Outcomes of cardiac rehabilitation with versus without a follow-up intervention rendered by telephone (Luebeck follow-up trial): overall and gender-specific effects

Oskar Mittag[a], Claudia China[a], Eike Hoberg[b], Eija Juers[c], Klaus-Dieter Kolenda[d], Gert Richardt[e], Carsten Maurischat[a] and Heiner Raspe[a]

The effects of a nurse-managed secondary prevention program for patients after acute cardiac events were examined. Special interest was given to gender-specific results. The design was a prospective, randomized, controlled trial involving 343 patients following 3 weeks of inpatient cardiac rehabilitation, randomly assigned to either of two study groups. Patients in the treatment group were contacted monthly by phone over 1 year. The main goals of the intervention were the reduction of behavioural coronary risk factors and enhancing quality of life. The program was conducted by specially trained nurses. The control group received written information only. Primary outcome was the Framingham risk score. Follow-up examination after 12 months was completed by 297 patients. Patients in the intervention group showed lower Framingham risk scores as compared to controls. Separate analyses by sex revealed that this was mostly due to the men in the sample. Women, on the other hand, showed a significant rise of clinically relevant anxiety/depressiveness in the control but not in the intervention group; in males there were no differences between study conditions. In conclusion, telephone counselling by specially trained nurses seems a cost-effective way to achieve a lasting reduction in cardiac risk factors and to maintain the effects of cardiac rehabilitation.

Effekte eines von Pflegepersonal durchgefuehrten Nachsorgeprogramms fuer Koronarpatienten wurden untersucht. Besondere Aufmerksamkeit galt moeglichen Gendereffekten. Es handelt sich um eine prospektive, randomisierte, kontrollierte Studie. 343 Patienten wurden nach stationaerer kardiologischer Rehabilitation auf eine von zwei Studiengruppen randomisiert. Patienten in der Interventionsgruppe wurden über ein Jahr ca. einmal im Monat telephonisch kontaktiert. Hauptziele der Intervention waren die effektive und nachhaltige Reduktion verhaltensgebundener Risikofaktoren sowie die Verbesserung der Lebensqualitaet. Das Programm wurde von speziell dafuer fortgebildetem Pflegepersonal durchgefuehrt. Die Kontrollgruppe erhielt nur schriftliches Informationsmaterial. Primaerer Endpunkt war das globale koronare Risiko (Framingham Score). Von 297 Patienten wurden komplette Daten bei der Abschlussuntersuchung nach 12 Monaten erhalten. Patienten in der Interventionsgruppe zeigten niedrigere Framingham-Scores als Kontrollpatienten. Getrennte Analysen nach Geschlecht ergaben, dass dieser Effekt hauptsaechlich auf die Maenner zurueckzufuehren ist; bei den Frauen zeigten sich keine Unterschiede zwischen den Studiengruppen. Auf der anderen Seite zeigte sich bei den Frauen in der Kontrollgruppe eine deutliche Zunahme an Angst bzw. Depressivitaet; ein entsprechender Effekt fand sich bei den Maennern nicht. Telefonische Nachsorge durch speziell fortgebildetes Pflegepersonal scheint ein kostenguenstiger Weg zu sein, koronare Risikofaktoren zu reduzieren und die Effekte von kardiologischer Rehabilitation aufrechtzuerhalten.

Se evaluaron los resultados de un programa secundario de prevención dirigido por el personal de enfermería para pacientes que han sufrido un trastorno cardiovascular agudo. Se dio una especial importancia a los resultados específicos para cada sexo. Se trata de un estudio prospectivo, aleatorizado, comparativo, en el que participaron 343 pacientes tras 3 semanas de haber recibido rehabilitación cardiovascular, a quienes se dividieron en dos grupos, de manera aleatoria. Los pacientes del grupo que recibió tratamiento fueron contactados por teléfono una vez al mes durante 1 año. Los principales objetivos de la intervención fueron reducir los factores de riesgo de las cardiopatías arterioscleróticas relacionados con el actuar de los pacientes, y mejorar la calidad de vida de éstos. La realización del programa estuvo a cargo de un grupo de enfermeras y enfermeros especialmente entrenados para ello. El grupo de referencia recibió información sólo por escrito. Los resultados iniciales se obtuvieron aplicando la escala de riesgo de Framingham. En las valoraciones de seguimiento, realizadas tras 12 meses, participaron 292 pacientes. Los valores en la escala de riesgo de Framingham fueron más bajos en los pacientes del grupo que recibió la intervención que en el grupo de referencia. Los análisis según el sexo revelaron que el aporte mayor a este resultado provino de los varones de la muestra. Por su parte, las mujeres del grupo de referencia presentaron un aumento importante de la ansiedad/depresión relacionada con el proceso de enfermedad, lo cual no se apreció en el grupo que recibió tratamiento. Entre los varones no se apreciaron diferencias relacionadas con las condiciones del estudio. En conclusión, el apoyo emocional por vía telefónica brindado por el

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personal de enfermería especialmente entrenado para ello parece ser una manera rentable de disminuir de forma perdurable los factores de riesgo para las cardiopatías arterioscleróticas, así como de perpetuar los resultados de la rehabilitación cardiovascular.

Cette étude examine les effets d'un programme de prévention secondaire sous surveillance du personnel infirmier pour les patients ayant souffert d'incidents cardiaques aigus. Une attention toute particulière a été donnée aux résultats selon le sexe. L'essai était de type prospectif, randomisé et contrôlé, avec la participation de 343 patients après 3 semaines de rééducation cardiaque dans des conditions d'hospitalisation, affectés de manière aléatoire à l'un ou l'autre des deux groupes d'étude. Les patients appartenant au groupe de traitement ont été contactés tous les mois par téléphone sur une période de 1 an. Les principaux objectifs de l'intervention étaient la réduction des facteurs comportementaux de risque coronaire et l'amélioration de la qualité de vie. Le programme était administré par des infirmiers spécialement formés. Le groupe témoin recevait simplement des informations écrites. Le principal résultat était le score de risque de Framingham. 297 patients ont subi des examens de suivi après 12 mois. Les patients appartenant au groupe d'intervention ont affiché des scores de risque de Framingham inférieurs à ceux du groupe témoin. Les analyses séparées par sexe révèlent que la différence porte principalement sur les hommes. Les femmes, par contre, affichent une augmentation significative des tendances dépressives/à l'anxiété, cliniquement pertinente dans le groupe témoin, contrairement au groupe d'intervention; chez les hommes, on ne note aucune différence entre les conditions d'étude. En conclusion, le conseil téléphonique administré par des infirmiers spécialement formés semble constituer un mode économique et efficace pour parvenir à une réduction durable des facteurs de risques cardiaques et préserver les effets de la rééducation cardiaque. ***International Journal of Rehabilitation Research*** **29:295–302 © 2006 Lippincott Williams & Wilkins.**

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[a]Institute of Social Medicine, University of Luebeck (Medical School), Luebeck, [b]Klinikum Holsteinische Schweiz, Malente, [c]Sozialstation Malente, [d]Ostseeklinik Holm, Schoenberg and [e]Segeberger Kliniken GmbH, Bad Segeberg, Germany.

Correspondence and requests for reprints to PD Dr Oskar Mittag, Institute of Social Medicine, University of Luebeck (Medical School), Beckergrube 43–47, 23552 Luebeck, Germany.
Tel: +49 451 7992515, fax: +49 451 7992522,
e-mail: oskar.mittag@sozmed.uni-luebeck.de

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Introduction

Ischemic heart disease (IHD) is an important source of disability and cost to health-care systems not only in the developed countries, as well as being one of the major causes of premature death. The high prevalence of IHD relates strongly to lifestyle and modifiable physiological factors. Modification of these risk factors has been shown to considerably reduce mortality and morbidity (Joliffe *et al.*, 2004). Also, psychological stress, including symptoms of depression and anxiety, is a frequent problem following cardiac events. The main goals of cardiac rehabilitation (CR) are the reduction of coronary risk factors (e.g. high cholesterol, hypertension, tobacco smoking, sedentary life style, fat intake) and the enhancement of psychological, as well as social, adjustment after acute cardiac events (Balady *et al.*, 2000; De Backer *et al.*, 2003; Leon *et al.*, 2005).

Evaluation of CR programs in Germany has shown that the effects do not last and the recommended goals of secondary prevention are not achieved in many cases (e.g. Enbergs *et al.*, 1997; Voeller *et al.*, 2000; Willich *et al.*, 2001). Though this is true for programs in the US (Gordon and Haskell, 1997) and also in other European countries (EUROASPIRE II Study Group, 2002), the situation in Germany is possibly even more serious since, unlike in most other countries, CR is rendered mostly by in-patient programs lasting for 3 weeks only. For this reason follow-up programs have been called for by rehabilitation experts and sponsors for a long time. The telephone intervention which we set up and evaluated in this study should be seen in this context.

Several studies have demonstrated that post-discharge interventions by phone yield favourable effects as far as somatic risk factors are concerned (e.g. DeBusk *et al.*, 1994; Vale *et al.*, 2002, 2003). Another recent trial by Lear *et al.* (2003) yielded a moderate, statistically non-significant reduction of global coronary risk. A health education program during CR with a 6-week telephone follow-up (Van Elderen *et al.*, 1994) yielded short-term effects with regard to physical activity and diet, but only the dietary changes lasted through 12 months; there were no effects regarding smoking cessation, anxiety and depression. In some studies gender-specific effects were found. M-HART (Frasure-Smith *et al.*, 1997), a large controlled trial of psychosocial interventions for post-infarction patients, failed to show a significant impact on psychological outcomes and mortality for the total group; analyses by sex even revealed an increased mortality

among women in the treatment group. The ENRICHD study also yielded less favourable results in the female group as compared to (white) men (Schneiderman *et al.*, 2004). Another follow-up trial (HANSA study), utilizing booster sessions instead of telephone calls, but with otherwise identical study design and primary endpoint as the present study, found statistically significant positive effects for men, but not for women (Hoberg *et al.*, 2004).

The present study was conducted to evaluate a 1-year telephone intervention program, following in-patient CR. The objectives of the program were to improve the long-term effects of CR by reducing the modifiable coronary risk factors and enhance the health-related quality of life of the participating patients. Special attention was paid to potential gender-specific effects.

Methods

Patient enrolment and participation

During the recruiting period 662 patients from three CR hospitals in northern Germany who previously had suffered from a cardiac event (myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention) were asked by the study nurses to participate in the study. At baseline 343 patients (52%) gave their written informed consent (approved by the University of Luebeck Medical School Ethics Committee) and subsequently were randomly assigned either to the treatment group or to an attention placebo group. Randomization was carried out centrally using a computer generated list of code numbers. Nurses were notified of the assignment by telephone calls from the coordinating study staff. Non-participation analysis revealed that the patients who participated were younger (−4 years) and had a higher socioeconomic status, and that there were slightly more men participating as compared to women.

Intervention

The intervention consisted of monthly nurse-initiated telephone contacts. It was manual-based, and included individually tailored counselling on sports and physical exercise, nutrition, non-smoking, and stress management and psychosocial issues; also medical (cardiac) problems were discussed in detail (China and Mittag, 2003). The counselling interventions were derived from concepts of cognitive-behavioural and health psychology (Prochaska and DiClemente, 1992; Rollnick *et al.*, 1992; Kanfer *et al.*, 2000). The nurses had received intensive training prior to the program including more than 60 teaching units, and they were under continuous supervision by an experienced psychologist and RN. All of them had worked with cardiac patients in various settings before entering the project.

Attention placebo

The control group received six flyers on general health topics (relaxation, sports and physical exercise, sleep disorders, low back pain, nutrition) by mail every second month as an attention placebo. Patients in the intervention group were given the same written information.

Measurement and follow-up examination

At baseline all participants were asked to answer a self-administered questionnaire on their psychological status (anxiety: Symptom Checklist-90 [SCL-90] (Franke, 2002); depression: Centre for Epidemiologic Studies Depression Scale [CES-D] [http://www.drk-schmerz-zentrum.de/content/07_infos/7-5_schmerzfragebogen.html]) and health-related behaviours (tobacco smoking, hours of physical activity per week, food intake). Risk factors (smoking status, diabetes, blood pressure, lipids, body mass index) were recorded from an assessment at admission to CR. Nurses documented all management procedures during the follow-up period. After 12 months all patients were invited to the respective rehabilitation hospital again, and they underwent another lifestyle and risk factor assessment (questionnaire, interview, physical and laboratory examination). Current medications were also documented.

Data analysis

Framingham (FRAM) scores were computed for both time points comprising age, sex, total cholesterol, high-density lipoprotein (HDL)-cholesterol, diabetes and smoking status as indicators of global coronary risk (Grundy *et al.*, 1999). Age was held constant for both time points in order to avoid accidental score changes in subsets of patients. Scores were standardized (z-transformation) separately for men and women since the raw scores per definition differ between sexes, thus obscuring the results for the combined analysis. Independent sample t-tests were used to evaluate differences in FRAM scores between the two study groups. Mann–Whitney U-tests were computed to evaluate change scores in continuous risk factors and psychological variables; McNemar χ^2 tests or exact-tests by binominal distribution respectively were used to evaluate changes in categorical variables. Groups were compared using Pearson χ^2 statistics for categorical factors and the independent samples t-test for continuous variables. Level of significance for all tests is $P = 0.05$ (two-tailed). Standardized effect sizes (SES) are reported where appropriate.

Results

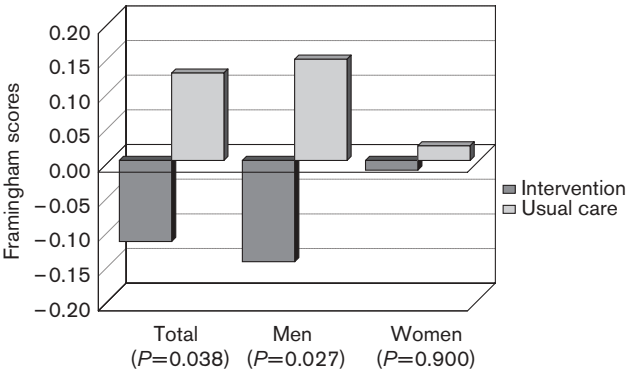
Basic demographic and medical characteristics of study participants, shown in Table 1, were comparable in both groups except for patients in the intervention group being slightly older than controls. Of the initial participants, 297 (87%) completed the follow-up examination (154 in the intervention group and 143 controls); five patients died prior to follow-up (one in the treatment group and four in the usual care group), 18 patients dropped out of

Table 1 Basic demographic and medical characteristics of study participants (baseline)

	Intervention ($N=171$)	Control ($N=172$)	*P*-value
Age, years (SD)	$M=58.8$ (9.66)	$M=60.9$ (9.92)	0.046
Sex, *n* (%)			
Male	135 (78.9)	146 (84.9)	
Female	36 (21.1)	26 (15.1)	0.153
Vocational status, *n* (%)			
Working	72 (42.9)	74 (43.8)	
Retired or other	96 (57.1)	95 (56.2)	
Missing	3	3	0.863
Diagnoses, *n* (%)			0.773
AMI	12 (7.0)	12 (7.0)	
PCI (+AMI)	75 (43.9)	71 (41.3)	
CABG (+AMI/PCI)	80 (46.8)	89 (51.7)	
Total cholesterol, mg/dl (SD)	$M=168.8$ (40.4)	$M=168.3$ (38.0)	0.911
HDL-cholesterol, mg/dl (SD)	$M=38.1$ (9.5)	$M=38.5$ (9.8)	0.726
Blood pressure, mmHg (SD)	$M=122.6$ (13.5)	$M=120.4$ (14.6)	0.149
Smoking, *n* (%)	71 (41.5)	65 (37.8)	0.480
Diabetes, *n* (%)	31 (18.1)	36 (20.9)	0.513
FRAM score, standardized (SD)	$M=0.0569$ (0.996)	$M=-0.0572$ (1.000)	0.290

AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; SD, standard deviation; HDL, high-density lipoprotein; FRAM, Framingham.

Fig. 1



Standardized Framingham scores (follow-up) in both study groups for the total sample and by gender.

the program, 17 patients did not attend the follow-up examination and the status of the remaining six patients remained unclear.

On average each patient received 10 calls (range: 4–12) lasting from 2 to 92 min (mean: 24 min). There was no difference as to the number of calls to men and women ($t = 0.97$, d.f. = 152, $P = 0.333$), but phone calls with female patients averaged almost 4 min longer than with males ($t = 2.71$, d.f. = 52.142, $P = 0.009$).

At follow-up the group difference in FRAM scores was statistically significant in favour of the intervention group (standardized scores: $M = -0.1174/0.1264$, SD = 0.89/1.09; $t = 2.10$, d.f. = 275.429, $P = 0.038$; SES = 0.22). Separate analyses by sex reveal that this effect was mostly due to the men in the sample (raw score: $M = 5.28/6.16$, SD = 3.69/3.25; $t = 2.29$, d.f. = 231.796, $P = 0.023$; SES = 0.27); in women there was no difference between groups (raw score: $M = 8.42/8.59$, SD = 4.29/5.46; $t = 0.13$, d.f. = 53, $P = 0.900$; SES = 0.03). These results are illustrated in Fig. 1.

Risk factors and psychological status at baseline and follow-up after 1 year for both study groups and by sex are outlined in Table 2. Comparisons of change scores between study groups indicate less increase in systolic blood pressure for the total sample ($t = -2.02$, $P = 0.043$) and for men ($t = -2.13$, $P = 0.034$) but not for women in the treatment group, and a marginally significant decrease of anxiety for female patients ($t = -1.93$, $P = 0.054$). Smoking rates considerably declined in either study group (intervention/usual care: McNemar $\chi^2 = 35.6/23.3$, $P < 0.001$) and were least pronounced in women controls (exact $P = 0.250$); there were only marginal changes with regard to diabetes in either group (exact $P > 0.999/0.727$).

We also looked at the rates of patients with clinically significant levels of anxiety (SCL > 59) and depression (CES-D > 22) at both time points (see Figs. 2 and 3). In the male group there was little difference between groups ($\chi^2 = 0.63/1.87$, d.f. = 3, $P = 0.890/0.599$), but in women controls the rate of patients scoring high on anxiety (+29%) or depressiveness (+14%) increases substantially during the follow-up period, whereas there was practically no increase in the treatment group ($\chi^2 = 9.95/7.99$, d.f. = 3, $P = 0.019/0.046$).

The rate of patients being physically active for at least 1 h per week in the intervention group increased during follow-up in males ($\chi^2 = 7.97$, d.f. = 3, $P = 0.047$), but not in women ($\chi^2 = 2.94$, d.f. = 3, $P = 0.401$). There were no differences between men and women as far as food intake was concerned. Also, use of medication according to guidelines (anticoagulants, β-blockers, angiotensin-converting enzyme inhibitors, calcium channel blockers, lipid-lowering therapy) did not differ between sexes. The rate of repeated infarction, percutaneous coronary intervention, coronary artery bypass graft or cardiac symptoms (angina) during the follow-up period did not differ between men and women.

Discussion

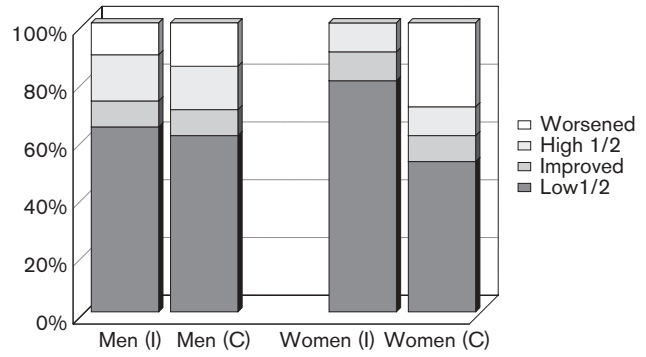
The present trial investigates a telephone counselling intervention aimed at the improvement of long-term effects of CR by reducing modifiable risk factors and thus lowering global coronary risk, as well as improving health

Table 2 Risk factors and psychological status at baseline and after 1 year for both study groups by gender; comparisons of change scores

	Intervention ($N=154$)		Control ($N=143$)		
	Baseline	Follow-up	Baseline	Follow-up	P_{change}
Total cholesterol, mg/dl (SD)	$M=167.0$ (39.4)	$M=170.4$ (38.1)	$M=168.3$ (38.5)	$M=171.3$ (38.1)	0.95[a]
Men	$M=166.4$ (38.5)	$M=169.5$ (39.5)	$M=166.7$ (37.7)	$M=169.8$ (35.1)	0.98[a]
Women	$M=164.0$ (43.0)	$M=173.8$ (32.3)	$M=177.4$ (42.7)	$M=179.3$ (27.9)	0.87[a]
HDL-cholesterol, mg/dl (SD)	$M=38.0$ (9.5)	$M=53.6$ (13.6)	$M=38.8$ (10.0)	$M=46.7$ (13.3)	0.25[a]
Men	$M=37.1$ (8.9)	$M=45.6$ (14.3)	$M=38.0$ (10.1)	$M=45.5$ (12.9)	0.48[a]
Women	$M=41.4$ (10.6)	$M=53.6$ (13.6)	$M=43.2$ (8.4)	$M=53.2$ (14.0)	0.48[a]
Blood pressure, mmHg (SD)	$M=122.5$ (13.7)	$M=132.0$ (17.1)	$M=119.9$ (14.1)	$M=136.1$ (20.6)	0.04[a]
Men	$M=123.2$ (13.3)	$M=131.3$ (17.8)	$M=120.1$ (12.6)	$M=134.9$ (19.3)	0.03[a]
Women	$M=120.1$ (15.1)	$M=135.5$ (14.3)	$M=119.0$ (21.0)	$M=142.5$ (26.1)	0.45[a]
Smoking, *n* (%)	59 (38.3)	18 (11.7)	46 (32.2)	19 (13.3)	$<0.01/<0.01$[b]
Men	47 (38.8)	16 (13.2)	41 (33.9)	17 (14.0)	$<0.01/<0.01$[b]
Women	12 (36.4)	2 (6.1)	5 (22.7)	2 (9.1)	$<0.01/0.25$[b]
Diabetes, *n* (%)	29 (18.8)	28 (18.2)	33 (23.1)	31 (21.7)	$>0.99/0.73$[b]
Men	22 (18.2)	21 (17.4)	12 (24.0)	28 (23.1)	$>0.99/>0.99$[b]
Women	7 (21.2)	7 (21.2)	4 (18.2)	3 (13.6)	$>0.99/>0.99$[b]
Anxiety, SCL-90 (SD)	$M=52.4$ (10.2)	$M=50.8$ (11.3)	$M=52.7$ (10.1)	$M=54.0$ (10.8)	0.08[a]
Men	$M=52.6$ (10.1)	$M=51.0$ (11.6)	$M=53.1$ (9.8)	$M=54.0$ (10.8)	0.33[a]
Women	$M=51.3$ (10.6)	$M=48.0$ (9.9)	$M=50.1$ (11.3)	$M=53.9$ (11.5)	0.05[a]
Depressiveness, CES-D (SD)	$M=13.1$ (8.0)	$M=11.0$ (8.6)	$M=13.7$ (8.1)	$M=12.1$ (8.9)	0.75[a]
Men	$M=12.2$ (7.8)	$M=10.5$ (8.7)	$M=13.0$ (7.5)	$M=11.3$ (8.5)	0.94[a]
Women	$M=16.2$ (8.0)	$M=13.2$ (10.0)	$M=17.5$ (10.0)	$M=17.0$ (10.2)	0.53[a]

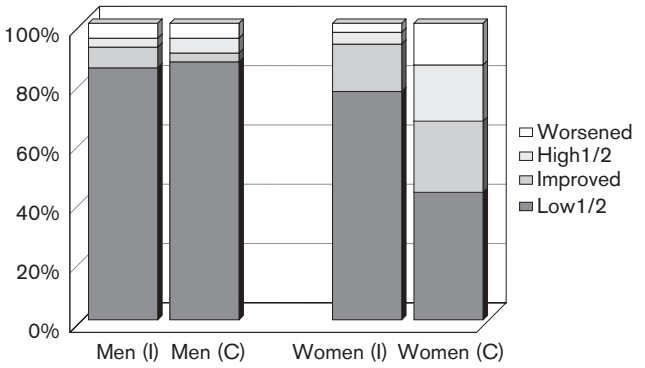
[a]Mann–Whitney *U*-test.
[b]McNemar χ^2/exact *P*.
HDL, high-density lipoprotein; SCL-90, symptom checklist-90; CES-D, Centre for Epidemiologic Studies Depression Scale.

Fig. 2



Anxiety (SCL-90 > 59) in both study groups at baseline and after 1 year by gender. I, intervention group; C, controls.

Fig. 3



Depression (CES-D > 22) in both study groups at baseline and after 1 year by gender. I, intervention group; C, controls.

related quality of life (psychological status). Overall the program was effective under study conditions (efficacy) yielding lower coronary risk scores in the intervention group compared to the control group. This result is in-line with those of other studies on the effects of long-term secondary prevention or follow-up programs (e.g. DeBusk *et al.*, 1994; Vale *et al.*, 2002, 2003; Hoberg *et al.*, 2004). It is even more significant since we tested against an attention placebo condition that very well might have had some enhancing effect (see Floer *et al.*, 2003).

Thus telephone counselling seems a cost-effective method to achieve significant reductions in cardiac risk factors and maintain the outcomes of CR. Since the effects of CR do not last in many cases, there is a need for follow-up programs such as the one presented here. Our approach to coaching patients by telephone supports the usual medical care rather than competing with it and can thereby integrate well into the existing health-care system. The program can easily be extended to other chronic diseases requiring changes in behavioural risk factors (e.g. diabetes). Just recently, Wewel *et al.* (2005) presented promising results from a telephone counselling program for the home-based rehabilitation of patients suffering from chronic obstructive lung disease.

The program in this study was conducted by specially trained nurses. This profession is ideal for taking a key

role in the management of chronic disease (DeBusk *et al.*, 1999; Mittag and China, 2003). Nurses not only possess thorough medical training, but also have a keen knowledge of the systems of health care, are aware of the patient's needs in day-to-day life and they also can bring the element of caring to the cost-contained medical system. Nurse case managers therefore should play a significant role coordinating, monitoring and coaching patients with chronic diseases. CR services in most countries are delivered by nurses, so this seems an appropriate method for continuing care of patients after they have completed a CR program. In Germany, CR is in the physician's domain and nurse case management requires not only the revision of familiar patterns of thought, but also the expansion of professional training in nursing.

A more detailed analysis of the overall results of this study by sex reveals that there are differences as to the results for men and women. As far as the primary endpoint (FRAM score) is concerned, it seems that the benefit for men was greater than for women. This result was mainly due to a lesser rise in systolic blood pressures in men in the intervention group as compared to women. The same result has been found in the HANSA study (Hoberg *et al.*, 2004). Vale *et al.* (2003) found favourable effects of their COACH program on blood pressures but they did not analyse their data by sex. At present, Wegscheider and Hoberg (2005) have run an analysis of the pooled data of the 'Luebeck Follow-Up Trial' and the HANSA study with a combined sample of more than 660 subjects. This was possible since the trials shared an almost identical design and endpoint. They found the same gender differences as to the individual risk factors caused by an interaction effect between type of intervention and gender for systolic blood pressure, with men achieving lower values at follow-up as compared to women. Including potential confounders (age, education, marital status, diagnoses and medication) in the statistical model did not weaken this result, but rather made it more pronounced, indicating that it is indeed a robust effect. We do not know, however, what these gender differences can be attributed to.

Frasure-Smith *et al.* (1997) have considered the hypothesis that the lack of treatment impact in men and the negative impact on women in M-HART might have been due to the program interfering with normal coping in some patients and thus paradoxically increasing stress. Our finding that the telephone intervention seems to have facilitated psychological coping in women does not support that assumption. Further analyses of the survival differences in the M-HART trial show that patients' coping style is important in determining long-term outcomes; there was evidence of a negative impact of treatment in repressors regardless of their sex (Frasure-Smith *et al.*, 2002). Since we did not survey coping styles, we could not explore that hypothesis any further.

A reanalysis of data from the M-HART-Trial by Cossette *et al.* (2002) also indicates that men and women may profit from different counselling approaches. Listening to non-cardiac concerns did work well for women, whereas men did better when nurses used cognitive and advice-based approaches. Gomér (2005) has just recently presented an intervention program especially for women with coronary disease. The program emphasizes coping with daily stressors, social support and dealing with negative affect. A 5-year follow-up showed much lower mortality rates in women enrolled in the program compared to the control-group. A short-term (12 weeks only) telephone counselling program, aimed at enhancing psychosocial adjustment in women following a cardiac event, evaluated by Gallagher *et al.* (2003), had no effect on anxiety or depression.

Another reason why the program had greater effects on systolic blood pressure in men as compared to women could be that the intervention failed to increase physical activity in women. In the ELMI trial (Lear *et al.*, 2003), no gender differences were found as to FRAM scores (Scott A. Lear, personal communication). This might be due to a self-selection bias given the willingness to participate in an exercise-based rehab program in addition to the telephone counselling. Different to the present study, women not willing to engage in physical exercises too heavily might not have participated in the trial. Bjarnason-Wehrens *et al.* (2006) in this connection have outlined a number of possible barriers to exercises in women such as age, comorbid conditions, incontinence and role expectations. CR designed for women has to account for these.

On the other hand, female patients, in contrast to men, seem to profit from the intervention with regard to their psychic status, the intervention protecting them from developing anxiety or depression after the cardiac event. This finding only partially corresponds with those of other studies utilizing telephone interventions. Beckie (1989) found a significant decrease in anxiety after 6 weeks of telephone support compared to a control group. Hartford *et al.* (2002) reported a shift to lower anxiety in both study groups, with a higher proportion of patients in the minimal anxiety category in the treatment group. Vale *et al.* (2003) found a statistically significant effect as to anxiety, but not for depression. Van Elderen *et al.* (1994) did not find any effect as to anxiety and depression. In all of these studies no analyses by sex were carried out. The overall impact of the M-HART program on psychological factors was very small for either men or women (Frasure-Smith *et al.*, 1997). The nurse-managed intervention in the MULTIFIT trial had a significant effect on reducing

anxiety in patients of either sex with low levels of anxiety, but other than that no differences were found between study groups or by gender as to anxiety or depression (Barr Taylor *et al.*, 1997). As in the present study, the small number of women in these trials does not permit definite conclusions on the effects by gender.

Altogether we find benefits of the telephone interventions that are specific for men and women. Men benefit from the program more with regard to somatic risk factors; in women there is a trend towards better outcomes in their psychological status and coping. Does that mean at present: 'All have won, and all must have prizes'? Yes and no. Yes, because the results presented here strongly support the need for long-term follow-up programs for both men and women, and no, because we do not yet know the reasons for the gender-specific effects described here. Further research is essential to address that issue more deeply.

Limitations of the study

There are limitations to the results reported above. First, the sample is only 18% women. The power to detect effects in women therefore is low. Unfortunately this is typical for most cardiac research.

Another problem is caused by the way the global coronary risk is assessed. The FRAM score is designed for assessing the risk for coronary healthy subjects and not for secondary prevention. We therefore used the FRAM score here as outcome measure, not as a risk calculator. To our knowledge there is, as yet, no score suitable for the assessment of the coronary risk of patients following cardiac events.

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