Encouragement of patients’ self-management in primary care for the prevention of cardiovascular diseases (DECADE): protocol for a cluster randomised controlled trial

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ABSTRACT

Introduction Cardiovascular diseases are the most common cause of death in Germany and among the most frequent reasons for encounters in primary care. Most patients with cardiovascular risks (CVRs) have difficulties implementing health-promoting behavioural changes. In this study, a complex intervention containing evidence-based patient materials and structured follow-up consultations are intended to strengthen patients’ self-management to improve health behaviour.

Methods and analysis In this cluster randomised controlled trial, we investigate the effects of the intervention "Decision aid, action planning and follow-up support for patients to reduce the 10-year risk of cardiovascular diseases" (DECADE) using a 2×2 design. All patients, including the control group (CG), receive a CVR calculation. Three intervention groups (IGs) receive one or both of two different components of the DECADE intervention: IG1 (patient materials), IG2 (follow-up consultations) and IG3 (patient materials and follow-up consultations). The study was planned to be conducted with 77 general practitioners in 3 German regions and a target sample size of 924 patients. The observation period for each patient amounts to 12 months with three patient surveys: baseline (t0), after 6 and 12 months (t1 and t2). The primary outcome is patient activation (Patient Activation Measure 13 (PAM13-D)) at t1. Secondary outcomes include PAM13-D at t2 and further patient-reported and clinical outcomes at t1 and t2. We will also analyse the cost-effectiveness of the intervention, the degree of usage and satisfaction with the intervention.

Ethics and dissemination The study was first approved by the lead ethics committee of the University of Freiburg on 15 April 2021 (vote number: 21-1078) and subsequently by the other ethics committees in the study regions (Ethics committee of medical association Baden-Württemberg (B-F-2021-078), Ethics Committee of the Technische Universität Dresden, Dresden (BO-EK-251052021), Ethics Committee of the State Chamber of Physicians of Saxony (EK-BR-92/21-1), Ethics Committee of the Hamburg Medical Association (2021-200013-BO-bet)). Informed consent is required for patients to participate in the study. The results of this study will be published in peer-reviewed journals and presented at congresses by the DECADE team. The DECADE lead management will communicate the results to the funder of this study.

STRENGTHS AND LIMITATIONS OF THIS STUDY

This study aims to fill the research gap concerning the role of patient activation in cardiovascular risk prevention in the primary care setting and examines the effects of the complex intervention “Decision aid, action planning and follow-up support for patients to reduce the 10-year risk of cardiovascular diseases” (DECADE) for supporting patients’ self-management.

As the DECADE intervention consists of two different components (patient materials and follow-up consultations), a cluster randomised trial with a 2×2 design was chosen, which is able to simultaneously investigate the single effects of both components and its interactive effect.

In a comprehensive evaluation, we conduct analyses coping with repeated measurements and clustered data to evaluate the effects of both intervention components on patient-reported and clinical outcomes, analyse the cost-effectiveness and perform additional formative analyses of reported valuations given by patients and general practitioners.

Since the prevalence of cardiovascular diseases and risk factors in Germany varies regionally, this study is being conducted in three regions (south, north and east).

Due to the COVID-19 pandemic and subsequent recruitment problems, we had to extend the recruitment period and had to reduce the originally calculated sample size, but still expect a power of 80% for a clinically relevant effect on the primary outcome.


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INTRODUCTION

Background and rationale

Cardiovascular diseases (CVD) are the most common reasons of death internationally and in Germany. They are among the most common reasons for hospital treatment, with increasing tendency and for encounters in primary care settings. CVD accounted for the highest proportion of total healthcare costs in Germany in 2015 at €46.4 billion. Premature CVD highly correlates with an increased incidence of strokes and transient ischaemic attacks in the younger population. The authors showed not only associations between typical cardiovascular risk (CVR) factors, such as hypertension, smoking and obesity, but also a growing percentage of younger patients without these risk factors, and thus presume that stress is playing an increasing role too. While in Germany, prescriptions of antihypertensive medication, antidiabetics and statins have increased in the last decades, the prevalence of smoking remained relatively high in adults (28.9%) and decreased only slightly in persons over 64 years of age. At the same time, sedentary behaviour and physical inactivity in adults, as well as body mass index (BMI), have also increased over the last decades. In 2019, 53.5% of adults in Germany were overweight (BMI>25 kg/m²), and 19% were obese with a BMI≥30 kg/m². The prevalence of diabetes mellitus had already reached 9.9% of insured persons in statutory health insurances (SHIs) in 2015. On average, 36% of male and 27% of female adults in Germany showed three or more risk factors for CVD.

Long-term health behaviour changes, including medication adherence, are useful in primary and secondary CVD prevention. Nevertheless, most patients with increased CVR have difficulties in implementing health-promoting behavioural changes. Consultations on health behaviour are often experienced as challenging and frustrating by both general practitioners (GPs) and patients. Due to physicians’ time constraints, regular consultations focusing on CVR are often assessed by GPs as impracticable in routine care.

Previous studies indicate that health information and decision aids for chronic diseases are often positively associated with improved healthcare outcomes. Rehabilitation research and studies of disease management programmes provide evidence that patient support and structured counselling may have effects on long-term behaviour and clinical parameters.

For these reasons, the intervention “decision aid, action planning and follow-up support for patients to reduce the 10-year risk of cardiovascular diseases” (DECADE) was developed. DECADE is based on the principles of the Health Action Process Approach (HAPA), in which it is assumed that behaviour changes progress in the motivational and volitional phases with distinct stages starting from risk perception, and continuing to maintenance and recovery of action. It is additionally based on patient-centeredness GP consultations with applied shared decision-making (SDM) and motivational interviewing. The intervention addresses GPs and their patients with lifestyle-related risk factors for CVDs. DECADE combines (a) the application of the CVR calculator ‘arriba’ recommended in the German GP S3 guideline for cardiovascular prevention (https://arriba-hausarzt.de/) with (b) structured patient-centred follow-up consultations and (c) patient materials, containing evidence-based health information, decision-making and action aids for patients. These materials are available as printed DECADE brochures and via access to the DECADE website. Due to its modular design, both components of the DECADE intervention (patient materials and follow-up consultations) can be used separately or in combination and according to the patients’ individual risk factors and preferences for behaviour changes and/or medical treatment. The following topics are addressed: physical activity, diet, weight, smoking, alcohol, blood pressure, cholesterol, blood glucose, stress, sleeping disorder, psychological comorbidities, infections, environmental influences and medication treatment. A comprehensive glossary and further internet links are provided. The DECADE website features the same content as the printed brochures and in addition two short motivational videos. Both components of the intervention, DECADE materials and DECADE follow-up consultations, can be applied in combination, they complement each other, but can also be implemented alone. The Intervention is targeted at primary and secondary prevention of CVD, tailored to each patient.

DECADE was successfully tested in the two-arm randomised DECADE pilot study with 6 GPs and 78 patients in South Baden (Germany). All the patients received a calculation of their individual 10-year risk of CVD using the ‘arriba’ calculator along with 3–4 follow-up consultations within 4 months. In one of two intervention arms, printed DECADE brochures were additionally offered to the patients. After 4 months, the group with DECADE brochures showed significantly higher patient activation (Patient Activation Measure 13 German Version (PAM13-D); primary outcome) than the group without access to DECADE brochures. In both groups, self-reported health status (EuroQol visual analogue scale
(EQ-VAS)\textsuperscript{45} improved, patients indicated that they were living a healthier lifestyle than before the study started\textsuperscript{44} and reported reduced lifestyle risk factors (Indicators of the rehabilitation status (IRES))\textsuperscript{46}.

Prior to the start of the current cluster randomised controlled trial (cRCT), the contents of the brochures were reviewed, in line with the current state of research. Additionally, the new sections on the CVR factors ‘infections’ and ‘environmental influences’ were added. The content of the brochures was also transferred to a new DECADE website. Patients can use both, the print and the web version of the patient materials.

Since the prevalence of CVD and risk factors in Germany varies regionally,\textsuperscript{46} this study is being conducted in three different regions: south (Freiburg, Baden-Württemberg), north (Hamburg) and east (Dresden, Saxony).

**Objectives**

The aim of the DECADE intervention is to strengthen patients’ self-management and lifestyle to reduce their CVR. In addition to increased patient activation, we assume that DECADE improves time management in GPs’ CVR consultations too.

In this cRCT, we investigate the effects of both components of the DECADE intervention (DECADE materials and DECADE follow-up consultations) on the primary outcome, patient activation (PAM13-D) and further secondary patient-reported outcomes as well as clinical outcomes. Additionally, we assess the cost-effectiveness ratio of both intervention components and perform formative evaluations.

**METHODS AND ANALYSIS**

In this study, specific communication training for GPs in accordance with the intervention arm is necessary. In order to prevent contamination of the patients in one intervention arm with other parts of the intervention, each GP builds one cluster to be randomised. We planned this study and will report its findings in accordance to the Consolidated Standards of Reporting Trials (CONSORT) extension for cluster randomised trials\textsuperscript{47} and used Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines when compiling this study protocol.

**Patient and public involvement**

In the iterative development process of the DECADE intervention, we involved outpatients and general population with lifestyle-related CVR factors, GPs and other experts to assess DECADE interventions in interviews, group discussions and in written form (see German Clinical Trial Register: https://www.drks.de/drks_web/setLocale_EN.do with the IDs: DRKS00003554; DRKS00010584, DRKS00025128). The process and results of the intervention development were presented and discussed in scientific congresses\textsuperscript{48–51} and published in open access.\textsuperscript{51} Especially qualitative assessments were used to improve the GP communication training and the technical usability of the DECADE website.

All patients of this cRCT, who declare their interest, will receive a free summary of the study results.

**Study design**

This study is conducted as a multiregional, parallel-group cRCT with four intervention arms in a 2×2 design. The sample is composed of GPs and their patients with at least one lifestyle-related risk factor for CVDs. GPs will be randomised to one of the four intervention arms shown in table 1. GPs in each intervention arm calculate the patients’ CVR by using ‘arriba’\textsuperscript{53} at baseline (t0) and at the end of the study (t2). In the control group (CG), no further instructions are provided; GPs treat patients as usual (TAU). In intervention group 1 (IG1), GPs hand over the DECADE materials (brochures and personalised access to the website) to their patients. Patients in IG2 receive 4–5 structured and patient-centred DECADE follow-up consultations within 12 months. Patients in IG3 receive both components of the DECADE intervention, the patient materials and the structured follow-up consultations. The trained project staff instructs each GP in detail on how to implement the intervention.

The intervention effect of the DECADE materials will be investigated by a comparison of the combined treatment groups (IG1+IG3) versus (CG+IG2). The intervention effect of the structured DECADE consultations will be investigated by a comparison of the combined treatment groups (IG2+IG3) versus (CG+IG1). The interactive effect of the DECADE materials and the structured DECADE consultations will be investigated by a comparison of the intervention effects in the presence of the alternative intervention with the intervention effect without the alternative intervention, that is, (IG3−IG2)−(IG1−CG)=(IG3−IG1)−(IG2−CG)=IG3−IG2−IG1+CG.

**Allocation and blinding**

Each participating GP constitutes one cluster. Thus, all patients enrolled with one GP receive the same intervention according to the randomised intervention arm.

For randomised assignment to one of the four intervention arms in a 1:1:1:1 ratio, we used block randomization (with randomly varying block size to be disclosed after the

<table>
<thead>
<tr>
<th>Table 1 Four intervention arms</th>
<th>CVR calculations</th>
<th>DECADE materials*</th>
<th>4–6 DECADE consultations</th>
</tr>
</thead>
<tbody>
<tr>
<td>CG (TAU)</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IG1</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>IG2</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IG3</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

*Patients may use print version and/or web version of the materials, also concomitantly.

CG, Control group; DECADE, decision aid, action planning and follow-up support for patients to reduce the 10-year risk of cardiovascular diseases; IG, intervention group; TAU, treatment as usual.
end of recruitment), stratified by the three participating regions Freiburg, Hamburg and Dresden. The study statistician produced these lists with a validated Statistical Ananlysis Software SAS macro based on the "SAS procedure PLAN" before the study started. Randomisation will be performed centrally, thus guaranteeing the concealment of randomisation to the GPs. Immediately after receipt of the written registration for study participation, the GP’s pseudonym will be entered into the corresponding regional randomisation list by the project coordinator.

Blinded implementation of the intervention is not possible as DECADE is a complex educative intervention. In accordance with the randomised intervention arm, GPs offer the respective interventions to their patients and are actively involved in their treatment.

Study population and recruitment procedure

Each of the three participating institutes of general practice informs GPs in their regions (Freiburg, Hamburg and Dresden) about the DECADE study via postal and electronic mail, telephone calls, face-to-face and/or online events or meetings. The study was also mentioned in a few contributions in medical journals. GPs willing to participate, sign an agreement with the institute of general practice of the respective region before their concealed allocation to an intervention arm. Without knowing her/his intervention arm, each GP fills out a first GP questionnaire. After study initiation, the enrolment of eligible patients can start.

Eligible GPs

Physicians are eligible to participate in this cRCT if they are GPs, GP trainees or internal medicine specialists working in a GP practice with full care (including home visits) and treating at least 500 patients of any SHI per billing period of 3 months. Practices should be located within a ~200 km radius of one of the three institutes of general practice. Participating GPs have to agree to comply with the study conditions as described in the detailed instructions.

Exclusion criteria for GPs are participation in the 2016 DECADE pilot study, the DECADE preliminary study (focus group interviews) in spring 2021, or participating in another study with similar target/interventions.

Eligible patients

GP practices inform patients via study posters and short leaflets, handed out during selected time slots in the consultation hours. GPs inform interested patients about the study verbally and hand out detailed written information. After the individual informed consent (translated consent form (ICF), see online supplemental material ICF), patients fill out a baseline questionnaire (t0). Additionally, a blood sample is taken, and blood pressure, height and weight are measured in the GP practices.

Patients of each gender, between 30 and 75 years old, and members of any SHI are eligible for the study. They have to meet at least one of the following lifestyle-related CVR factors: smoking, overweight or obesity, lack of exercise, unhealthy diet, high alcohol consumption, unhealthy stress behaviour and/or sleeping disorder. Admitted to the study are patients with or without primary arterial hypertension and/or hypercholesterolemia and/or diabetes mellitus type 1 and/or manifest arteriosclerosis.

Exclusion criteria for patients are any acute cardiovascular event, nursing requirements, severe or severe acute illnesses or short life expectancy, severe cognitive impairments, severe mental illnesses, alcohol addiction, severe eating disorders, pregnancy, planned medical rehabilitation or insufficient understanding of the German language (reading, speaking).

Patients who participated in the DECADE pilot study (2016), the DECADE preliminary study (focus group interviews; spring 2021), or who are simultaneously participating in another study with similar targets/interventions, are not eligible for this study.

GP practices transfer copies of the informed consents (see online supplemental material ICF), t0 questionnaires, and clinical data of each patient separately to the corresponding institute of general practice. A patient is considered included when her/his informed consent and first study data at t0 are received by the institutes of general practice.

Data collection

Three German institutes of general practice at the Medical Centers at the Universities of Freiburg, Hamburg-Eppendorf and Dresden simultaneously collect data for this DECADE study: patient-reported outcomes via three questionnaires, patients’ clinical data, recorded usage data of the DECADE website and monitoring data from the GPs and institutes of general practice. Additionally, we collect GP-reported data via two questionnaires before the study initiation of the GP and after her/his last patient has finished the study (see table 2). The timeline for participants is shown in figure 1. The complete content of collected data with measurement time points is shown in online supplemental tables 1–5 with all related sources reported in the reference list.41–45,54–65

Patients’ data

Questionnaires and clinical data

After their informed consent (see online supplemental material ICF), patients fill out the baseline questionnaire (t0). The blood pressure, height and weight will be measured and a blood sample will be taken in the GP practice. When laboratory values are available, a subsequent consultation takes place. In the presence of the patients, all the GPs compute by using the ‘arriba’ calculator (a) patients’ actual risk of experiencing a cardiovascular event within the next 10 years (CVR Score 0 to >50%) and (b) possibilities to reduce the CVR Score according to treatment measures (possible CVR Score in %). All the patients receive their results via an ‘arriba’-generated
individual leaflet. GPs submit copies of the informed consent forms (see online supplemental material ICF), sealed to questionnaires, and copies of the ‘arriba’ leaflets separately to the corresponding institute of general practice.

GPs of the CG treat patients as usual for the next 12 months, no additional requirements are specified. Patients of the IG1 and IG3 receive the DECADE materials and patients of the IG2 and IG3 receive the DECADE follow-up consultations (after ±7 days; 3 months, 6 months, optionally also after 9 months, and after 12 months with the last consultation).

All the patients obtain the follow-up questionnaires after 6 and 12 months by postal mail and are asked to return them to the regional institutes of general practice. After 12 months of inclusion, GP practices again collect clinical data (blood pressure, weight, height, blood sample) so that a second ‘arriba’ CVR consultation can take place. GP practices send a copy of the ‘arriba’-generated patient leaflets to the corresponding institute of general practice. Complete variables of patient questionnaires and clinical data are presented in online supplemental tables 1 and 2.

**Usage data of the DECADE website**

Patients of the IG1 and IG3 are offered access to the DECADE website in addition to the printed DECADE brochures. The frequency and duration of the DECADE website visits are recorded by the web analytic system Matomo (https://matomo.org/ in accordance with the European Data Protection Regulation https://primguin.de/magazin/matomo-datenschutzkonform). Recorded data of each user profile is shown in online supplemental table 3.

**Monitoring data**

Data, such as DECADE consultation dates and additional CVR consultations, relevant clinical events, study dropouts and any other relevant events are collected by the GP practices. Additionally, each practice lists all the informed but not included patients anonymously with a serial number, date, age, sex, risk factors and their reason for not wanting to participate, if applicable. Complete variables are shown in online supplemental table 4.

**GPs’ data**

Participating GPs are asked to complete two GP questionnaires: one before the study initiation, prior to knowing the respective intervention arm, and one after the last patient of each practice has finished the study. Participation in this survey is optional and possible with informed consent. Each GP can withdraw from the survey at any time, regardless of participation in the cRCT. We ask about sociodemographic data, GP practice characteristics and attitudes towards SDM, patient activation and health counselling by GPs with existing instruments (Clinician Support for Patient Activation Measure (CS-PAM)64 and Shared Decision Making Questionaire for physicians (SDM-Q-Doc),65 both adapted) and self-developed instruments. We further survey GPs’ valuation of the intervention and the usefulness of the intervention to patients from the GPs’ perspective (self-developed). All the collected data and measurement time points of the GP questionnaire are shown in online supplemental table 5.

**Data management**

The standard operating procedure (SOP) for the DECADE data management and DECADE data protection concept specify the handling of all study data such as recruitment, randomisation, study initiation of GPs, data collection, transmission, storage and proofing, closeout of GPs and the data deletion process. GPs of each region (Freiburg, Hamburg and Dresden) send collected study data of participating patients, separated into personal identity data and pseudonymised research data, to their corresponding institute of general practice. Patients receive t1 and t2 questionnaires from the regional institutes of general practice which they complete and return to the sender. If expected data is not received, the physicians or the patients will be reminded according to the SOP and available contact information. The data management teams store and archive all personal identity data and pseudonymised research data separately. They
Information & recruitment of GPs via postal and e-mail information, information in online- and presence events. Due to the COVID-19 pandemic, an expansion of the recruiting period and radius, and a reduction of the sample size were required.

Collaboration agreement: GP and IGP

Cluster-randomization (on GP-level)

First GP-questionnaire (before study initiation / without knowledge of the study arm)

Enrollment: 12 patients by each GP with informed consent according to the study arm, baseline patient-questionnaire, blood sample, BP, weight & height

2-7 days after blood sample: consultation “arriba” CVR-calculation.
All patients receive an individual “arriba”-leaflet

DECADE-materials

DECADE-follow-up consultations
Shared decision on objectives
Progress consultation
First follow-up patient-questionnaire

DECADE-materials

DECADE-follow-up consultations
Shared decision on objectives
Progress consultation

First follow-up patient-questionnaire

DECADE-materials

DECADE-follow-up consultations
Shared decision on objectives
Progress consultation

Last follow-up patient-questionnaire

In GP-practice: last clinical data (blood sample, BP, weight & height)

2-7 days after blood sample: consultation “arriba”-CVR-calculation.
All patients receive an individual “arriba”-leaflet.

Offer: DECADE-materials & DECADE-follow-up consultations

Offer: DECADE-follow-up consultations

Progress consultation

Offer: DECADE-materials

Progress consultation

Last GP-questionnaire: after last patient of the practice finished the study

Data collection ends

Figure 1 Participant timeline. BP, blood pressure; CG, control group; CVR, cardiovascular risk; DECADE, decision aid, action planning and follow-up support for patients to reduce the 10-year risk of cardiovascular diseases; GP, general practitioner; IGP, institute of general practice; IG, intervention group; t0, baseline; t1, first follow-up; t2, last follow-up.
record incomplete and not plausible data in self-evident correction documents. GP practices record other relevant data as part of the study monitoring. These data will be regularly transferred to the corresponding institute of general practice and finally collected at the closeout.

Plausibility checks of the data will be performed first by visual inspection and finally by using project-specific syntaxes in each institute of general practice. The data management teams send their checked data files to the project coordinator, who merges the data. After proofing and finalisation of the overall data file, the statisticians perform the main analyses and cost-effectiveness analyses. Additional formative examinations will be conducted by the DECADE project members.

The funder does not influence data collection, data management or data analysis. It will have no access to the raw data but is only given information on how the recruitment and follow-up assessments are progressing.

Study timeline
Figure 1 shows the participant timeline.

Consequences of the COVID-19 pandemic for this cRCT
Due to the COVID-19 pandemic, the start of planned GP enrolment, scheduled in May 2021, was delayed to October 2021, thus recruitment coincided with the fourth wave of the pandemic in Germany. Vaccination campaigns in GP practices, COVID-19 infections and serious personnel shortages caused a workload overload for practice staff and resulted in a severely delayed recruitment of GPs and patients. The recruitment procedure started in October 2021 with the first included GP; the first patient was enrolled on 3 November 2021. The recruitment period was extended from the originally planned 6 months to 15 months until 16 January 2023. According to the study duration of 12 months for each patient, the planned end of data collection (last patient out) is in January 2024.

Primary and secondary outcomes
The primary outcome is the patient-reported, validated instrument ‘Patient Activation Measure 13’ (PAM13-D) at the 6-month follow-up (t1) after baseline (t0). We decided to use the PAM13-D as the primary outcome, as it measures knowledge, skills and self-confidence to manage health or health behaviour. The 13 Items of the PAM13-D include statements about risk perception, action expectation, self-efficacy, experiences in maintaining behaviour changes, beliefs in maintaining against barriers and skills to communicate health problems with healthcare providers. The questionnaire therefore largely corresponds to the HAPA, on which the DECADE intervention is based. Additionally, the DECADE intervention aims to support patients regardless of the number and type of CVR factors or the level of the cardiovascular 10-year risk. We therefore assume that PAM13 appropriately measures the effects of the DECADE intervention. In a large number of studies, changes in self-management—measured by PAM13—were associated with changes in health-related behaviour, health outcomes and costs. Patient activation is measured by 13 items on a Likert scale from 1 (strongly disagree), 2 (disagree), 3 (agree) to 4 (strongly agree). The row sum score (13–52) will be transformed from 0 (lowest) to 100 (highest) patient activation.42

Tables 3–5 present an overview of all the secondary outcomes.

In each questionnaire instrument, at least 50% of the items have to be completed, in order to be considered in the data analysis. An exception is the ‘goal attainment scale’ of patient questionnaires: if at least one goal is selected, these data will be analysed.

To calculate the scores of the instruments, only completed items are considered; no data will be imputed.

Statistical methods
Sample size calculations
The calculation of the required number of patients is based on the primary outcome change in PAM13-D, calculated as the difference in PAM13-D at t1 compared with t0. In the DECADE pilot study, the prespecified intention-to-treat analysis of n=78 patients in the linear regression model adjusted for baseline PAM13-D, baseline CVR Score and GP showed an improvement of mean 3.3 (+6.1 SD) by the printed DECADE materials within 4 months for the endpoint change in PAM13-D compared with the CG. This corresponds to an effect size of 0.54.

In this cRCT, which examines the effect over a longer period of time and in a more heterogeneous setting, we planned a power of 90% to show the effects at a two-sided significance level of 5% for both parts of the DECADE intervention (DECADE materials and DECADE follow-up consultations) assuming an effect size of 0.3. The investigations on the effects of the two interventions to be examined are considered as separate research questions, thus no alpha adjustment is performed for multiple testing. Under these assumptions, it would be necessary to randomise 470 patients in a trial randomising the individual patients. Due to the cluster randomisation with an assumed correlation of patients within GPs, a variance inflation factor (VIF) has to be considered. The intraclass correlation coefficient (ICC) is assumed to be 0.1 for the calculation of the VIF. This assumption seems reasonable because, according to the CONSORT statement for cluster randomised trials, the ICC is usually small, often not higher than 0.05. In the DECADE pilot study, modelling a random practice effect resulted in an estimated ICC of 0.1.

For this cRCT, np=12 patients per GP should be enrolled, resulting in a VIF of (1+(np−1)×ICC)=2.1, and thus a total of 987 patients must be included in the analyses. Due to experiences from the pilot study, we expect that 20% of patients will not have a PAM13-D measurement at 12 months (dropout of 10% at each measurement time point t1 and t2); therefore, 103 GP practices, each contributing 12 patients, were originally planned to be randomised, to recruit a total of 1236 patients.
However, due to the ongoing difficulties caused by the COVID-19 pandemic in GP practices, we did not expect to recruit 103 GPs who enrol 1236 patients in a fundable timeframe. Considering the above-mentioned conditions (assumed effect size of 0.3, ICC of 0.1, dropout of 10% at t1 and t2), we expect achieving a power of 80% (instead of the initially planned 90%) to show an effect on the primary endpoint, if 77 GPs each enrol 12 patients (total N=924 patients (revised target sample size)). The difficulties in recruitment do not cause any changes in data collection or intervention. After the end of the recruitment period on 16 January 2023, N=76 GPs had enrolled N=797 patients. The mean number of patients per GP is 10.49, with a SD of 3.164. With an ICC of 0.1, as assumed in the initial planning, this leads to a VIF of 2.044. If we still assume a dropout of 10% at time t1, the data of 717 patients will be available for the primary analysis. With this number of patients, we still expect a power of 80% if the effect size is 0.3.

### Statistical analysis

The analysis of the primary outcome is performed in the modified ‘full analysis set’, which includes all patients in their randomised intervention arm for whom at least one postbaseline measurement of PAM13-D is available. This analysis addresses the treatment policy estimated as defined by ICH E9(R1).

Analysis of change in PAM13-D will be conducted using a linear mixed models for repeated measures (MMRM) including the fixed effects of the DECADE materials (IG3+IG1 vs IG2+CG), DECADE follow-up consultations (IG3+IG2 vs IG1+CG), the interactive effect between DECADE materials and DECADE follow-up consultations, the PAM13-D baseline value, the CVR baseline value, the measurement time point (t1 vs t2), the interactive effects between the interventions and the measurement time point, and the practice as a random effect to account for the cluster randomisation.

The effects of the interventions at month 6 and month 12 will be estimated with 95% CIs. The primary confirmatory tests of the null hypothesis that the effect of the intervention is zero will be based on the estimated effects at month 6.

Most patient-reported outcomes, surveyed at t0, t1 and t2, and clinical data, collected at t0 and t2, will be analysed with MMRM, using analogue models as we used to test the primary outcome. For the outcomes collected only at t1 (month 6) and t2 (month 12) this corresponds to a linear mixed model without repeated measurement of the outcome. We analyse descriptively the impact of the DECADE materials and DECADE follow-up

### Table 3  Patient-reported secondary outcomes: changes from baseline (t0) to t1 and t2

<table>
<thead>
<tr>
<th>Patient-reported secondary outcomes</th>
<th>Origin/source</th>
<th>Items, n</th>
<th>Measurement time</th>
<th>Type of analysis</th>
<th>Analysing period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Activation Measure: Likert scale: 0 (strongly disagree) to 3 (agree strongly); transformed sum score: 0 (lowest patient activation) to 100 (highest patient activation)</td>
<td>PAM13-D</td>
<td>13</td>
<td>t0 baseline</td>
<td>MMRM</td>
<td>t0-t2</td>
</tr>
<tr>
<td>Self-rated health: Visual analogue scale: 0 (lowest health status) to 100 (highest health status)</td>
<td>EQ-5-D VAS</td>
<td>1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Body mass index (kg/m²) calculated by self-declaration of height (cm) and weight (kg)</td>
<td>IRES</td>
<td>1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self-rated diet: Likert scale: 0 (unhealthy) to 4 (very healthy)</td>
<td>IRES</td>
<td>1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self-rated exposure to stress: Likert scale: 0 (not burdened at all) to 4 (very strongly burdened)</td>
<td>IRES</td>
<td>1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self-rated alcohol consumption: Likert scale: 0 (never) to 4 (daily or almost daily)</td>
<td>WHO ASSIST V3</td>
<td>1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Physical activity: Sum score: Minutes of physical activity in everyday life and work plus sports per week</td>
<td>BSA</td>
<td>2</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Smoking status: Smoking within the last 3 months (yes/no)</td>
<td>Self-developed</td>
<td>1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

BSA, Physical Activity and Sport Activity; CVR, cardiovascular risk; DA, descriptive analysis; EQ-5-D VAS, EuroQuol German version visual analogue scale; IRES, Indicators of the rehabilitation status; MMRM, mixed models for repeated measures; PAM13-D, Patient Activation Measure 13; t, measurement time point.
consultations on patient-reported changes in health, surveyed at t1 and t2. Tables 3–5 present the secondary outcomes with their scales, measurement time points and types of analyses.

No alpha adjustment for multiplicity in the analysis of the secondary outcomes will be performed. Only the result of the primary efficacy analysis will be interpreted in a confirmatory manner. P values from analyses of the secondary outcomes will be interpreted in a descriptive sense.

No interim analyses are planned.

### Table 4  Patient-reported secondary outcomes: analyses t1 and t2

<table>
<thead>
<tr>
<th>Patient-reported secondary outcomes</th>
<th>Origin/source</th>
<th>Items, n</th>
<th>Measurement time</th>
<th>Type of analysis</th>
<th>Analysing periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-rated change in health behaviour: 1 (less healthy), 2 (not different than before), 3 (healthier)</td>
<td>Siegel and Stößel(^{44})</td>
<td>1 x x</td>
<td>DA t1 and t2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goal attainment: Likert scale: 0 (not attained at all/worse than before) to 5 (more attained than planned); Mean score: 0 (lowest attainment) to 5 (highest attainment)</td>
<td>GAS(61) adapted (pilot study(^{41}))</td>
<td>12 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction with goal attainment: Likert scale: 1 (very satisfied) to 5 (very unsatisfied); Mean score: 1 (highest satisfaction) to 5 (lowest satisfaction)</td>
<td>Self-developed (pilot study(^{41}))</td>
<td>12 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-rated knowledge increase: Likert scale: 0 (strongly disagree), 1 (disagree), 2 (agree), 3 (agree strongly); Mean score: 0 (lowest knowledge increase) to 3 (highest knowledge increase)</td>
<td>Self-developed</td>
<td>3 x x MMRM t1 and t2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shared decision-making in CVR consultations; Likert scale: 0 (strongly disagree), 1 (disagree), 2 (agree), 3 (agree strongly); Mean score: 0 (lowest participation) to 3 (highest participation)</td>
<td>SDM-Q-9(^{63}) adapted</td>
<td>4 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valuation of CVR consultations: Likert scale: 1 (very satisfied) to 5 (very dissatisfied); Mean score: 1 (highest satisfaction) to 5 (lowest satisfaction)</td>
<td>Self-developed (pilot study(^{41}))</td>
<td>7 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CVR, cardiovascular risk; DA, descriptive analysis; GAS, Goal Attainment Scale; MMRM, linear mixed models for repeated measures; SDM-Q-9, Shared Decision Making Questionnaire; t, measurement time point.

### Table 5  Secondary clinical outcomes: changes from baseline (t0) to t2

<table>
<thead>
<tr>
<th>Secondary clinical outcomes, collected by GP practices</th>
<th>Origin/source</th>
<th>Items, n</th>
<th>Measurement time</th>
<th>Type of analysis</th>
<th>Analysing period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>Copy of the ‘arriba’-generated patient leaflet</td>
<td>1 x x</td>
<td>MMRM t0–t2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td></td>
<td>1 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL)</td>
<td></td>
<td>1 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (%) in patients with diabetes</td>
<td></td>
<td>1 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculated CVR Score (0%–50%) in patients without manifest arteriosclerosis</td>
<td></td>
<td>1 x x</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CVR, cardiovascular risk; GP, general practitioner; HbA1c, haemoglobin A1c; HDL, high-density lipoprotein; MMRM, linear mixed models for repeated measures; t, measurement time point.

### Cost-effectiveness analyses

To obtain an estimation of the cost-effectiveness ratio, the costs of the DECADE follow-up consultations are related to the primary and secondary outcome measures. The costs of the DECADE follow-up consultations are priced using standardised unit costs\(^{70}\) and summed up with the printing costs of the DECADE brochures. Standardised unit costs represent societal opportunity costs of service utilisation and are based on published billing data and/or publications of official statistics. The resulting cost at the patient level is evaluated as an additional endpoint.
analagous to the analysis strategy described above. In addition, cost-effectiveness ratios are determined for the different endpoints and comparisons, and the associated CIs are calculated by applying Fieller’s theorem.\(^7\)\(^1\)

Cost-effectiveness ratios include costs per unit of improved patient activation (PAM13-D) and unit costs of absolute risk reduction (CVR Score).

Furthermore, we analyse to what extent intervention-related effects regarding the outcomes of patient activation (PAM13-D) and CVR Score can be ‘translated’ into cost savings (through reduced utilisation of services). In the publication by Greene et al.,\(^6\) this relationship is well examined.

### Additional and formative analyses

All data collected and used for additional and formative analyses are presented in the online supplemental tables.

In explorative analyses, we describe patient-reported changes in diet (based on Food Frequency Questionnaire FFQ\(^5\)) and changes in consumption of tobacco products (self-developed) between t0 and t1 and t0 and t2 and compare the results between both components of the DECADE intervention.

Usage data of the DECADE website will be analysed in an explorative approach. We will analyse the frequency and duration of patients’ logins and visits of subpages and proof differences between the intervention arms IG1 and IG3 and associations with sociodemographic characteristics, patient activation (PAM13-D), health status (EQ-VAS) and CVR factors.

Valuation of different parts of the DECADE interventions will be analysed descriptively by the patient-reported and GP-reported data as following:

- Description of the sociodemographic data of GPs and the characteristics of the GP practices.
- Analyses of GPs’ attitudes towards patient participation (adapted SDM-Q-Doc\(^6\)) patient activation (adapted CS-PAM\(^6\)) and health behaviour consultations (self-developed) at the beginning and the end of the study and comparison of the results between the intervention arms.
- Description of GPs’ and patients’ satisfaction with the components of the DECADE intervention and the ‘arriba’-generated leaflet, as well as GPs’ perspective regarding the usefulness of the intervention for their patients, the feasibility of the intervention in terms of content and time, their perceived cost-benefit ratio and whether GPs will perform the follow-up consultations in the future (self-developed). Additionally, we will compare GPs’ and patients’ valuations of the DECADE intervention components.
- Description of correlations between sociodemographic and practice characteristics and attitudes of the GPs towards patient activation (CS-PAM) as well as patient activation (PAM13-D).

Monitoring data will be descriptively analysed. Frequencies of consultations, dropouts and non-participants will be used for interpreting the results of the main analyses, cost-effectiveness analyses and for a dropout analysis. During the runtime of the study, monitoring data will be used for process evaluation with the objective to react early in cases of deviations from the study protocol or an extraordinary increase in clinical events.

### ETHICS AND DISSEMINATION

#### Ethics and data protection

This study complies with the ethical principles for medical research involving human subjects according to the Declaration of Helsinki.\(^7\)\(^2\)\(^2\) The study has been first approved by the leading ethics committee of the University of Freiburg (vote No.: 21-1078 on 15 April 2021) and further by the ethics committee of medical association Baden-Württemberg, the Ethics Committee of the Technische Universität Dresden, Dresden, the Ethics Committee of the State Chamber of Physicians of Saxony and the Ethics Committee of the Hamburg Medical Association. The ethics committees were subsequently informed about two minor changes: (1) technical modification in electronic data transfer. These changes were approved by IT security and the privacy officers of all collaborators and integrated into the informed consent forms prior to the start of the study (see online supplemental material ICF). (2) Minor changes concerning the formative evaluation (especially the GP questionnaire).

The information was acknowledged and approved by the leading Ethics Committee on 31 August 2021 (V2) and 31 March 2022 (V3). In case of any major modifications, an amendment to the ethical vote will be submitted and in the matter of minor changes, the Ethics Committees will be informed.

The DECADE study is registered in the German Clinical Trials Register (DRKS-ID: DRKS00025401; Trial registration date: 21 June 2021) and in the International Clinical Trials Registry Platform (https://clinicaltrial.gov/ct2.aspx?search=DECADE). The first patient enrolled on 3 November 2021 and the recruitment ended on 16 January 2023. We plan for the last patient to leave the trial in January 2024. We have published modifications as regards the recruitment period sample size in the register and will issue updates with any other relevant changes.

All members of the DECADE team, collecting or managing data agreed to the data protection concept of the study, based on the European General Data Protection Regulation (https://gdpr-info.eu/), in which all rules, responsibilities and the corresponding risk estimation are defined.

Participation in the DECADE study is voluntary. Non-participation does not lead to any disadvantages compared with TAU. Patients may only participate after being informed verbally and in written form by their GP. GP practices must send a copy of the signed informed consent form (see online supplemental material ICF) to their corresponding institute of general practice. The consent can be withdrawn by patients at any time without...
any disadvantages. In case of withdrawal, all data will be anonymised. Study participants can assert their data subject rights at any time.

All personal identity data are stored/archived separately from the pseudonymised research data. Identity data will be erased/destroyed 3 years after the project’s completion. This process anonymises all research data. After 10 years of the project’s completion, all research data will be deleted/destroyed.

Data handling

The specific tasks of the collaborating institutions have been defined in the specific data protection concept and a joint controller agreement according to Article 26 of the European Data Protection Regulation, both signed by the responsible parties. Following our data protection concept and the informed consent form (see online supplemental material ICF), the data from this study will be shared, managed and pseudonymously analysed between/by the DECADE project staff. According to the license agreement of the PAM13-D instrument, we will transfer PAM13-D-related limited and anonymised data to the developers of this instrument. As determined in the informed consent form, no other data will be shared with third parties. The data transfer will be realised via a secure cloud of the Medical Center of the University of Freiburg.

Possible risks and benefits

Patients do not incur any risk by participating/non-participating in the study, since the individual connection of the patients to their GPs throughout the study period is given. Patients of all intervention arms may seek counselling from their GPs in addition to the predefined DECADE consultations. Patients will be asked about adverse events by their primary care physicians. Additionally, a note for patients to report adverse events is included in the patient information. These are documented and reported without delay to the institutes of general practice. Information is added to the monitoring data which is used to identify extraordinary or adverse events. If contrary to expectations, there should be unusual risks for patients, all ethical committees will be informed and the interruption, modification or termination of the study will be considered. The ethics committees will also be informed of any changes to the protocol.

GPs might improve their CVR consultations by participating in this study. Additional costs associated with the study will be compensated with an expense allowance of €20 per questionnaire and a laboratory fee of €4.50 per examination. After the end of data collection for this study, all GPs will be invited to a DECADE communication training to be able to offer full intervention. GPs of the CG and IG2 receive the DECADE materials for distribution to their study patients. This offer is free of cost for GPs and study patients.

Patients in all intervention arms may have health benefits from participating in the study. They receive free ‘arriba’ consultations and, during or after the data collection, DECADE materials and DECADE follow-up consultations. Additionally, the patients obtain stamps in the value of about €10 for completing the questionnaires.

Dissemination policy

For dissemination, the results of the DECADE study are to be published in peer-reviewed scientific journals and presented at congresses and conferences. The DECADE team is involved in all publication plans and aims to publish scientific articles on questions of interest, for which appropriate authorships will be determined according to the guidelines for ‘Safeguarding Good Research Practice’. The consortium leadership in Freiburg will communicate the results to the study’s funder (The Federal Joint Committee Germany) with the aim that effective measures will be implemented in routine care.

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Contributors IT is the first author of this study protocol. She developed the intervention, carried out the DECADE pilot study, led the proposal for this research project, coordinates all tasks of this cRCT, including planning, implementation, and development of questionnaires, data assessments, data management and evaluation of the overall study. CS carried out the main statistical analyses of DECADE pilot study, developed the study design of this cRCT and will perform the main statistical analysis of this study. AM is the project leader of DECADE. He participated especially in the further development of the communication training for GPs and the development of the DECADE website. He is responsible for all medical questions in the project and participates in the project coordination. MB, MK, HH, AR, TG and SK executed pretests of questionnaires, participated in the optimisation of the survey instruments, study documentation, the development of the DECADE website, GP training, the development of ethical approvals and data protection concept. They recruit GPs in their regions, execute the initiation of GPs and the data management. They are contact persons for all study participants (patients...
and GP practices) of their region. MB and MK were also involved in updating the DECADE materials. KK planned the cost-effectiveness analyses and is responsible for its realisation. TK and MS supported the development of the study, the study application and the planning and implementation of all work packages at the Hamburg site. They also supervise the Hamburg staff, AR and HH. HR was involved in the development of the DECADE website, GP training and survey instruments. She coordinates the study including the recruitment, data assessment, data management, and evaluation and interpretation of data for the study site Dresden. AB critically reviewed the manuscript. All authors participated in the preparation of this manuscript and reviewed it critically.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

**Patient consent for publication** Not applicable.

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**REFERENCES**


Title: Nutrition, alcohol use, and physical activity vary between regions in Germany.

Abstract: Although there has been an increased focus on the importance of health behavior in recent years, there is a lack of comprehensive evidence on how health behavior varies between regions in Germany. The purpose of this study was to describe the distribution of selected health behaviors in a large-scale national survey.

Methods: We analyzed data from the Health Behavior in Germany Study (GBG), a nationally representative survey conducted in 2012. The survey included 20,000 participants aged 14 years and older. We used logistic regression to examine the association between region and health behavior, controlling for age, sex, education, and income.

Results: We found significant regional differences in the prevalence of selected health behaviors. For example, the prevalence of smoking was highest in the northwestern region and lowest in the southeastern region. Similarly, the prevalence of alcohol use was highest in the southern region and lowest in the northeastern region. Also, the prevalence of physical activity was highest in the western region and lowest in the eastern region.

Conclusion: Our findings highlight the importance of considering regional differences when designing and implementing health policies and programs. Future research should explore the underlying reasons for these regional differences and develop effective strategies to address them.

Keywords: Health behavior, regional differences, Germany, GBG.