Disease management programmes for patients with coronary heart disease—An empirical study of German programmes

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Abstract

Objective: To evaluate healthcare and outcomes of disease management programmes (DMPs) for patients with coronary heart disease (CHD) in primary care, and to assess selection of enrolment for these programmes.

Methods: A cross-sectional survey of 2330 statutorily insured patients with a history of acute myocardial infarction (AMI) was performed in 2006 by the population-based KORA Myocardial Infarction Register from the region of Augsburg, Germany. Patients enrolled in DMP-CHDs receive evidence-based care, with patients not enrolled receiving standard care. To control for selection bias, a propensity score approach was used.

Results: Main factors influencing DMP participation were age (OR 0.98, 95% CI 0.96–0.99), diabetes (OR 1.56, CI 1.25–1.95) and time since last heart attack (OR 0.98, CI 0.95–0.99). Significantly more patients enrolled in DMP-CHDs stated that they received medical counselling for smoking (OR 3.77, CI 1.07–13.34), nutrition (OR 2.15, 1.69–2.74) and for physical activity (OR 2.58, 1.99–3.35). Furthermore, prescription of statins (OR 1.58, CI 1.24–2.00), antiplatelets (OR 1.96, CI 1.43–2.69) and beta-blockers (not significant) were higher in the DMP group. With respect to outcomes, we did not see relevant differences in quality of life and body mass index, and only a minor reduction in smoking.

Conclusions: Enrolment into DMPs for CHD exhibits systematic selection effects. Participants tend to experience – at least on a short to medium term and for AMI patients – better quality of healthcare services. However, since DMP-CHDs were initiated only 2 years ago, we were unable to identify significant improvements in health outcomes. Only the reduction in smoking provides a first indication of better quality outcomes following DMP-CHD. Thus, policy-makers must provide appropriate incentives to sickness funds and physicians in order to ensure initiation and continuation of high quality DMPs.

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1. Introduction

In the 1990s, health organisations in developed countries started to offer new models of healthcare for chronically ill patients – so-called disease management programmes (DMPs). These programmes intended to improve the quality and cost-effectiveness of healthcare for chronic conditions by implementing evidence-based guidelines and establishing clinical pathways [1–3]. Under the German statutory health insurance (SHI), the legal framework for sickness funds to implement DMPs was created in 2002 [4,5]. The first DMP started in January 2003. Up to September 2007, a total number of 14,000 DMPs1 (17 regions, more than 200 sickness funds) were registered for various diseases (diabetes mellitus type 1 and 2, breast cancer, coronary heart disease and asthma/chronic obstructive pulmonary disease). In September 2007, the number of patients voluntarily enrolled in DMPs reached almost 3.6 million [7].

DMPs for coronary heart diseases (CHD) constitute a prominent share of all programmes. Cardiovascular diseases including CHD and chronic heart failure are the most common cause of death in industrialised countries, and impose a significant economic burden on the US and European healthcare systems [8,9]. The prevalence of CHD in Germany is about 7%, affecting almost 6 million people [10]. Healthcare costs of CHD in 2004 were approximately 7 billion EUR, and total costs (including productivity losses and informal care) were estimated at 13 billion EUR [11,12]. In Germany, deficits in medical care of patients with CHD, e.g., insufficiently prescribed standard medication, high percentage of CHD patients with increased blood pressure, smoking or adiposity, resulted in the introduction of DMP-CHDs in the middle of 2004 [13,14].

To date, no study has systematically compared DMP-CHDs (evidence-based treatment) with usual care (standard treatment) in Germany. Cardiovascular diseases including CHD and chronic heart failure are the most common cause of death in industrialised countries, and impose a significant economic burden on the US and European healthcare systems [8,9]. The prevalence of CHD in Germany is about 7%, affecting almost 6 million people [10]. Healthcare costs of CHD in 2004 were approximately 7 billion EUR, and total costs (including productivity losses and informal care) were estimated at 13 billion EUR [11,12]. In Germany, deficits in medical care of patients with CHD, e.g., insufficiently prescribed standard medication, high percentage of CHD patients with increased blood pressure, smoking or adiposity, resulted in the introduction of DMP-CHDs in the middle of 2004 [13,14].

To date, no study has systematically compared DMP-CHDs (evidence-based treatment) with usual care (standard treatment) in Germany. This is despite the fact that the German sickness funds are obliged by the Social Security Code to evaluate DMPs. There may be two reasons for this: first, DMPs for CHD only started in 2004, leaving limited time for evaluation. Second, and more importantly, evaluation is difficult because of the regulatory linkage between certified DMPs and the risk adjustment system. From this system, sickness funds receive higher payments for each patient who is enrolled in a DMP-CHD (in the case of CHD on average €1700/year for patients not enrolled and €4460/year for enrolled patients [17]). This has driven sickness funds to enrol potential candidates for the DMP as fast as possible, and thereby reduces the possibilities for recruiting control groups [6].

International investigations show positive as well as controversial effects of DMP-CHDs. A systematic review on DMPs for CHD concludes that, while those programmes can improve processes of care, reduce admissions to the hospital, and enhance patients’ functional status, their “impact on survival and recurrent infarctions, and their cost-effectiveness, as well as the optimal mix of components remain uncertain” [18]. A recent study shows positive effects of DMP-CHDs on process and outcome quality [19]. The majority of studies were conducted in the US, and thus arise from a different system than the German social security system. Furthermore, as DMPs are set up in different ways, the effects of the programmes can vary. Thus, an evaluation of the German DMP-CHDs would complement the international discussion on these aspects.

Considering this background, the objective of this study is to evaluate the medical care of patients with acute myocardial infarction (a subgroup of persons with CHD) who are enrolled in DMP-CHDs, and compare this with patients with acute myocardial infarction who have not been enrolled in DMP-CHDs. In particular, the following research questions will be analysed:

1. What differences can be found in characteristics of patients enrolled in DMP-CHDs compared with patients not enrolled (selection of enrolment)?
2. Is medical care received by DMP-CHD enrolled patients more extensive and guideline-orientated than medical care for not enrolled patients (quality of healthcare services)?
3. What differences in the results of medical care can be identified for DMP-CHD enrolled patients, as

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1. Despite the sheer number of DMPs, they are highly standardised within each indication [6].
2. During the 1990s, freedom of free consumer choice and a system of risk adjustment were introduced in the SHI. Until 2001, the risk adjustment system was based on age, sex and entitlement to invalidity pensions. This former system left sickness funds ample opportunities to select risks respectively, and these funds faced tremendous lack of financial incentives to actively manage care [15,16].
compared with not enrolled patients (quality of health outcomes)?

2. Description of the German DMP-CHD

In Germany, in 2001, the mandated Federal Joint Committee set DMPs’ minimum common requirements, which propose regulation on the following issues (Social Code, Book V, §137f):

- treatment guidelines for providers,
- necessary quality assurance measures,
- conditions and process of patient enrolment,
- training of and information for providers and patients,
- documentation of diagnostic measures, therapeutic arrangements, and treatment results and
- evaluation of effectiveness and costs.

Based on the defined minimum requirements, sickness funds agree contracts with providers and install their own provisions for informing and motivating patients to enrol, and for patient education and programme evaluation [4]. Each DMP then needs to be accredited by the Federal Insurance Office, which mainly checks whether the programme fulfils the legal requirements. The sheer number of applications and certifications, as mentioned in the Introduction, suggests a high level of diversity. However, contracts for disease management programmes between sickness funds and healthcare providers are highly standardised. This is because contracts are often based on designs suggested by the national organisations of sickness funds, and physicians are very much interested in standardised enrolment and documentation procedures for all patients [6].

Disease-specific requirements for DMPs are defined by the Joint Federal Committee in an ordinance [20,21]. Overall therapy targets of DMP-CHDs are the reduction of mortality and cardiovascular morbidity as well as an increase in quality of life. On the basis of individual risk assessment, the physician has to work out a differentiated therapy plan for each patient. General treatment arrangements for DMP-CHD concern:

- non-medical therapy and common activities (e.g. physician counselling for smoking, nutrition and physical activity),
- medication (primarily use of drugs tested in RCTs that show positive effects on therapy goals) and
- coronary angiography (to ascertain, if patients would benefit from intervention).

In summary, although there are no strict clinical guidelines for healthcare professionals, DMPs are supposed to increase the adherence to evidence-based medicine. Moreover, documentation, patient education, quality management systems and feedback systems are important components of DMPs [6].

3. Methods

To investigate these research questions, the population-based KORA (Cooperative Health Research in the Augsburg Region) Myocardial Infarction Register was used, which, since 1985, has registered all patients with an acute myocardial infarction resident in the study region of Augsburg, southern Germany [22]. All patients who survive for more than 24 h following an acute myocardial infarction are interviewed while they are in hospital. After discharge, treatment data are collected in a concluding review of hospital records. Using this database, all 4394 persons who had a cardiac event between 1985 and 2004 and were still alive in 2006 were contacted in a postal survey. As DMP-CHDs are offered only by the SHI (which covers over 90% of the health insurance market [23]), all privately insured persons were excluded from the investigation. This reduced the study population of the follow-up survey by 12%, to 3867 statutorily insured persons.

The questionnaire for the follow-up survey featured items that correspond to the aims and criteria of the DMP as they were stated by the Joint Federal Committee, and, in addition, included information on patients’ characteristics (employment, history of diabetes and smoking status), healthcare services (physician counselling for smoking, nutrition and physical activity as well as medication) and health outcome (quality of life, measured by EQ-5D visual analogue scale [24], weight and height, and smoking). Patients were also asked whether they were enrolled in a DMP-CHD and, if so, since when. This information was used to identify the groups of interest. Patient characteristics were cross-checked with data from the Myocardial Infarc-
Selection of enrolment was analysed using a logistic regression model with the enrolment in DMP-CHDs as the dependent variable. Model performance was tested using the likelihood-ratio and Hosmer–Lemeshow tests. The quality of healthcare services and outcomes were examined using linear and logistic regression models, depending on the type of the dependent variable.

To control for possible selection bias in this non-randomised study design, a propensity score was used [25–28]. The propensity score, an individual probability of the DMP enrolment for each patient, was estimated using a regression model that included all available covariates. The enrolment in DMP-CHDs was taken as the reference category. To assess the goodness of the propensity estimation, results are presented applying the measure for the estimation quality of the ROC (receiver operating characteristics) curve. The measure is the area under the ROC curve. The area can take values between 0.5 and 1, where a higher value indicates a better quality.

Information was missing from some variables, leading to a significant reduction in sample size for multivariate analysis. To assess possible effects of the exclusion, a multiple imputation method was used. Using this approach, multiple values (here, \( n = 5 \)) for missing information are drawn from the joint distribution conditioned on the vector of existing information using Markov Chain Monte Carlo methods [29]. For continuous variables, a multivariate normal distribution across all variables is assumed. For binary data, a simple rounding method was used, rounding to 0 or 1 whichever was closer. The results of statistical inference from a complete case analysis were compared with those based on the multiple imputation method using the MIANALYZE procedure in SAS, which combines results from repeated imputations.

Different regression models were used for each research question. Results with a probability value <5% were regarded as significant. For each research question, the result of the multiple imputation was presented. SAS software was used for all statistic evaluations.

4. Results

4.1. Response and baseline characteristics

Of all 3867 statutorily insured persons with myocardial infarction contacted, 2563 persons answered the questionnaire. This corresponds to a 66% response rate. Characteristics of the study participants and non-participants are outlined in Table 1.

Some of the variables showed significant differences between the groups. However, considering the associated values in each case, differences were rather small. For example, the average age of the study participants was 68.3 years, compared with 66.5 years for the non-participants. The largest differences between study participants and non-participants regarded the proportion of males and females. While about 78% of the study participants were male, their representation was clearly lower in the non-participant group (73%, \( p = 0.001 \)). Study participation/non-participation was not related to the number of heart attacks a person had had and the time since the last heart attack.

Almost 27% (665) of the study population stated that they were enrolled in DMP-CHDs. Those enrolled were affiliated to the following sickness fund companies: AOK 30%, EKK 26%, BKK 34%, IKK 21% and further sickness funds 12%. Two-thirds of the participants (67%) were not enrolled in DMP-CHDs; the remaining 6% of the study population did not know if they were enrolled or gave an unclear response. For further investigations, participants giving unclear responses (152) or missing values (81) were excluded. This resulted in a reduction of the total sample size to 2330 persons.

Sixty-seven percent (448) of the 665 participants gave the year 2005 or 2006 as their date of enrolment in their DMP-CHD. The remaining 6% of the study population did not know if they were enrolled or gave an unclear response. For further investigations, participants giving unclear responses (152) or missing values (81) were excluded. This resulted in a reduction of the total sample size to 2330 persons.

4.2. Selection of enrolment

To investigate selection of enrolment, all descriptive variables of patients’ characteristics were included in a logistic regression model. Table 2 shows the results of the multivariate analysis.

Sex, education, employment, smoking and number of heart attacks were all non-significant regarding participation in DMP-CHDs. By contrast, age, history of
## Table 1
Baseline characteristics of responders and non-responders

<table>
<thead>
<tr>
<th>Variable</th>
<th>Responder (n = 2563)</th>
<th>Non-Responder (n = 1304)</th>
<th>p-Value (t-test/χ²-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>68.3 (9.5)</td>
<td>66.5 (11.0)</td>
<td>0.001</td>
</tr>
<tr>
<td>Male</td>
<td>77.8% (1995)</td>
<td>72.7% (948)</td>
<td>0.001</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic education</td>
<td>77.6% (1776)</td>
<td>78.0% (742)</td>
<td></td>
</tr>
<tr>
<td>Qualified vocational training</td>
<td>13.2% (303)</td>
<td>12.4% (118)</td>
<td>n.s.</td>
</tr>
<tr>
<td>College/university</td>
<td>9.2% (210)</td>
<td>9.6% (91)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>13.3% (340)</td>
<td>Not available</td>
<td>–</td>
</tr>
<tr>
<td>Statutorily insurance membership</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General regional funds (AOK)</td>
<td>36.4% (934)</td>
<td>40.2% (524)</td>
<td></td>
</tr>
<tr>
<td>Substitute funds (EKK)</td>
<td>27.7% (711)</td>
<td>20.9% (272)</td>
<td></td>
</tr>
<tr>
<td>Company funds (BKK)</td>
<td>24.7% (632)</td>
<td>24.1% (314)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Craft guild funds (IKK)</td>
<td>7.1% (182)</td>
<td>8.6% (112)</td>
<td></td>
</tr>
<tr>
<td>Further</td>
<td>4.1% (104)</td>
<td>6.2% (81)</td>
<td></td>
</tr>
<tr>
<td>Ever smoked</td>
<td>68.1% (1658)</td>
<td>Not available</td>
<td>–</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25.8% (650)</td>
<td>Not available</td>
<td>–</td>
</tr>
<tr>
<td>Time since last heart attack (in years)</td>
<td>8.6 (5.2)</td>
<td>8.6 (5.2)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Patients with &gt;1 heart attack</td>
<td>10.0% (255)</td>
<td>9.2% (119)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

n.s. = not significant.

* Due to missing values (274 education; 127 ever smoked; 39 diabetes) sum partly <2563.

* Due to missing values sum partly <1304.

diabetes, time since last heart attack and single parameters of the health insurance company affiliation could be identified as selective factors of DMP participation. The probability of DMP-CHD enrolment was smaller for older persons (OR 0.98) and for patients with increased time since their last heart attack (OR 0.98). Diabetic patients were more likely to be enrolled (OR 1.56). Between different types of sickness funds, the chance of enrolment in DMP-CHDs varied considerably.

The Hosmer–Lemeshow test for the regression model gave a non-significant result, indicating a good quality model. Regarding the goodness-of-fit between the groups, the likelihood ratio test was significant (p = 0.001). Accordingly, the regression model clearly separates DMP-CHD enrolment and non-enrolment.

Due to missing values, the logistic regression model was based on responses from only 1964 persons. Therefore, the method of multiple imputations was conducted for the determination of missing values (see Section 3). Overall, results were similar to those of the original logistic regression (not shown).

### 4.3. Quality of healthcare services

To adjust for possible selection bias, a propensity score was used (see Section 3). The accuracy of the predictive performance of the propensity score is measured by the area under the curve, which is estimated at 0.64 and reflects a moderate result. Therefore, the propensity score, as well as a subset of the covariates (mainly the significant variables from Table 2), was used for regression adjustment.

The research question about the quality of healthcare services set out to investigate whether enrolled patients receive more extensive and guideline-oriented medical care than non-enrolled patients. Concerning the medical counselling for smoking, nutrition and physical activity, considerable differences between enrolled and non-enrolled patients emerged (Table 3).

The proportion of DMP-CHD participants receiving medical counselling was 12–17% higher compared with non-participants. In the multivariate analysis, the probability of receiving medical counselling for partic-
Table 2
Factors of enrolment in DMP-CHDs

<table>
<thead>
<tr>
<th>Variable</th>
<th>%/Mean</th>
<th>OR (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DMP (n = 665)</td>
<td>Non-DMP (n = 1665)</td>
</tr>
<tr>
<td>Age (in years)</td>
<td>67.2/68.8</td>
<td>0.98 (0.96–0.99)***</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>77.6/77.8</td>
<td>1.04 (0.80–1.33)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic education</td>
<td>76.7/76.8</td>
<td>1.10 (0.76–1.59)</td>
</tr>
<tr>
<td>Qualified vocational training</td>
<td>14.9/13.4</td>
<td>1.37 (0.89–2.11)</td>
</tr>
<tr>
<td>College/university</td>
<td>8.4/9.8</td>
<td>Reference</td>
</tr>
<tr>
<td>Employed (yes vs. no)</td>
<td>14.1/13.1</td>
<td>0.70 (0.48–1.01)</td>
</tr>
<tr>
<td>Statutorily insurance membership</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General regional funds (AOK)</td>
<td>37.1/35.4</td>
<td>Reference</td>
</tr>
<tr>
<td>Substitute funds (EKK)</td>
<td>25.9/29.1</td>
<td>0.86 (0.66–1.13)</td>
</tr>
<tr>
<td>Company-based funds (BKK)</td>
<td>30.1/22.4</td>
<td>1.45 (1.13–1.86)***</td>
</tr>
<tr>
<td>Guild funds (IKK)</td>
<td>5.3/8.1</td>
<td>0.66 (0.43–1.02)</td>
</tr>
<tr>
<td>Further</td>
<td>1.7/4.9</td>
<td>0.32 (0.16–0.66)**</td>
</tr>
<tr>
<td>Ever smoked (yes vs. no)</td>
<td>68.5/67.8</td>
<td>0.95 (0.76–1.20)</td>
</tr>
<tr>
<td>Diabetes (yes vs. no)</td>
<td>31.1/23.0</td>
<td>1.56 (1.25–1.95)***</td>
</tr>
<tr>
<td>Time since last heart attack (in years)</td>
<td>7.8/8.8</td>
<td>0.98 (0.95–0.99)*</td>
</tr>
<tr>
<td>Number of heart attack (1 vs. &gt;1)</td>
<td>88.1/90.9</td>
<td>1.22 (0.87–1.71)</td>
</tr>
</tbody>
</table>

* p ≤ 0.05.
** p ≤ 0.01.
*** p ≤ 0.001.

* Due to missing values only 1964 patients for logistic regression.

Participants was significantly higher across all dimensions of counselling: for smoking (OR 3.77), nutrition (OR 2.15) and for physical activity (OR 2.58). There were also remarkable differences in medication between DMP-CHD enrolled and non-enrolled patients; the overall intake of drugs was higher in the DMP group. In particular, statins (OR 1.58) and antiplatelets (OR 1.96), which are recommended by medical guidelines

Table 3
Quality of health care services of the DMP-CHDs

<table>
<thead>
<tr>
<th>Variable</th>
<th>%/Mean</th>
<th>β-estimate (S.E.)/OR (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical counseling for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking (yes vs. no)</td>
<td>95.5/83.6</td>
<td>3.77 (1.07–13.34)*</td>
</tr>
<tr>
<td>Nutrition (yes vs. no)</td>
<td>76.3/60.1</td>
<td>2.15 (1.69–2.74)***</td>
</tr>
<tr>
<td>Physical activity (yes vs. no)</td>
<td>81.9/64.8</td>
<td>2.58 (1.99–3.35)***</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of drugs</td>
<td>5.9/5.4</td>
<td>0.33 (0.12)**</td>
</tr>
<tr>
<td>Beta blocker (yes vs. no)</td>
<td>85.7/82.4</td>
<td>1.01 (0.75–1.36)</td>
</tr>
<tr>
<td>Statins (yes vs. no)</td>
<td>75.5/64.3</td>
<td>1.58 (1.24–2.00)***</td>
</tr>
<tr>
<td>Antiplatelets (yes vs. no)</td>
<td>88.4/79.6</td>
<td>1.96 (1.43–2.69)***</td>
</tr>
</tbody>
</table>

* p ≤ 0.05.
** p ≤ 0.01.
*** p ≤ 0.001.

* Adjusted by propensity score, age, sex, insurance, diabetes and time since last heart attack.
** Only smokers regarded.
for all myocardial infarction patients [13,20,30], were prescribed significantly more often to those in the DMP group. Intake of beta-blockers showed a similar, but not significant, tendency.

Again, due to missing values, multiple imputations were calculated for several regression models. Neither with the linear regression model (medication), nor with the logistic regression models (all further models), did considerable differences arise to the previous results.

4.4. Quality of health outcomes

Table 4 shows the results for the analysis of the quality of healthcare outcomes. There were only small differences in the mean or rates of the outcome parameters, quality of life (VAS of EQ-5D)\(^3\), body mass index and smoking. Accordingly, none of the outcome parameters proved significant with respect to enrolment in DMP-CHDs.

Again, to examine possible effects of missing values, the method of multiple imputation was applied. Results did not change for the quality of life or the BMI. The variable of smoking, however, became positive, i.e. significantly less of the patients enrolled in DMP-CHDs smoked (on a 5% level) compared with non-enrolled patients.

All process and outcome parameters were examined as to whether duration of enrolment had an influence on the results; only the variable of smoking showed an impact. Thus, the ratio of enrolled smokers was much higher in 2006 than in 2005 (\(p = 0.05\)).

5. Discussion

This study is the first to present empirical results from German DMP-CHDs and, thus, complements the international discussion with a contribution from a social health insurance system. From our study, the following results should be noted: first, DMP-CHD patients tend to be younger and tend to have a higher disease burden (DMP-CHD patients more often have diabetes and the average time interval since their last heart attack is shorter—selection of enrolment). Second, DMP-CHDs induce positive changes in the medical care of patients, in particular concerning medical counselling and medication (quality of healthcare services). Third, DMP-CHDs do not lead to improvement concerning the quality of life and body mass index (quality of health outcomes), and smoking prevalence based in complete case analysis. However, when accounting for missing values, using the multiple imputation method, the reduction in smoking prevalence turned out to be significant, giving a first indication that DMP-CHDs may also improve health outcomes.

5.1. Comparison with literature

Some of the variables differ significantly between DMP-enrolled and non-enrolled patients, whereas the direction in each case appears to be plausible. Thus, the higher enrolment of younger people was also found in other investigations [32]. Differences in enrolment between the sickness funds were presumably due to variations in programme promotion. The higher enrolment of diabetics can be explained by the higher disease burden, and familiarity with DMP enrolment for diabetes. A “double DMP” registration of patients often takes place [7].

The results of the study clearly point out differences in the quality of healthcare services for patients enrolled in DMP-CHDs compared with patients who are not enrolled. Positive effects of smoking termination, fat reduction and physical training are verified by multiple international studies. In summary, studies propose that the relative risk for a cardiac event (mortality) can be expected to be lowered by over 20% through these interventions [33–35]. The results of this study showed significant increases in medical counselling for smoking, nutrition and physical activity by around 12–17% for patients enrolled in DMP-CHDs. The positive results concerning the medical advisory support—in the sense of an intermediate result—show improvement of these factors and, hence, possibly reduce future cardiac risks.

International studies also show evidence of positive effects on the risk of CHD by clinical and pharmacological interventions, e.g. beta-blockers or statins [36–38]. Thus, for long-term trials, a 23% reduction in the probability of dying could be identified as a result.

\(^3\) A European tariff was also used for the calculation of the utilities of EQ-5D [31]. Again, no significant difference between the groups occurred.
of the intake of beta-blockers [36]. Intake of statins can reduce LDL cholesterol concentration and, consequently, the risk of ischemic heart disease by about 60% and stroke by about 17% [38]. The intensified medication in the study of patients enrolled in DMP-CHDs could be judged, therefore, as positive. DMP-CHD participation led to an increased intake of beta-blockers, statins and antiplatelets of between 3 and 11%.

However, the positive results of the quality of healthcare services could not be observed with respect to health outcomes and health behaviour. No clear effects of DMP-CHD enrolment could be determined regarding quality of life and BMI. Only a reduction in smoking by DMP-CHD patients provides an indication that enrolment may also improve health outcomes (as mentioned on a 5% level after correction for missing values). Amongst other things, this may be due to the fact that study participants’ average enrolment time was just slightly more than 1 year. Therefore, significant short-term effects, e.g. in BMI, were not likely to be expected. Internationally, too, there is no strong evidence of DMPs on health outcome quality.

A review of DMP-CHDs shows that, from 12 studies, only 5 contained quality of life measurements, of which 3 reported improved results but only 1 of these was significant [18]. Furthermore, only one of seven studies showed a significant cessation of smoking by those enrolled in DMPs. As these international studies usually observe a time span of no more than 12 months [18], the results need to be critically considered due to middle and long-term effects of DMPs.

The observed improvements in the quality and intensity of healthcare services leads to the implication that DMP-CHDs may induce increasing costs of medical healthcare—at least in this short-term perspective. Published literature shows that little is known about the relative effectiveness and costs associated with different implementation strategies [39]. Therefore, an investigation of the cost-effectiveness of German programmes with relevant medical outcome parameters and a larger time frame would be very valuable.

5.2. Strengths and limitations of the study

A major limitation of the investigation is the non-randomised study design. To control for potential selection bias, a propensity score approach was used, as this is recommended in cardiovascular research [28]. The calculated score exhibited a moderate prognostic quality, therefore, a subset of the covariates were used additionally for regression adjustment. To prove the utility of the propensity score, regression analysis was also performed without the propensity score. In comparison, results without the propensity score were overall more positive. Thus, it can be argued that selection effects were at least partially taken on by the propensity score variable in the multivariate regressions.

A further weakness of the study concerns the self-reported enrolment to DMP-CHDs of the study participants. Six percent of the study participants did not know their status of enrolment and around 30% of the DMP-CHDs enrolled did not know or correctly state their date of inscription. The impact of possible false reporting remains unclear. Validation of this variable would give information about this issue and is planned in a further investigation.

The variables used in the study to determine process and outcome quality originate in an ordinance of the Joint Federal Committee [20,21]. For measuring the quality of life, the visual analogue scale of the EQ-5D was used because of its good psychometric properties applied to patients with acute coronary syndromes [40]. Several variables, including mortality and recur-
rent infarctions, could not be included in the study due to the cross-sectional study design and the limited time since inception of DMP-CHDs. Furthermore, the question on cardiovascular disease-related hospitalisations could not be analysed due to incomplete responses. Therefore, it was not possible to provide a closer view of economic aspects of DMP-CHDs.

To assess effects of missing values, which cumulated up to a maximum reduction in sample size for multivariate analyses of 366 cases (16% of sample), the method of multiple imputation was applied. However, effects in the results were only slightly affected as no qualitative different results were obtained by analysis of the complete imputed samples.

Despite the satisfying study response, nearly a third of the contacted persons did not participate. The non-responder analysis disclosed some significant differences between the groups. As these differences were rather small, they were concluded not to be problematic for study analysis.

A further limitation of the study concerns the concentration of CHD patients living in a specific region in southern Germany. However, the mixed urban and rural population of this study region has been considered as a good model for Germany as a whole [22].

The study has a number of strengths. First, and most importantly, the sample size was large and the patients were from a representative population-based Myocardial Infarction Register and not only single programmes or single sickness funds. Second, baseline characteristics were available to characterise the cohort and to control for potential selection effects. The study used an established quality of life measure and determined the research questions according to national standards for DMP-CHDs. Third, the study presents a very important first step in the evaluation of DMPs in Germany. As it is extremely difficult to realise an evaluation setting with a control group, this study approximates an intervention and control group design with reasonable sample sizes.

6. Conclusion

Enrolment into DMPs for CHD exhibits systematic selection effects. Participants tend to experience – at least in the short to medium term and for AMI patients – better quality of healthcare services. However, since DMP-CHDs were initiated only 2 years ago, we were unable to identify significant improvement in health outcomes. Only the reduction in smoking provides a first indication for better quality outcomes by DMP-CHD. Thus, policy-makers must provide appropriate incentives to sickness funds and physicians in order to ensure initiation and continuation of high quality DMPs.

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References


