (level 1) nested within general practices (level 2), and all estimates were calculated in the model including the condition variable and general practices as random intercept, allowing for correlation between patients from the same general practice (39). Furthermore, sensitivity analysis including age and sex in the logistic regression were carried out.

Patient and public involvement

Patients were not formally involved in the development of the trial. The 'Check-In' intervention was, however, developed in close integration with general practitioners. Before 'Check-In' was rolled out in the bigger scale the feasibility of the intervention was tested in a pilot study. In the pilot study the questionnaire was tested among the target group by interviewing them after they filled it in and non-

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responders were contacted by phone to include their experiences and reasons to not answer. Participants will not be directly contacted with results. All findings, including null findings will be communicated to the public by use of press releases and a report in lay-language.

Results

Participant flow

Of the 126 general practices invited, 32 clinics, including 56 GPs, agreed to participate (clinic level participation 25%). Figure 1 shows the flow diagram of 'Check-In'. In total, 17,063 patients were mailed a baseline questionnaire. Of the 8,508 (49%) who responded to the baseline questionnaire, 1,104 met the inclusion criteria regarding level of education and marked that they could be contacted again (range per general practice clinic: 12-110 individuals; median=18). Of the 1,104 participants, 549 were randomised to the 'Check-In' group and invited to the prescheduled health check, which 364 attended (attendance rate of 66%). Of the 1,104 participants, 850 completed the follow-up questionnaire at 12 months (response rate of 77%). The number analysed for the 'per protocol' depended on the specific outcome – for the primary outcome daily smoking this was 710, 303 for the 'Check-In' group and 407 for the usual care group. For the ITT analyses, the number of analysed equal the number allocated to 'Check-In' and usual care group, respectively (Figure 1).

Baseline characteristics

Table 1 shows the baseline characteristics for the 'Check-In' and usual care group. The average age was 54 years, about half were men and more than 40% were unemployed or on social security. About 41% reported daily smoking and 17% in the 'Check-In' group and 20% in the usual care group reported 'binge drinking at least weekly'. Median BMI was 26, with 20% obese in 'Check-In' group and 23% in usual care

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group at baseline. Overall, 61% in the 'Check-In' and 64% in the usual care group, respectively, had at least one NCD and 18% had ≥3 NCDs in the two groups. Around 88% had had contact with their GP within the last year. The baseline characteristics were well balanced between the 'Check-In' and usual care group (Table 1).

Effectiveness of 'Check-In' on daily smoking and other health behaviour

After 12 months of follow-up no difference was found between the 'Check-In' and usual care group on daily smoking (ITT: odds ratio (OR)=0.99; 95% confidence interval (95% CI):0.58-1.09), binge drinking (ITT: OR=0.82; 95% CI:0.59-1.14), physical inactivity (ITT: OR=0.97; 95% CI:0.74-1.27) or obesity (ITT: OR=0.90; 95% CI:0.67-1.21) (Table 2) – this was seen in both the per protocol and ITT analysis. No differences were found for comparison of number of cigarettes/day (ITT: Coefficient (coef.)=0; 95% CI: -2.9-2.9)), units of alcohol/day (ITT: coef.=0; 95% CI: -1.7-1.8) and BMI (ITT: coef.=-0.5; 95% CI: -1.2-0.1)(Table 3) indicating no effect of 'Check-In' on daily smoking or other health behaviour. Further, no difference between the two groups were found regarding self-efficacy where both groups had a median at 29 (IQR for 'Check-In' 25,33; IQR for usual care 24,34) (data not shown).

Effectiveness of 'Check-In' on detection of metabolic risk factors and NCDs

At 12-month follow-up, we found a difference in incidence of depression in the 'Check-In' group when compared to usual care (OR=2.90; 95% CI: 1.34-6.29) and a tendency for COPD (OR=1.44; 95% CI: 0.83-2.50) (Table 4). No differences between the 'Check-In' and usual care groups was observed for incidence in hypertension, hypercholesterolemia and diabetes. The estimates for hypothyroidism and hyperthyroidism have not been reported for ethical reasons as there were too few cases to report. (Table 4).

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We found no differences between the Check-In and the usual care group in prevalence of hypertension, hypercholesterolemia, COPD, T2DM, hypothyroidism, hyperthyroidism or depression (Supplementary file 4) – this was seen in both the per protocol and ITT analysis.

Stability of our results and sensitivity analysis

The ICC was low (ICC=0.008) indicating that patients within the same general practice were not clustered, and all estimates from multi-level analyses (data not shown) showed no different in estimates compared with estimates from logistics regression. The adjusted sensitivity analysis did not affect the estimates (data not shown). In addition, the baseline characteristics for those lost to follow-up and those not lost to follow-up were comparable, however, the proportion of daily smokers and physical inactive were higher among those lost to follow-up compared to those not lost to follow-up (Supplementary file 5).

Potential side effects

To evaluate potential side effects of 'Check-In' we analysed perceived level of stress for the 'Check-In' and usual care group at 12-month follow-up. We found no difference between the two groups; both groups had a median at 16 on the perceived level of stress scale (IQR for 'Check-In' 11,20; IQR for usual care 11,21) (data not shown).

Discussion

In this randomised controlled trial, we found no effect of an intervention of GPs invited individuals with low SEP to a prescheduled preventive health check. We found no differences in smoking status, alcohol consumption, physical inactivity, BMI or in the prevalence of metabolic risk factors and NCDs at 12-month

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follow-up between the 'Check-In' group and usual care group. We did, however, find a difference in incidence of depression, as measured by first prescription of antidepressant medication between the 'Check-In' and the usual care group at 12-month follow-up.

The baseline characteristics showed that more than 40% of the participants were daily smokers (Table 1) as compared to 17% in the general Danish population (40). This indicated that we did reach a group with a more adverse health behaviour profile than the general population. However, the intensity of the intervention might have been too low to achieve sufficient change of adverse health behaviour among individuals with low socioeconomic position, which may have contributed to the lack of measurable behavioural change in 'Check-In'. In a previous Danish study of health checks a significant higher smoking abstinence rate were found in a high intensity intervention group compared to usual care (41). The high intensity intervention included a consultation based on motivational interviewing, complementary samples of nicotine products, a self-help pamphlet, and the offer of participation in six smoking cessation group counselling sessions over a period of 5 months (41). Moreover, higher socioeconomic position was a predictor of successful smoking cessation (41). In contrast, 'Check-In' relied on the behaviour change services offered by the municipality since 2007 (15, 42). The idea in 'Check-In' was that patients with adverse health behaviour amenable to intervention at the health check should be offered a referral to the municipality health centre for a free lifestyle change program. However, project data indicated that the opportunity of a referral may have been under-utilized as some of the patients rejected a referral to the municipality, and in some cases, the GP considered a referral to be irrelevant. The result was a low level of intensity of the part of the intervention targeting adverse health behaviour.

Our results are, however, in line with the results from another study focusing at patients with high risk of cardiovascular disease, as they found no differences in the proportion of non-smoking among patients in the intervention compared with usual-care group (43).

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The lack of effectiveness of 'Check-In' regarding more new hospital contacts and prescription medication for metabolic risk factors and NCDs can be ascribed to the fact that more than 60% of individuals included in the study were known with one or more NCDs at baseline. Most had visited their GP within the last year with a median number of contacts to the GP of 7 and 8 in the 'Check-In' and usual care group respectively (Table 1). Patients with a known NCD may, as such most likely, already be in some kind of scheduled treatment at their GP. This illustrates that in terms of health, it is indeed a high-risk group participating in 'Check-In', but the intervention may not in absolute numbers have picked up many individuals undiagnosed with metabolic risk factors or NCDs, although we did see that there were more persons who initiated treatment with antidepressants in the 'Check-In' group compared to the usual care group. This is in line with another Danish study (44). Even so, we cannot completely rule out that the effectiveness regarding depression was due to chance because of the small sample size in 'Check-In'.

Strengths and weaknesses

One strength of the study was that the randomisation resulted in two balanced groups at baseline and minimised the influence of known and unknown confounding in the comparison of the 'Check-In' and the usual care group. Another strength was the use of both patient-reported-outcomes and register-based outcomes, where the use of register-based data allowed us to follow all individuals in the study independent of attendance and respond to follow-up questionnaire. A third strength in 'Check-In' was the real-life setting, where the health checks were carried out at the general practice clinics to which the patients were registered. Previous trials testing the effectiveness of preventive health check have been criticized for designing a special unit to deliver the health check (6). In 'Check-In' it was an assumption that GPs, may be in a better position to deliver preventive health services than other health professionals and can offer professional advice accounting for the patients' state of health in order to encourage compliance (45).

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A potential limitation in the study was contamination between groups, which potentially occurred if patients in the usual care group had treatment beyond usual care, e.g. a health check in the intervention period or if GPs because of the project had more awareness of the preventive work such as smoking cessation when seeing patients allocated to usual care regarding other health issues. However, the risk of contamination is low because GPs did not know who were allocated to the usual care group and couples living together were allocated to same group. If contamination had occurred the observed effectiveness of the intervention is most likely conservative. Another limitation is the lack of data on smoking status in non-respondents and that we had no access to GP chart notes – any condition not leading to hospital contact are not registered. However, our inclusion of prescription medication should ensure the capture of conditions only managed in general practice.

Furthermore, our sample calculations were based on several assumptions which can be discussed. The assumption that half are motivated to quit smoking can seem high and cannot be verified in the design. This assumption is, however, supported by the literature where 63% of daily smokers in Denmark with no education beyond lower secondary school are found to be motivated to quit smoking (40). Moreover, the 10% a-priori loss to follow-up was conservative when compared to the fact that the actually loss was 24%. Nevertheless, in total, 228 and 225 daily smokers were enrolled in the 'Check-In' intervention and control group, respectively, which exceeded the sample size calculations that indicated that we needed 150 daily smokers in each group. This indicates that despite a higher loss to follow-up than expected the sample was most likely large enough to detect had there been any effect of 'Check-In' regarding adverse health behaviour. It can be argued that the GPs who participated in 'Check-In' were especially motivated, hence, if no effect on health behaviour and detection of metabolic risk factors and NCDs are found with these GPs it is plausible to say that no effect will be found if the intervention were rolled out to all GPs. However, further studies are needed to understand non-participants and to understand the process after a preventive health at the GP.

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Conclusion

This study suggests that a systematic offer of a preventive health check at the general practice aimed at individuals with low SEP have no effect on adverse health behaviour or incidence on metabolic risk factors or NCDs compared to usual care. The explanations can be low intensity of intervention, a high prevalence of metabolic risk factors and NCDs among the participants at baseline, a high number of contacts with the GP in general or that general practices are not an effective setting for primary prevention.

List of abbreviations

95% CI = 95% confidence interval

BMI = body mass index

Coef. = coefficient

COPD = chronic obstructive pulmonary disease

EDI = electronic data interchange

GP = general practitioner

ITT = intention-to-treat

IQR = interquartile range

NCD = non-communicable disease

OR = odds ratio

RCT = randomised controlled trial

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SEP = socioeconomic position

T2DM = type-2 diabetes mellitus

Declarations

Ethics approval and consent to participate

'Check-In' was developed to examine primary prevention aspects beyond existing standard clinical practice, thus no persons were refused access to standard clinical care. Participation was voluntary, and our information material highlighted the option to withdraw without further explanation and without consequences for any treatment or other contact with the GP. Personal identification is encrypted, and data is kept in accordance with the requirements of the Danish Data Protection Agency.

The trial was notified to the Danish Data Protection Agency (permission 2015-57-0008, Acadre no. 16/100534) and the National Committee on Health Research Ethics was notified of the project. However, according to the Act on Research Ethics Review of Health Research Projects (section 14.2), projects like 'Check-In' do not need ethical approval from a Research Ethics Board (Protocol no.: H-1-2013-FSP). The trial is registered at ClinicalTrials.gov (Early detection of and intervention towards chronic diseases; ID NCT01979107; October 25, 2013).

Consent for publication

Not applicable.

Data sharing statement

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The data that support the findings of this study is located at Statistics Denmark and is only available under licence and are therefore not publicly available.

Competing interests

All authors declare that they have no competing interests.

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organisation for the submitted work [or describe if any]; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

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Authors' contributions

NKL participated in the design of the study and its coordination and drafted the manuscript. JST participated in the design of the study. NKL and JST performed the statistical analysis. MBJ participated in the design of the study and its coordination. JLT participated in the design of the study. LBL participated in the design of the study. MG participated in the design of the study. CJ participated in the design of the study. SOD participated in the design of the study and its coordination and supervised the statistical analysis. All authors read and approved the final manuscript.

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NKL affirms that the 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 (and, if relevant, registered) have been explained.

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Legends

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Table 1: Baseline characteristics for participants with low socioeconomic position allocated to a preventive health check at the general practitioner ('Check-In') or to usual care. Values are number (percentages) unless stated otherwise.

Table 2: Effectiveness of 'Check-In' on smoking status (primary outcome) and other health behaviour at 12-months follow-up measured as dichotomized outcomes. Values are number (percentages), ORs and *p* values for the intervention effectiveness. The analyses are performed as per protocol and ITT with multiple imputation.

Table 3: Effectiveness of 'Check-In' on health behaviour measured as continuous outcomes at 12-months follow-up measured as continuous outcomes. The analyses are performed as per protocol and ITT with multiple imputation.

Table 4: Effectiveness of 'Check-In' on incidence of chronic obstructive pulmonary disease, diabetes, disorder of the thyroid gland, hypertension and hypercholesterolemia. The analyses are performed per protocol and as ITT.

Figure 1: CONSORT flow diagram showing recruitment of general practices and patients in Check-In

Supplementary file 1: Example of the study-specific electronic data interchange message to the GP, computed based on the patient-reported questionnaire, including summarized scores and categorization of items – and showing the different options. Translated from the Danish version used in the intervention

Supplementary file 2: Assessment specification of primary outcome (smoking status) and secondary outcomes (other patient-reported health behaviour)

Supplementary file 3: Algorithms used to define the metabolic risk factors and non-communicable diseases

Supplementary file 4: Effectiveness of Check-In on prevalence of non-communicable diseases at 12-month follow-up. The analyses are performed per protocol and as ITT

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Supplementary file 5: Baseline characteristics for those lost to follow-up and those not lost to follow-up, by allocated group

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Table 1

	'Check-In' group (n=549)	Usual care group (n=555)
Demographic and socioeconomic characteristics		
Age, years [median (IQR[2];IQR[3])]	54 (49;59)	54 (49;59)
Men	282 (51)	293 (53)
Danish/other Western ethnic background	437 (79)	446 (81)
Married/cohabitant	279 (51)	270 (49)
Children living at home	137 (25)	134 (24)
Employment status		
Employed	269 (49)	266 (48)
Unemployed/social security	224 (41)	239 (43)
Retired/other	56 (10)	49 (9)
Health behaviour		
Cigarette smoking		
Daily smoker	228 (42)	225 (41)
Not daily smoker	312 (58)	326 (59)
Cigarettes/day*, [median (IQR[2];IQR[3])]	18 (10;20)	20 (10;20)
Current non-drinkers	171 (32)	174 (32)
Drinks/week¤, [median (IQR[2];IQR[3])]	6 (3; 15)	6 (2; 16)
Binge drinking at least weekly	94 (17)	110 (20)
Physical inactivity§	268 (49)	286 (52)
BMI (kg/m^2), [median (IQR[2];IQR[3])]	25.9 (23.1;29.1)	26.2 (23.4;29.7)
Obese (BMI ≥ 30 kg/m^2)	104 (20)	124 (23)
Self-rated bad to very bad health	213 (39)	225 (41)
Self-efficacy, [median (IQR[2];IQR[3])]	29 (24;33)	29 (24;33)
Morbidity and contact with GP		
Non-communicable diseases		
Any chronic condition	337 (61)	359 (65)
Hypertension	118 (22)	133 (24)
Hypercholesterolemia	97 (18)	99 (18)
COPD	124 (23)	127 (23)
Diabetes	175 (32)	191 (34)
Hypothyroidism	55 (10)	44 (8)
Hyperthyroidism	24 (4)	22 (4)
Depression	79 (15)	81 (15)
Number of non-communicable diseases		
0	212 (39)	196 (35)
1	147 (27)	149 (27)
2	93 (17)	112 (20)
≥3	97 (18)	98 (18)
Contact with GP within the last year	495 (90)	480 (87)
Number of contacts with the GP within the last year&, [median (IQR[2];IQR[3])]	7 (4;13)	8 (4;14)

*Among daily smokers; ¤among those who drink alcohol; &among those who visit their GP within the last year; §less than 150 minutes of moderate-intensity physical activity.

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Table 2

Dichotomies outcomes	n (%)		Effectiveness ('Check-In' vs usual care)	
	'Check-In' group (n=549)	Usual care group (n=555)	*OR* (95% CI)	*P* value
Primary outcome				
Daily smokers				
Per protocol, n=710	94 (31)	147 (36)	0.80 (0.58-1.09)	0.16
ITT; multiple imputation	203 (37)	205 (37)	0.99 (0.76-1.30)	0.95
Secondary outcomes				
Binge drinking ≥ weekly				
Per protocol, n=718	55 (18)	84 (20)	0.87 (0.60-1.27)	0.48
ITT; multiple imputation	98 (18)	116 (21)	0.82 (0.59-1.14)	0.24
Physical inactivity (<150 min/week)				
Per protocol, n=721	132 (43)	186 (45)	0.92 (0.68-1.23)	0.56
ITT; multiple imputation	252 (46)	260 (47)	0.97 (0.74-1.27)	0.84
Obese (BMI ≥ 30 kg/m^2)				
Per protocol, n=684	68 (23)	90 (23)	1.01 (0.71-1.45)	0.95
ITT; multiple imputation	131 (24)	122 (22)	0.90 (0.67-1.21)	0.93

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Table 3:

Continuous outcomes	Median (IQR[2];IQR[3])		Effectiveness ('Check-In' vs usual care)	*P* value
	'Check-In' group (n=549)	Usual care group (n=555)	Coef. (95% CI)	Median regression[¤]
Cigarettes/day[#]				
Per protocol, n=239	17 (14;20)	15 (10;20)	2 (-4.7-8.7)	0.35
ITT; multiple imputation	15 (7;20)	15 (7;20)	0 (-2.9-2.9)	0.99
Drinks/week[&]				
Per protocol, n=419	7 (4;19)	8 (4;17)	-1 (-2.8-0.8)	0.38
ITT; multiple imputation	7 (4;17)	7 (4;15)	0 (-1.7-1.8)	0.95
BMI				
Per protocol, n=684	25.9 (23.5;29.7)	26.4 (23.8;29.6)	-0.5 (-1.2-0.2)	0.19
ITT; multiple imputation	25.9 (23.2;29.4)	26.4 (23.6:29.8)	-0.5 (-1.2-0.1)	0.11

[¤]Median regression estimates the median of the dependent variable; [#]Among daily smokers; [&]Among those who drink alcohol

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Table 4

	n (%)		Effectiveness ('Check-In' vs Usual care)	
	'Check-In' group	**Usual care group**	***OR* (95% CI)**	***p* value**
Any new chronic condition[#]				
Per protocol, n=919	82 (23)	120 (22)	1.05 (0.77-1.45)	0.75
ITT, n=1104	125 (23)	120 (22)	1.07 (0.80-1.42)	0.65
Hypertension				
Per protocol, n=704	40 (14)	60 (14)	1.01 (0.66-1.56)	0.96
ITT, n=856	55 (13)	60 (14)	0.88 (0.60-1.31)	0.54
Hypercholesterolemia				
Per protocol, n=752	13 (4)	20 (4)	1.00 (0.49-2.05)	0.99
ITT, n=908	18 (4)	20 (4)	0.90 (0.47-1.73)	0.76
Chronic Obstructive Pulmonary Disease				
Per protocol, n=711	19 (7)	23 (5)	1.24 (0.66-2.31)	0.51
ITT, n=844	32 (8)	23 (5)	1.44 (0.83-2.50)	0.20
Diabetes mellitus				
Per protocol, n=604	8 (3)	15 (4)	0.74 (0.31-1.76)	0.49
ITT, n=720	14 (4)	15 (4)	0.89 (0.42-1.87)	0.76
Hypothyroidism[¤]				
Per protocol, n=919	-	-	-	-
ITT, n=840	-	-	-	-
Hyperthyroidism[¤]				
Per protocol, n=878	-	-	-	-
ITT, n=1051	-	-	-	-
Depression				
Per protocol, n=789	12 (4)	9 (2)	2.05 (0.85-4.91)	0.11
ITT, n=944	25 (5)	9 (2)	2.90 (1.34-6.29)	0.007

[#]Hypertension if no hypertension at baseline, hypercholesterolemia if no hypercholesterolemia at baseline, COPD if no COPD at baseline, diabetes if no diabetes at baseline, hypothyroidism if no hypothyroidism at baseline, hyperthyroidism if no hyperthyroidism at baseline or depression if no depression at baseline

[¤]Too few in each group to report for ethical reasons

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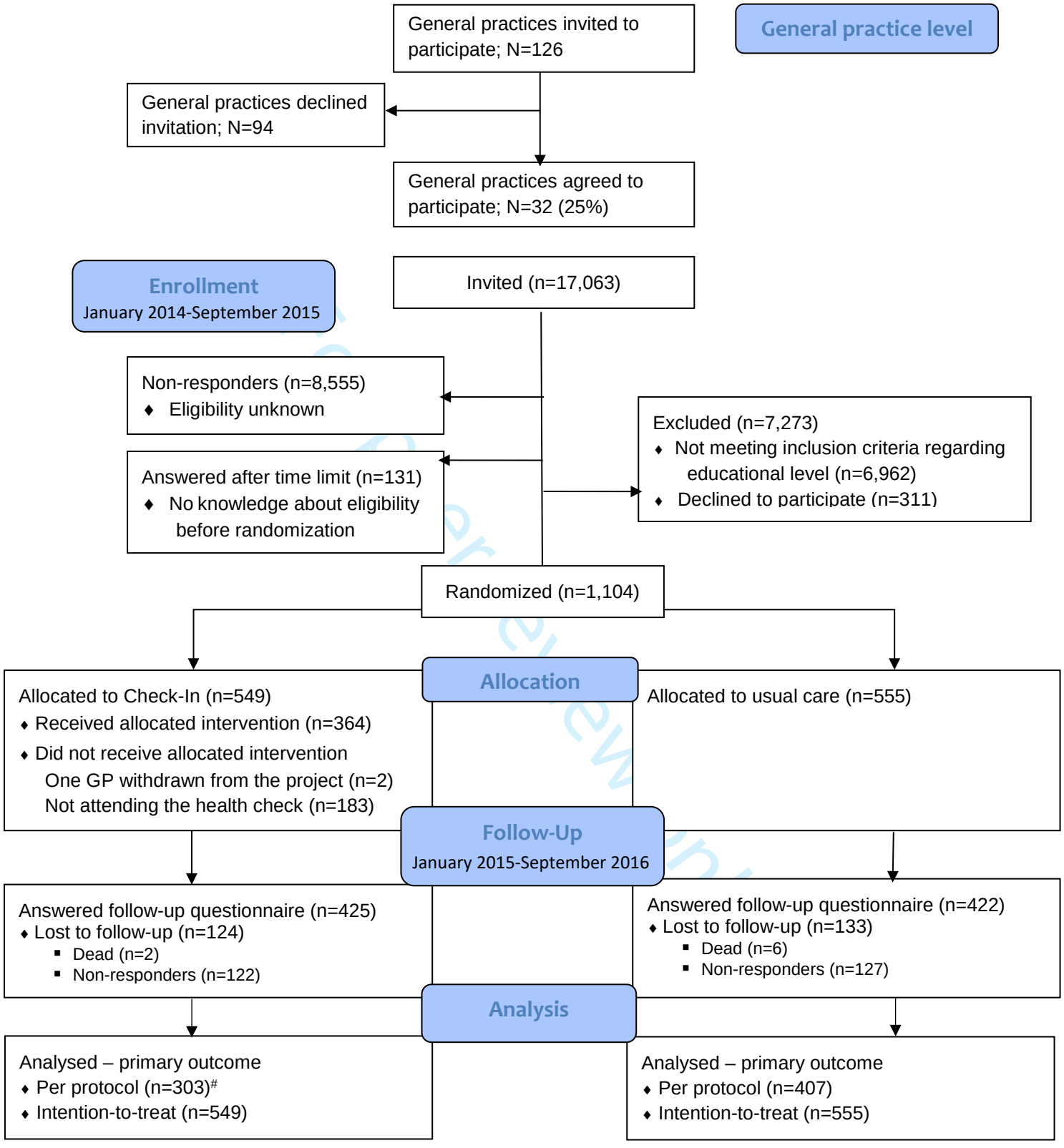
Figure 1: CONSORT flow diagram showing recruitment of general practices and patients in 'Check-In'



In the per protocol analyses are only included individuals who responded the questionnaire and who followed the 'treatment' for the allocated group (for individuals allocated to intervention this meant attending the health check and responding to the questionnaire; for individuals allocated to usual care this meant responding to the questionnaire). Hence, of the 425 responders in the intervention group 303 individuals attended the health check and could be included in the per protocol analyse. Of the 422 responders in the usual care group 407 answered the questions regarding the smoking status and could be included in the per protocol analyse.

Supplementary 1

Sender: DAK-E

Headline: Results from patient-reported factors

Overall result: the patient has an overall increased risk of developing a chronic disease / the patient is at no risk of a chronic disease
School and educational level: the patient has basic/upper secondary school level and no education/special worker/vocational education/short education/medium education/long/other/missing.

Social: The patient lives alone/with partner; with children living at home/without children living at home
Weight (kilograms):
BMI: < 18.5 underweight / 18.5-24.9 normal weight / 25-30 overweight / >30 obese

Smoker status: Daily smoker/occasional smoker/ex-smoker/never
Cigarettes per day:
COPD risk score: Score 0-4 dyspnoea is not caused by COPD / score 5-10 dyspnoea is probably caused by COPD

Alcohol consumption per week (number of units):
Frequency of binge-drinking: daily/weekly/monthly/rarely/never
Follows the Danish Health Authority recommendations for alcohol consumption: yes/no

Diet score: 0-4 unhealthy dietary habits / 5-8 dietary habits can be improved / 9-12 healthy dietary habits
Specification of diet: high intake of sugar/low intake of fruit and berries/low intake of vegetables and root crops/low intake of fish and seafood.

Physical activity (minutes per week):
Follows the Danish Health Authority recommendations of 150 minutes of physical activity per week: yes/no
Specification: low physical training/low everyday exercise
Diseases in the near family: hypertension/hypercholesterolemia/blood clots in the heart/blood clots in the brain/blood clots in the lungs or legs/diabetes/COPD/don't know/none

Self-rated health: excellent/very good/good/bad/very bad
Confidence in own ability to act (self-efficacy): the patient has under/over average confidence in own ability to act

Stress level: not high stress level/high stress level (high stress level = stress level ≥15 for men and stress level ≥17 for women)

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Supplementary 2

Outcome	Items	Response categories
Smoking (primary outcome)	*"Do you smoke?"*	1. *"Yes, daily"* 2. *"Yes, I smoke occasionally"* 3. *"No, I stopped less than six months ago"* 4. *"No, I stopped more than six months ago"* 5. *"No, I have never smoked"*
	"How much do you approximately smoke each day? / How much did you approximately smoke at the time you smoked?"	*Number of cigarettes per day: ____* *Number of cheroots per day: ____* *Number of cigars per day: ____* *Number of pipe stops per day: ____*
Alcohol	*"Do you drink alcohol?"*	1. *"Yes"* 2. *"No, never"*
	"How many units of alcohol do you typically drink each day during the week?"	*For each day in the week note:* *Units of beer:* *Units of wine:* *Units of liquor:*
	"How often do you drink more than five units of alcohol on the same occasion?"	1. *"Daily or almost daily"* 2. *"Weekly"* 3. *"Monthly"* 4. *"Rarely"* 5. *"Never"*
Physical activity	*"For how many hours during a week do you perform exercise that makes you short of breath (e.g. running, soccer, aerobics, tennis, jogging or similar)?"*	1. *"0 minutes"* 2. *"Less than 30 minutes"* 3. *"30-60 minutes (½-1 hour)"* 4. *"60-120 minutes (1-2 hours)"* 5. *"More than 120 minutes (more than 2 hours)"*
	"For how many hours during a week do you perform light exercise? / How much time during the week do you spend on everyday exercise (e.g. a walk, easy gardening, cleaning, biking to and from work or similar)?"	1. *"0 minutes"* 2. *"Less than 30 minutes"* 3. *"30-60 minutes (½-1 hour)"* 4. *"60-90 minutes (1-1½ hours)"* 5. *"90-150 minutes (1½-2½ hours)"* 6. *"150-300 minutes (2½-5 hours)"* 7. *"More than 300 minutes (more than 5 hours)"*
BMI	BMI is generated from these two items: *"What is your height? (in centimetres)"* *"What is your weight? (in kilos)"*	$BMI = \frac{weight\ in\ kilos}{(height\ in\ metres)^2}$

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Supplementary 3

Condition	ICD-10 codes from the Danish National Patient Register	ATC-codes from the Danish National Prescription Registry	Definition
Hypertension	I11, I12, I13, I15	C07B, C03A, C03B, C03E, C03X; or C03C, C03D, C07A, C09 if person does not have ICD I20, I21, I25.1, I50; or C08 if person does not have ICD I20-25#	Diagnosis and/or medicine C07B, C03A, C03B, C03E, C03X; or C03C, C03D, C07A, C09 if person does not have ICD I20, I21, I25.1, I50; or C08 if person does not have ICD I20-25[#]
Hypercholesterolemia		C10	Medicine
Chronic Obstructive Pulmonary Disease	J44	R03	Diagnose and/or medicine
Diabetes mellitus	E10, E11, E12, E13, E14	A10	Diagnosis and/or medicine
Hypothyroidism	E02, E03, E063	H03AA01	Diagnosis and/or medicine
Hyperthyroidism	E05, E062	H03B	Diagnosis and/or medicine
Depression	F32, F33	N06A	Diagnosis and/or medicine

[#] to exclude treatment for underlying heart disease

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Supplementary 4

	n (%)		Effectiveness (Check-In vs Usual care)	
	Check-In group	**Usual care group**	***OR* (95% CI)**	***p* value**
Any chronic condition[#]				
Per protocol, n=919	202 (56)	306 (55)	1.01 (0.78-1.32)	0.92
ITT, n=1104	296 (54)	306 (55)	0.93 (0.75-1.21)	0.68
Hypertension				
Per protocol, n=919	111 (30)	172 (31)	0.98 (0.73-1.30)	0.87
ITT, n=1104	154 (28)	172 (31)	0.87 (0.67-1.12)	0.28
Hypercholesterolemia				
Per protocol, n=919	77 (21)	113 (20)	1.05 (0.76-1.45)	0.77
ITT, n=1104	106 (19)	113 (20)	0.94 (0.70-1.26)	0.66
Chronic Obstructive Pulmonary Disease				
Per protocol, n=919	59 (16)	81 (15)	1.13 (0.79-1.63)	0.51
ITT, n=1104	91 (17)	81 (15)	1.16 (0.84-1.61)	0.36
Diabetes mellitus				
Per protocol, n=919	57 (16)	83 (15)	1.06 (0.73-1.52)	0.77
ITT, n=1104	87 (16)	83 (15)	1.07 (0.77-1.49)	0.68
Hypothyroidism				
Per protocol, n=919	19 (5)	26 (5)	1.12 (0.61-2.06)	0.71
ITT, n=1104	29 (5)	26 (5)	1.13 (0.65-1.95)	0.65
Hyperthyroidism[¤]				
Per protocol, n=919	-	-	-	-
ITT, n=1104	-	-	-	-
Depression				
Per protocol, n=919	48 (13)	71 (13)	1.04 (0.70-1.53)	0.86
ITT, n=1104	80 (15)	71 (13)	1.16 (0.82-1.64)	0.39

[#]Hypertension, hypercholesterolemia, COPD, diabetes, hypothyroidism, hyperthyroidism or depression

[¤]Too few in each group to report for ethical reasons

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Supplementary 5

Baseline characteristics	Lost to follow-up		Not lost to follow-up	
	Check-In group N (%)	Usual care group N (%)	Check-In group N (%)	Usual care group N (%)
Age, years [median (IQR)]	53 [48;57]	54 [49;57]	55 [50;59]	55 [50;59]
Men	81 (61)	61 (49)	212 (50)	221 (52)
Daily smoker	64 (48)	66 (54)	161 (38)	162 (39)
Binge drinking	29 (23)	16 (14)	81 (20)	78 (19)
Physical inactive	86 (66)	69 (57)	200 (48)	199 (47)
Obese	30 (24)	28 (25)	94 (23)	76 (18)
Contact with GP within the last year	114 (86)	112 (90)	366 (87)	383 (90)

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2, 3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4, 5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	None
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5, 7, 8, 9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6, 7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8, 9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	None
Sample size	7a	How sample size was determined	9, 10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	None
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6, 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	Not relevant
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10, 11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2-4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2, 4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13 and supplementary
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15, 16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14, 16
Other information			
Registration	23	Registration number and name of trial registry	18
Protocol	24	Where the full trial protocol can be accessed, if available	Not published
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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