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# Does nurse-based case management for aged myocardial infarction patients improve risk factors, physical functioning and mental health? The KORINNA trial

**Matthias Hunger[1], Inge Kirchberger[2,3], Rolf Holle[1], Hildegard Seidl[1], Bernhard Kuch[4,5], Rupert Wende[4] and Christine Meisinger[2,3]**

## Abstract

**Background:** Older patients with acute myocardial infarction (MI) are often lacking optimal support to continue rehabilitation after discharge from hospital. The objective of the study was to examine whether a home-based case management programme led by nurses can improve atherogenic risk factors, physical functioning, and mental health in the first year following discharge.

**Methods:** The KORINNA study is a randomized two-armed parallel group trial including 329 patients (aged 65–92 years) from the Augsburg Hospital in southern Germany. The intervention consisted of an individualized follow-up programme with a duration of 1 year, including home visits and telephone calls. The control group received usual care. Secondary outcome measures included clinical parameters (blood pressure, lipid parameters), functional status measures, cognitive status, depressive symptoms, and nutrition risk.

**Results:** At 1-year follow up, patients in the intervention group ($n = 116$) had significantly better low-density lipoprotein cholesterol levels (−8.4 mg/dl, 95% CI −16.4 to −0.4), hand grip strength (+2.53 kg, 95% CI 0.56 to 4.50), and SCREEN-II nutrition risk scores (+2.03, 95% CI 0.58 to 3.48) than patients in the control group ($n = 136$). The intervention group also had better mean scores with regard to self-reported disability, activities in daily living, and mental health, but differences were not always significant and meaningful.

**Conclusions:** The results of the KORINNA study indicate that nurse-based case management can improve blood lipid levels, functional status, and nutrition risk of aged patients with MI.

## Keywords

Case management, clinical trial, myocardial infarction, nurse-based, physical functioning

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## Introduction

Discharge from hospital to home is a vulnerable situation for older adults.[1] Patients after myocardial infarction (MI) are at particular risk since they often report unmet information needs and have a high prevalence of comorbidity associated with physical disability, multiple medications, and increased risk for adverse outcomes.[2,3] Counselling and providing information is an integral part of post-MI care since it helps empowering patients to manage the consequences of their illness in daily life.[4,5] However, patients are nowadays discharged earlier from hospital so that the time spent in hospital may not always be sufficient to prepare the

[1]Helmholtz Zentrum München, Institute of Health Economics and Health Care Management, Neuherberg, Germany
[2]Helmholtz Zentrum München, Institute of Epidemiology II, Neuherberg, Germany
[3]KORA Myocardial Infarction Registry, Central Hospital of Augsburg, Augsburg, Germany
[4]Department of Internal Medicine I – Cardiology, Central Hospital of Augsburg, Augsburg, Germany
[5]Donau-Ries-Kliniken, Department for Internal Medicine/Cardiology, Nördlingen, Germany

**Corresponding author:**
Matthias Hunger, Institute of Health Economics and Health Care Management, Helmholtz Zentrum München, Ingolstaedter Landstr. 1, 85764 Neuherberg, Germany.
Email: matthias.hunger@helmholtz-muenchen.de

patients for further rehabilitation.[6] As a consequence, home-based intervention programmes, mainly led by nurses, have been proposed as a way to continue the rehabilitation process after discharge.

Cardiac rehabilitation in Germany is mainly offered as comprehensive in-hospital treatment over a period of 3 weeks,[7] but data from the German pension insurance suggest that patients aged above 60 receive in-hospital rehabilitation less often than younger persons.[8] No home-based early post-discharge programmes are currently available in Germany.

Several randomized trials have evaluated whether nurse-based secondary prevention programmes can positively influence process of care, risk factor profile, and health status in patients with coronary heart disease.[9–12] However, their results cannot be generalized to higher age groups. Only very few studies examined intervention programmes for older people with coronary heart disease and no study has yet explicitly addressed case management programmes in older patients with MI.[13–15]

The purpose of this study was to analyse the effect of a case management intervention led by trained nurses on risk factor profiles, physical functioning, and mental health in older patients with MI. We report the results of the secondary outcomes in the KORINNA trial.[3] The primary endpoint was time to first unplanned readmission to hospital or death, and results have been described elsewhere.[8]

## Methods

### Trial design

The KORINNA study was a single-centre randomized two-armed parallel group trial (trial registration number ISRCTN02893746). The study protocol was approved by the Ethics Committee at the Bavarian Chamber of Physicians and can be found elsewhere.[3] Informed consent was obtained from each patient. Eligible participants were all patients aged 65 years and older with a first or recurrent MI during the recruitment period (from September 2008 to May 2010) who were treated in the Augsburg Hospital. The Augsburg hospital is the largest hospital in the region of Augsburg, a city with 300,000 inhabitants in the south of Germany. Exclusion criteria mainly resulted from the choice of the primary endpoint; for example, patients who already lived in institutionalized care or already planned to move to it were excluded. Also, patients with dementia, insufficient German language skills or with severe comorbidity (i.e. associated with a life expectancy of less than 1 year, e.g. terminal cancer), were excluded. Limitations in vision and hearing were no exclusion criterion. Sample size calculation was based on the primary endpoint (detecting a reduction in the readmission rate by 15% with a power of 80% and a two-sided type 1 error level of 5%). The planned sample size was 338. A balanced randomization procedure using randomized blocks within strata for sex, age ($<$70 vs. 70–79 vs. $\geq$80 years), and number of comorbidities (diabetes and chronic heart failure) was used to ensure that these important prognostic factors are well balanced between treatment groups. Blinding of participants was not possible because home visits were only offered in the intervention group. However, by separating between clinical staff that delivered the intervention and clinical staff that took outcome measurements, observer blindness in the follow-up assessment was maintained.

### Intervention

The intervention bas been described in detail in the study protocol.[3] It consisted of a nurse-led individualized home-follow up programme with a duration of 1 year. The control group received usual care. Especially, patients could receive in-hospital cardiac rehabilitation or could be enrolled in a long-term disease management programme by their treating physician.

The intervention programme started with an initial session of 1 hour, taking place shortly before hospital discharge, where patients were provided with information about disease, comorbidities, and medication. Information was given orally and in written form of a so-called 'heart book'. After discharge, home visits (up to four) and telephone calls (at least every 3 months) were carried out according to patient need and risk level. The risk level was assessed by the study nurse during the first home visit based on compliance, social network, and New York Heart Association Functional Classification (NYHA) class.[8] The risk level classification suggested by Russell et al.[16] was used. Key elements of the intervention were to detect problems and risks (e.g. regarding intake of medication, decompensated heart failure), to give advice regarding different aspects of disease management (e.g. nutrition and health behaviour), and to refer to the general practitioner, if necessary. Based on an assessment of these potential intervention areas using a structured interview guide, the study nurse determined the individual content of the intervention. Standards for home visits, telephone interviews, and intervention modules were provided by a standard operating procedure. Patients with chronic heart failure were encouraged to regular weight control. During the visits, blood pressure and weight were measured. In individuals with diabetes, additional measurements of blood glucose were performed.

### Outcomes

With the exception of blood parameters, all outcomes have been assessed at baseline and 1 year

after discharge. While the baseline assessment took place during the index hospitalization, the 1-year assessment was administered in two stages. First, all patients were contacted by telephone and a standardized interview was conducted including the questionnaire on malnutrition risk. Then, patients were invited to undergo a final examination in the hospital (or, if necessary, at the patients' home) where all other outcomes were assessed (Figure 1).

### *Clinical parameters*

Blood pressure values at baseline were taken from the patients' medical records. Blood pressure at follow up

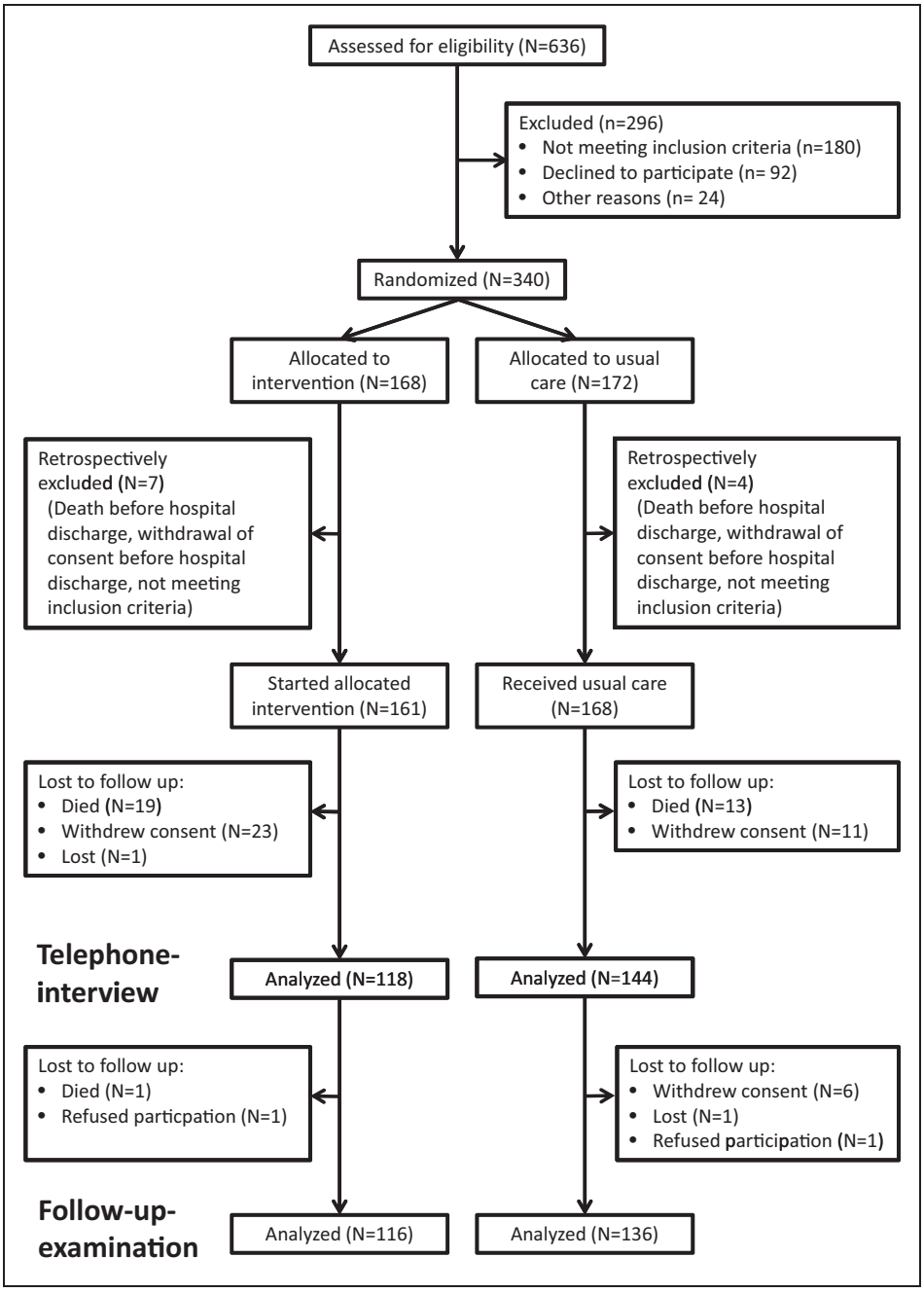


**Figure 1.** Flow of participants through the KORINNA trial.

was measured after 5 min of sitting rest. From a non-fasting venous blood sample collected at follow up, cholesterol levels were determined.

### Functional status

Patients' functional status was assessed using three different instruments. The Barthel Index is a 10-item instrument measuring disability in terms of the level of functional independence a person can obtain in personal activities of daily living.[17] Weighted item scores can be summed up to create a total score between 0 (totally dependent) and 100 (totally independent). The Health Assessment Questionnaire Disability Index (HAQ-DI) assesses the extent of patients' functional ability over the past week and comprises 20 items grouped into eight categories.[18] Each item is answered on a scale between 0 (without any difficulty) and 3 (unable to do) and the highest item score in each category determines the category score. The HAQ-DI score is calculated as the average score of all categories. Hand grip strength is an easy-to-measure indicator of general muscle strength and was measured in kilograms using a JAMAR hydraulic hand dynamometer (Saehan, Masan, Korea).[19] The test was administered by a trained nurse and participants were asked to perform three trials with each hand. We determined the final score as the mean of the maximum values for the right and left hands.

### Malnutrition risk

Malnutrition risk was measured using the eight-item version of the SCREEN-II (Seniors in the Community: Risk Evaluation for Eating and Nutrition, version II) questionnaire which focuses on food intake and challenges that could decrease it.[20] Possible scores range from 0 to 48 with lower values indicating higher risk.

### Cognitive status

Cognitive status was measured by the Mini-Mental State Examination (MMSE).[21] The MMSE can be administered in approximately 10 min and comprises 11 questions on different cognitive functions such as orientation, memory, language, and drawing. The maximum total score is 30.

### Depression

Depressive symptoms were assessed by the 15-item version of the Geriatric Depression Scale (GDS-15).[22] Items of the GDS-15 have a yes/no format and can be added to a sum score between 0 and 15. Barthel Index and MMSE were administered and scored by the study physician. HAQ-DI and GDS-15 were administered through personal interviews conducted by the study physician and a study nurse, respectively.

### Statistical analysis

For each outcome, the intervention effect was determined as the difference in mean scores between intervention and control group 1 year after the index hospitalization. In clinical trials using stratified randomization procedures, analyses need to be adjusted for the stratification variables in order to give valid inference.[23] Thus, we estimated the group differences using linear regression models adjusting for sex, age, and number of comorbidities. In a second step, group differences were additionally adjusted by the baseline value of the respective outcome measure in question, corresponding to an analysis of covariance (ANCOVA) model. In randomized trials, both methods provide an unbiased estimate of the treatment effect, but ANCOVA usually has more power.[24] Furthermore, in the case of missing values, ANCOVA only requires that data are 'missing at random' given age, sex, comorbidity, and baseline value.[25] Unadjusted analyses, in contrast, would require the more restrictive assumption that missing values occur 'completely at random', but this is often unlikely to hold since in clinical trials, drop out is often associated with health status.[26]

Analysing group differences for several outcomes implies multiple testing for which the control of the overall type I error level cannot be achieved. Thus, the statistical analyses reported in this article are only to be regarded as exploratory analyses. No adjustment for multiple testing was made.

## Results

A total of 340 patients were enrolled, of which 168 were assigned to the intervention group and 172 to the control group (Figure 1). After randomization, seven patients in the intervention group and four patients in the control group were excluded because they died, withdrew consent before hospital discharge, or did not meet the inclusion criteria.[8] Within the 1-year observation period, 43 patients in the intervention group and 24 patients in the control group were lost to follow up, mainly due to death or withdrawal of consent. A total of 118 patients in the intervention group and 144 patients in the control group participated in the 1-year telephone interview. After that, 10 additional patients were lost, so that data from the final examination were available from 116 patients in the intervention group and 136 patients in the control

group. Median time between hospital discharge and 1-year telephone interview was 355 days (interquartile range 352–361 days) and median time between telephone interview and final examination was 22 days (interquartile range 13.5–33.5 days). Baseline characteristics between the groups were similar except for the proportion of individuals with diabetes, which was higher in the control group (Table 1).

Table 2 shows the mean scores of the different outcome measures in the two treatment arms at 1 year together with the respective adjusted mean differences. No significant difference between intervention and control group could be observed for systolic and diastolic blood pressure levels. Mean low-density lipoprotein (LDL) cholesterol levels were significantly lower for patients in the intervention group (−8.41 mg/dl, 95% CI −16.41 to −0.41 mg/dl), but there was no significant difference with respect to the ratio of total cholesterol to high-density lipoprotein cholesterol.

Concerning functional status, patients in the case management group showed more favourable scores for HAQ-DI (−0.15, 95% CI –0.32 to 0.01) and Barthel Index (+3.23, 95% CI 0.14 to 6.32); however, these differences were only borderline significant. There was a significant effect of the intervention on hand grip strength with a mean difference of 2.53 kg (95% CI 0.56 to 4.50 kg) between the groups.

There was no significant difference between intervention and control group with respect to cognitive status measured by the MMSE, but patients in the case management group showed slightly better mean depression scores (−0.58, 95% CI –1.17 to 0.00), although this difference nearly reached formal significance.

There was a significant beneficial effect of the intervention on nutrition behaviour in that patients in the intervention group had higher SCREEN-II nutrition risk scores 2.03 (95% CI 0.58 to 3.48).

Estimates from the ANCOVA model were generally very similar to those from the analysis of posttest scores, but confidence intervals were mostly smaller. ANCOVA estimates could not be calculated for cholesterol since no blood sample was collected at baseline. Also, ANCOVA estimates for grip strength may be less reliable than the difference of post-test scores since 50 participants could not perform the grip strength test at baseline and could thus not be included in the ANCOVA model.

## Discussion

This study examined whether a case management intervention by trained nurses following discharge from hospital can improve risk factor profiles, physical functioning, and mental health in aged MI survivors.

**Table 1.** Patient characteristics at baseline.

| Characteristic | Intervention ($n = 161$) | Control ($n = 168$) |
|---|---|---|
| Sociodemographics and comorbidities | | |
| Age (years) | 75.2 ± 6.0 | 75.6 ± 6.0 |
| Male | 101 (62.7) | 103 (61.3) |
| Diabetes mellitus | 45 (28.0) | 61 (36.3) |
| Congestive heart failure | 48 (29.8) | 47 (28.0) |
| BP[a] | | |
| Systolic BP (mmHg) | 121.6 ± 13.7 | 124.2 ± 13.5 |
| Diastolic BP (mmHg) | 71.4 ± 7.8 | 71.3 ± 8.3 |
| Physical functioning/mental health[a] | | |
| HAQ-DI score | 0.762 ± 0.808 | 0.752 ± 0.752 |
| Barthel Index | 90.8 ± 17.1 | 90.8 ± 17.5 |
| Hand grip strength (kg) | 28.6 ± 12.6 | 28.2 ± 12.1 |
| MMSE | 26.7 ± 4.1 | 26.4 ± 3.8 |
| GDS | 3.25 ± 3.11 | 3.24 ± 2.64 |
| SCREEN-II | 35.8 ± 7.2 | 36.4 ± 6.3 |

Values are mean ± SD or *n* (%); [a]Due to missing values in the observed outcomes, the numbers of observations range between 156 and 161 in the intervention group and 163 and 167 in the control group, except for grip strength (128 and 135 patients, respectively); BP, blood pressure; GDS, Geriatric Depression Scale; HAQ-DI, Health Assessment Questionnaire Disability Index; MMSE, Mini-Mental State Examination; SCREEN-II, Seniors in the Community: Risk Evaluation for Eating and Nutrition, version II.

**Table 2.** Clinical parameters, physical functioning and mental health scores at 1 year.

| | Intervention | | Control | | Difference adjusted by stratification variables | | Difference adjusted by stratification and baseline variables[a] | |
|---|---|---|---|---|---|---|---|---|
| Outcome | *n* measured | Mean ± SD | *n* measured | Mean ± SD | Mean (95% CI) | *p*-value | Mean (95% CI) | *p*-value |
| Clinical parameters | | | | | | | | |
| Systolic BP (mmHg)[b] | 116 | 133.95 ± 18.57 | 135 | 134.19 ± 18.91 | −0.09 (−4.83 to 4.66) | 0.9715 | 0.40 (−4.35 to 5.15) | 0.8682 |
| Diastolic BP (mmHg)[b] | 116 | 74.16 ± 11.33 | 135 | 73.85 ± 10.24 | 0.22 (−2.49 to 2.93) | 0.8732 | 0.00 (−2.79 to 2.80) | 0.9993 |
| LDL cholesterol (mg/dl)[b] | 116 | 92.03 ± 30.02 | 131 | 100.31 ± 33.63 | −8.41 (−16.41 to −0.41) | 0.0394 | NA[c] | NA[c] |
| Total cholesterol/HDL[b] cholesterol (mg/dl) | 116 | 3.60 ± 1.14 | 131 | 3.71 ± 1.14 | −0.10 (−0.39 to 0.18) | 0.4763 | NA[c] | NA[c] |
| Physical functioning/mental health | | | | | | | | |
| HAQ-DI score[b] | 116 | 0.53 ± 0.66 | 136 | 0.77 ± 0.81 | −0.15 (−0.32 to 0.01) | 0.0681 | −0.16 (−0.31 to −0.02) | 0.0311 |
| Barthel Index | 116 | 97.63 ± 8.33 | 135 | 93.64 ± 15.47 | 3.23 (0.14 to 6.32) | 0.0403 | 3.68 (0.71 to 6.66) | 0.0155 |
| Hand grip strength (kg) | 115 | 30.98 ± 11.55 | 133 | 26.86 ± 11.54 | 2.53 (0.56 to 4.50) | 0.0119 | 0.61 (0.51 to 0.71) | <0.0001 |
| MMSE | 116 | 28.10 ± 2.81 | 133 | 27.73 ± 2.79 | 0.22 (−0.47 to 0.91) | 0.5312 | 0.14 (−0.46 to 0.73) | 0.6541 |
| GDS[b] | 115 | 2.34 ± 2.31 | 134 | 3.15 ± 2.64 | −0.58 (−1.17 to 0.00) | 0.0519 | −0.40 (−0.92 to 0.11) | 0.1233 |
| SCREEN-II | 117 | 38.93 ± 6.09 | 142 | 36.57 ± 6.15 | 2.03 (0.58 to 3.48) | 0.0063 | 2.09 (0.71 to 3.46) | 0.0031 |

[a]Because of missing values of the measures at baseline, sample sizes are reduced by between 1 and 9 observations. An exception is hand grip strength where 50 participants provided no baseline measurement; [b]Smaller values are better; [c]Not applicable since no blood sample was collected at baseline and adjusted differences could not be estimated; BP, blood pressure; GDS, Geriatric Depression Scale; HAQ-DI, Health Assessment Questionnaire Disability Index; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MMSE, Mini-Mental State Examination; SCREEN-II, Seniors in the Community: Risk Evaluation for Eating and Nutrition, version II.

Elderly patients are more likely to have specific characteristics that complicate the implementation of secondary prevention models, including multiple comorbid conditions, functional deficits, cognitive impairments, and emotional problems.[15] Also, interventions need to more intensively address the potential lack of social support and reduced medication compliance related to polypharmacy. Furthermore, specific intervention elements such as fall prevention or prevention of malnutrition are more relevant than in younger age groups.

High LDL cholesterol is the major atherogenic risk factor for heart disease and studies have shown that lowering of blood cholesterol in secondary prevention can improve mortality and vascular event rates.[27] The KORINNA intervention led to significantly reduced LDL cholesterol levels compared to usual care, but the magnitude of this effect was smaller than in similar studies. For example, in a meta-analysis including more than 1000 patients, the mean reduction caused by the telehealth interventions was around 16 mg/dl (i.e. nearly twice as large as in our study).[11] However, these interventions defined specific target levels and motivated patients to an aggressive pursuit of these goals including frequent blood cholesterol tests and an intensive monitoring of progress.[28,29] In the KORINNA intervention, in contrast, lipid levels were not monitored, but patients were educated on the impact that unhealthy food and nonadherence to statin therapy can have on dyslipidaemia.

Our case management intervention seems to have a positive effect on patients' functional status. Participants in the intervention group had higher scores for hand grip strength and the two questionnaire instruments, although differences for HAQ-DI and Barthel Index were only borderline significant. Nevertheless, the positive effect on the HAQ-DI was in the range of the minimally important difference, which is between 0.10 and 0.22.[18] A reason for the positive intervention effect on physical functioning could be the promotion of physical activity and compliance with treatment regimens. From a review of trials for treating congestive heart failure, Leidy et al.[30] concluded that the primary impact of pharmacological or nonpharmacological interventions was on functional status rather than on any other health-related quality of life domain. Previous work mainly assessed functional status by the physical domain scores of SF-36 or SF-12.[15,28,31–33] In each of these studies, participants in the intervention group scored higher than those in the control group; however, the difference was not always significant. Similar results have been reported if other instruments were used.[13,15,33] All of these studies, however, included a large number of patients in younger age groups. Only the study of Naylor et al.[15] exclusively included patients aged 65 years or older, but improvements in the intervention group after 1 year were also not significant for neither physical nor mental health. In contrast, Hanssen et al.[31] observed a positive treatment effect on physical and mental health for individuals aged 70 years and above, whereas there was no significant difference between intervention and control group in younger age groups.

Similar to the results of our study, several previous trials in patients with coronary heart disease observed positive effects of home-based prevention programmes on reducing depressive symptoms; however, these effects were always small and not significant.[29,34,35]

Nutritional recommendations were a major part of our case management programme and our results on the SCREEN-II questionnaire suggest that the intervention could significantly reduce nutrition risk. We only know of three similar trials that also employed nutrition questionnaires,[29,36,37] one of which also showed a significant beneficial effect of the corresponding telehealth intervention.[36] However, these studies are only partly comparable since they assessed nutrition levels in terms of the intake of various unhealthy foods whereas SCREEN-II focused more on risk factor questions (e.g. about appetite or swallowing difficulties).[20]

One might argue that the positive effect of the intervention observed for many variables could be caused by a selection process since more patients in the intervention group withdrew consent or died. Therefore, we examined whether there were already important differences between intervention and control group at baseline if only patients with complete follow-up data were considered. This was not the case for any of the outcome measures and the size of the estimated differences was only about one-tenth of those observed at follow up.

A strength of our study is that it explicitly addressed older MI patients. Previous intervention programmes were rarely tailored to the specific needs of this population group so that it was unclear whether the results from these trials could be generalized to higher ages. In light of the demographic change, however, studies in elder patients are expected to gain importance for reasons of healthcare research and financing.

A limitation of our study is that the trial was only conducted at one hospital in the South of Germany. As a result, findings may not be generalizable to regions with other population characteristics and healthcare structures. Another limitation is that 116 of the 636 patients assessed for eligibility did not participate in the trial although they would have met the inclusion criteria. In the case that there were systematic differences between patients randomized to the trial and those excluded, this may reduce the external validity of our findings. However, patients who declined

participating in the KORINNA study had a very similar comorbidity profile (diabetes and chronic heart failure) as the study participants although they were on average 2 years older. Finally, 26 participants in the intervention and 19 participants in the control group withdrew consent or were lost during the study period. Our statistical analyses accounted for the fact that these dropouts may depend on sex, age, comorbidity, and group assignment. However, if observations were missing not at random, then the treatment effect in our study may partly be estimated with bias.

In conclusion, the KORINNA study indicates that a nurse-based case management can improve blood lipid levels, functional status, and nutrition risk of aged patients with MI. Further research should examine whether such beneficial effects continue into the long run.

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## Conflict of interest

The authors declare that there is no conflict of interest.

## Presentation

Parts of the results reported in this article were presented in German at the Eighth Annual Conference of the German Society for Epidemiology (DGEpi), Leipzig in September 2013.

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