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Does a telephone follow-up intervention for patients discharged with acute myocardial infarction have long-term effects on health-related quality of life? A randomised controlled trial

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Aims. An earlier combined proactive and reactive telephone follow-up intervention for acute myocardial infarction patients after discharge from hospital showed positive effects after six months. The aim of the present study was to assess whether the intervention has long-term effects up to 18 months after discharge.

Design. A prospective randomised controlled trial with 18 months follow-up.

Method. The trial was conducted with 288 patients allocated to a telephone follow-up intervention group (n = 156) or control group (n = 132). The primary endpoint was health-related quality of life using the SF-36. Secondary endpoints included smoking and exercise habits, return to work and rehospitalisation due to chest pain.

Results. There were significant improvements over time on most dimensions of health-related quality of life in both the intervention and control group to US norm population levels on most SF-36 dimensions and summary scores. The intervention group showed no overall significant improvement beyond six months in the physical or mental summary scores, but there was a significant effect for those aged 70 or above. Although there was a promising effect for rehospitalisation due to chest pain, no significant differences were found between the groups on the secondary endpoints after six months.

Conclusion. This study demonstrated that despite positive short-term effects at six months, the telephone follow-up intervention had no long-term effects on health-related quality of life or secondary endpoints. However, the potential for improvement beyond six months was less than anticipated reflecting a reduced morbidity among acute myocardial infarction patients.

Relevance to clinical practice. Telephone follow-up after discharge from hospital is an easy implementable follow-up intervention enabling individualised provision of information and support in a time often experienced as stressful by patients. Our study indicates that six months is an adequate support period. Despite positive results six months after discharge no significant added long-term effects of telephone follow-up, compared to usual care were found in this study.

Key words: coronary heart disease, patient information, quality of life, randomised controlled trials, rehabilitation, telenursing

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Introduction

There has been little clinical and research interest in interventions for acute myocardial infarction (AMI) patients in the second phase of rehabilitation, immediately following discharge from hospital and up to six weeks afterwards (Mayou *et al.* 2002), despite this being a period when many patients experience stress and have unmet information needs

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(Hanssen *et al.* 2005). At this time patients are also most receptive to suggestions about making lifestyle changes that reduce the risk of recurrent cardiovascular disease (Cundey & Frank 1995, Jones & West 1995). Telephone follow-up intervention (TFI) initiated by hospital health professionals is seen as a good method for exchanging information and providing health education and quality after-care services for patients with problems after discharge from hospital to home (McBride & Rimer 1999, Car & Sheikh 2003, Hanssen *et al.* 2005, Mistiaen & Poot 2006). In some studies, TFI has shown promising results in cardiac populations in increasing patient satisfaction (Riegel *et al.* 2002), reducing psychological distress (Roberts *et al.* 1995), increasing lifestyle changes (McBride & Rimer 1999), promoting attendance at cardiac rehabilitation (Harkness *et al.* 2005) and reducing rehospitalisation (Riegel *et al.* 2002). Nevertheless, there are areas of debate as other studies have refuted these results (Frasure-Smith *et al.* 1997, Dinnes *et al.* 1999, Gallagher *et al.* 2003).

In a recent review of the effects of TFI on postdischarge problems in different populations, including cardiac patients, within three months of discharge the authors concluded that there was inconclusive evidence of its effects (Mistiaen & Poot 2006). However, the results must be considered with caution as the studies reviewed were of low methodological quality, only a few outcomes were measured across more than one study and three months may have been too soon to assess the effects of TFI (Mistiaen & Poot 2006). Furthermore, the components of TFI and telephone delivered interventions (TDI) that are essential to their efficacy are largely unknown. There remain several unanswered research questions, for example: how can TDI better reach minority and poorly served populations; what is the optimal number, length and timing of calls to maximise intervention potency while minimising costs; who are the best persons to deliver interventions; and, how can TDI be used most effectively to encourage multiple behavioural changes (McBride & Rimer 1999, Mistiaen & Poot 2006).

In our previous research, we compared the outcomes of standard postdischarge care with the short-term effects of a combined proactive and reactive TFI designed to provide information, education and support (Hanssen *et al.* 2007). The intervention started in the first week after discharge and although there were no significant effects on health-related quality of life (HRQOL) after three months, the TFI significantly improved HRQOL and frequency of weekly exercise after six months. In addition, we found that the intervention had a promising effect on improving smoking cessation rates after AMI.

Aims

The aim of the present study was to assess to what extent the intervention has a long-term effect on HRQOL, up to 18 months after discharge. Furthermore, we wanted to assess the long-term effects on the secondary endpoints, smoking and exercise habits, return to work and rehospitalisation due to chest pain. In addition, we wanted to explore whether there were age-group differences in the effect on HRQOL.

Methods

Design and setting

The prospective randomised controlled trial was conducted at Haukeland University Hospital, Bergen, Norway, from September 2001–2005. This study was approved by The Regional Committee for Medical Research Ethics and the Privacy Issues Unit at Norwegian Social Science Data Services.

Patients and randomisation

All patients admitted to the hospital with a diagnosis of AMI confirmed through medical records were screened for inclusion in the study unless they had a coexisting severe chronic disabling disease, resided in a nursing home, were unable to receive telephone calls or fill in questionnaires, were living in an area where the local hospital provided any nurse-initiated postdischarge follow-up services, or if they had or were expected to have coronary artery bypass graft surgery during their hospital stay. After the first year of the study patients older than 80 years of age were also included. After hospitalisation for preferably at least two days, patients consenting to participate in the study were randomised to an intervention or control group using a simple randomisation procedure. Once group allocation was disclosed each subject was informed orally and in writing what his or her participation in the study involved.

Intervention group

The TFI has been described in detail previously (Hanssen *et al.* 2007). Briefly, all patients randomised to the intervention group received, in addition to current clinical practice (see below), a structured intervention encompassing reactive and proactive telephone follow-up after discharge. Weekly nurse-initiated telephone calls were arranged for the first four weeks; subsequently calls were arranged six, eight, 12 and 24 weeks after discharge.

The patient follow-up included primarily responses to individual needs and support of patients' own coping efforts with respect to lifestyle changes and risk factor reduction. Although we emphasised an individualised approach that provided information based on needs, readiness and motivation to learn, we also introduced topics relevant for AMI patients during the TFI. The aim was to normalise common problems or queries and to facilitate the asking of questions by patients. The topics included issues such as physical discomfort, anxiety, levels of physical activities and medications, with further elaboration if desired by the patient. Several strategies for responding to individual patient concerns were also emphasised in the intervention. These included repeating information about how the patient himself or herself could reduce the risk of further cardiovascular disease; providing emotional support and alternative coping strategies when the patient appeared to use inappropriate strategies; identifying problems; clarifying values; setting realistic goals; encouraging visits to the general practitioner; and if necessary, discussing questions with a cardiologist.

The proactive follow-up intervention lasted until six months after discharge. Although patients could terminate the follow-up calls earlier, they were encouraged to respond to the first five or six phone calls within the first two months after discharge. An open telephone line with twice-weekly dedicated telephone times was offered to patients and next-of-kin throughout the study.

Control group

All patients in the control group were managed in accordance with current clinical practice consisting of one visit to a physician at the outpatient clinic six to eight weeks after discharge and subsequent visits to the patient's general practitioner. Rehabilitation programmes or supervised exercise are only offered to a very small proportion of AMI patients in this region.

Data collection

Demographic and clinical data were collected by self-report and from medical records during hospital stays (Table 1). Baseline data on HRQOL were collected one week after discharge. Endpoints were assessed by self-report using mailed questionnaires and from the medical records 12 and 18 months after discharge. For the questionnaires one reminder was sent each time.

The 36-item Short Form Health Survey (SF-36) version 1.0 (Ware *et al.* 2000, Ware & Kosinski 2001) was used to measure HRQOL. This assesses eight dimensions: physical functioning, bodily pain, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, energy/vitality and general health perception. The scores on the eight dimensions were first transformed into scales from 0 (worst health) to 100 (best

Table 1 Baseline characteristics from in-hospital data of the randomised groups (N = 288)

	Intervention (n = 156)	Control (n = 132)
Demographic characteristics		
Age in years, N, mean (SD)	156, 59·5 (12·9)	132, 60·9 (10·8)
Gender, n/N (%)		
Men	132/156 (84·6)	101/132 (76·5)
Women	24/156 (15·4)	31/132 (23·5)
Marital status, n/N (%)		
Married/cohabitating	118/154 (76·6)	107/130 (82·3)
Employment, n/N (%)		
Full time	70/153 (45·8)	59/129 (45·7)
Part time	6/153 (3·9)	11/129 (8·5)
Not working	77/153 (50·3)	59/129 (45·7)
Highest level of education, n/N (%)		
Primary school	43/136 (31·6)	42/121 (34·7)
High school	48/136 (35·3)	43/121 (35·5)
College/university	45/136 (33·1)	36/121 (29·8)
Clinical characteristics		
Previous CVD, n/N (%)	42/155 (27·1)	27/130 (20·8)
Previous AMI, n/N (%)	19/156 (12·2)	16/131 (12·2)
Family history of CVD, n/N (%)	92/136 (67·7)	80/116 (69·0)
Smoking habits, n/N (%)		
Daily smokers	77/154 (50·0)	61/131 (46·6)
Never smoked	29/154 (18·8)	34/131 (26·0)
Ex-smokers	48/154 (31·2)	36/131 (27·5)
Exercise habits, n/N (%)		
Not exercising	22/130 (16·9)	13/109 (11·9)
Once weekly	33/130 (25·4)	25/109 (22·9)
2–3 times weekly	49/130 (37·7)	44/109 (40·4)
At least 4 times weekly	26/130 (20·0)	27/109 (24·8)
Diabetes (type I/II), n/N (%)	13/153 (8·5)	15/131 (11·5)
Hypercholesterolemia n/N (%)	60/155 (38·7)	62/131 (47·3)
Hypertension, n (%)	44/156 (28·2)	41/131 (31·3)
Body mass index in kg/m^2, N, mean (SD)	148, 26·5 (3·7)	129, 25·9 (3·2)
Thrombolysis, n/N (%)	19/156 (12·2)	19/132 (14·4)
Primary PCI, n/N (%)	53/156 (34·0)	41/131 (31·3)
Total PCI, n/N (%)	115/156 (73·7)	100/131 (76·3)
Length of stay days, N, median (IQR)	155, 5 (4–6)	130, 5 (4–7)
STEMI, n/N (%)	98/156 (62·8)	84/131 (64·1)
Peak CKMB in U/l, N, median (IQR)	156, 108·0 (36·3–240·5)	129, 88·0 (29·5–203·5)

SD, standard deviation; IQR, inter-quartile range; CVD, cardiovascular disease; AMI, acute myocardial infarction; primary PCI, percutane coronary intervention within 24 hours; total PCI, PCI during hospital stay; STEMI, ST-segment elevation myocardial infarction; CKMB, creatinine kinase myocardial band; U/L, units/litre.

health). Further, norm-based scores were calculated, with each dimension scaled to have a mean of 50 and a standard deviation (SD) of 10, thus incorporating the 1998 US norm (Ware *et al.* 2000, Ware & Kosinski 2001) into the scoring algorithm. Two summary scales, the physical component summary score (PCS) and the mental component summary score (MCS) were calculated. Scoring, including imputation for missing items, was conducted according to the original guidelines (Ware *et al.* 2000, Ware & Kosinski 2001).

Lifestyle endpoints including assessment of exercise and smoking habits, were investigated with questions developed specifically for this study. With respect to exercise we asked, 'How often on average do you exercise each week?' The response options were none, once, two to three times and four times or more. For smoking, a variable was constructed for those who smoked before the AMI, with the response options 'still smoking' and 'have stopped smoking'.

For patients who were working before their AMI, return to work was assessed by asking the date when they returned to work, either part time or full time. The endpoint rehospitalisation due to chest pain was assessed from medical records. Rehospitalisation because of AMI, stent occlusion, lung embolus and planned hospital admissions for angiography and revascularisation were excluded. In addition, we asked patients to report dates and reasons for hospital admissions after discharge, including admission to hospitals other than those within our patient record system.

Effect size and statistical analysis

When planning the study we were not aware of any studies reporting the effects of telephone follow-up on HRQOL. We intended to include 300 patients, based on a pragmatic assessment underpinned by expecting a small to medium effect size for the intervention on the primary outcome of the study, the PCS score on the SF-36 questionnaire. We anticipated 5–10% of patients would drop out at each time point, leaving approximately 200 patients in the study. We expected to be able to detect an effect size of 0·4 on the PCS score with a significance level of 0·05 (two tailed) and a power of 0·80.

Descriptive statistics for continuous variables with approximately normal distribution are presented as means and standard deviations (SD) and for continuous variables with non-normal distribution as median values and inter-quartile ranges (IQR). Demographic and clinical variables at baseline were compared in the intervention and control group using the chi-squared test, Student's *t*-test or the Mann–Whitney *U*-test, as appropriate. To determine any differences between the intervention and control group in participants lost to follow-up from discharge to the fifth measurement point after 18 months, we used two-way analysis of variance (ANOVA) with Bonferroni correction and the chi-squared test. Multivariate analysis of variance (MANOVA) with Bonferroni correction was performed to explore the extent of age group and treatment group interactions in changes from baseline to 18 months after discharge for the SF-36 PCS and MCS summary scores. Fisher's exact test was used to compare the intervention and control groups with respect to exercise and smoking habits at 12 and 18 months after discharge. Student's *t*-tests were used to compare SF-36 scores at baseline and 18 months in the sample with US normal population scores (Ware & Kosinski 2001); to compare changes in SF-36 scores from baseline to 18 months after discharge between the intervention and control group; and to analyse if changes from baseline within the control and intervention groups were significant. To analyse any effect on the SF-36 scales from group and time we performed an ANOVA with repeated measures using the general linear model (GLM) module in SPSS (Norman & Streiner 2000), allowing for testing of time × group interaction and baseline both in the model and as a covariate. Survival analysis using the log-rank test (Mantel 1966) was used to analyse difference between intervention and control group on exact time to rehospitalisation and return to work. Further, the life table approach was used to analyse differences between the groups on time to smoking cessation as the exact time of smoking cessation was not available. All analyses were performed according to the intention-to-treat principle. All tests were two-tailed. Data were analysed using SPSS version 13.0.

Results

Study patients

In total, 413 patients fulfilled the inclusion criteria and were invited to participate in the study. One hundred and twenty-five (28%) were excluded from the study and 288 patients remained for randomisation (Fig. 1). Of the 156 randomised to the intervention group, 137 completed the telephone follow-up with a median of six calls (IQR: 5–8 calls) with each call lasting on average 6·88 minutes (SD 3·89).

The most frequent loss to follow-up took place in the period from randomisation to one week after discharge, before the baseline was established. From randomisation to the fifth measurement point after 18 months, the loss to follow-up was 26% in the control group and 35% in the intervention group. Compared to those remaining in the study those lost to follow-up had significantly longer hospital

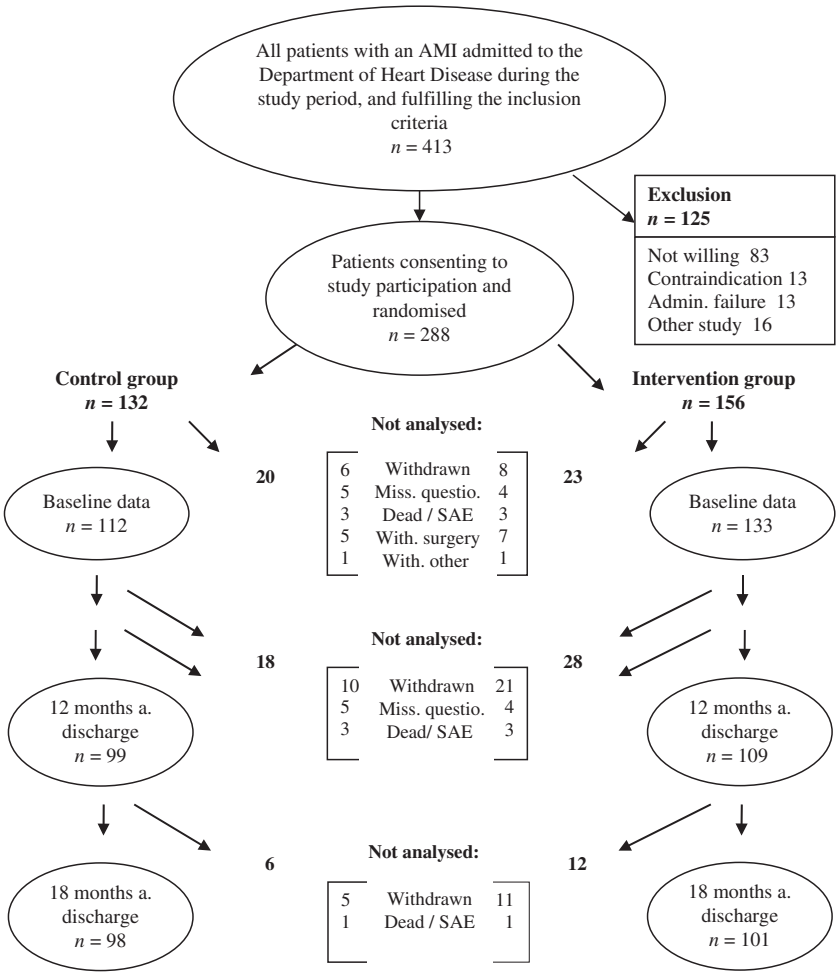

Figure 1 Recruitment and subjects. SEA: serious adverse events.

stays, poorer HRQOL scores at baseline, a larger proportion of non-smokers and smokers and a smaller proportion of ex-smokers. Analysing baseline SF-36 dimensions with respect to group and loss to follow-up there was a significant group × loss interaction on the general health scale ($p = 0{\cdot}003$), where those lost from the control group scored lower than those lost from the intervention group.

Baseline characteristics including HRQOL and lifestyle factors

The demographic and clinical characteristics of the intervention and control groups are shown in Table 1. There were no statistical differences between the control and intervention groups with respect to the demographic and clinical variables including exercise habits and smoking status. The baseline scores of both groups on the SF-36 were comparable except for the role–emotional scale, where the control group scored significantly lower than the intervention group (Table 2). Except for the bodily pain and mental health subscales all subscale scores were significantly lower in our sample ($p < 0{\cdot}001$) than the US population mean scores (Ware & Kosinski 2001), indicating that patients' HRQOL scores were negatively affected in all these dimensions.

Long-term effect of the intervention on HRQOL

When comparing change in HRQOL scores from baseline to 18 months after discharge there were significant improvements on most dimensions in both groups (Table 2). After 18 months both groups scored significantly lower than the US norm on the role–emotional subscale (Ware & Kosinski 2001). Further, the intervention group scored significantly lower than the norm in the general health scale and the control group in the role physical subscale. Both groups were comparable with the US norm population on the other subscales and on the summary scores (Ware & Kosinski 2001). When comparing differences in change between the intervention and control

Table 2 Baseline[a] norm-based SF-36 scores, scores 18 months after discharge, and differences in mean change between the intervention and control group

	Intervention group				Control group					
	Baseline[a]		After 18 months		Baseline[a]		After 18 months		Difference between groups	
SF-36 norm-based scores[b]	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	Mean[g] 95% CI	*p*-value[h]
PF – physical functioning[d]	133	44·08 (7·90)	101	51·50[f] (6·29)	112	44·48 (8·30)	98	50·42[f] (7·58)	−0·79 (−3·06 to 1·48)	0·491
RP – role physical[d]	129	33·69 (9·32)	101	48·06[f] (10·80)	111	32·75 (8·64)	97	45·53[e f] (12·09)	−0·94 (−4·76 to 2·88)	0·627
BP – bodily pain	132	49·60 (10·27)	101	53·99[f] (9·29)	111	49·75 (9·76)	98	53·01[f] (9·30)	−0·77 (−4·00 to 2·47)	0·641
GH – general health[d]	131	47·34 (8·43)	101	47·82[e] (10·25)	112	47·76 (9·06)	97	49·92 (10·03)	0·25 (−2·15 to 2·64)	0·838
VT – vitality[d]	133	47·10 (9·34)	101	51·51[f] (9·84)	111	47·50 (9·77)	98	51·48[f] (9·31)	0·58 (−1·95 to 3·12)	0·650
SF – social functioning[d]	133	43·46 (11·90)	101	50·61[f] (8·12)	112	43·93 (11·45)	98	50·43[f] (9·24)	0·55 (−3·95 to 2·85)	0·751
RE – role emotional[d]	130	38·73[c] (12·64)	101	47·79[e f] (11·38)	110	35·37[c] (12·21)	98	46·93[e f] (12·40)	2·59 (−1·58 to 6·77)	0·221
MH – mental health	133	49·74 (9·42)	101	51·86 (9·20)	111	50·66 (10·07)	98	53·19[f] (8·59)	0·31 (−2·11 to 2·73)	0·800
SF-36 summary scores										
PCS – overall physical[d]	127	43·17 (7·53)	101	50·73[f] (8·62)	109	43·70 (6·77)	97	49·46[f] (8·45)	−1·44 (−3·89 to 1·02)	0·250
MCS – overall mental[d]	127	46·14 (10·29)	101	50·00[f] (10·35)	109	45·23 (10·45)	97	50·97[f] (9·56)	1·65 (−1·35 to 4·65)	0·280

[a]Baseline defined as one week after discharge.
[b]Norm-based scoring using the 1998 SF-36 (v1) US population norms with mean = 50 and SD = 10 (Ware & Kosinski 2001).
[c]Statistical significant difference ($p < 0·05$) between the control and intervention group independent sample *t*-test (without correction for multiple testing).
[d]Total sample statistically significant ($p < 0·001$) below US normal population (Ware & Kosinski 2001) level at baseline in this dimension/summary score.
[e]Group statistically significant below US normal population (Ware & Kosinski 2001) level $p < 0·05$ at 18 months in this dimension/summary score.
[f]Significant improvement from baseline to 18 months in this dimension/summary score.
[g]Negative change favours intervention group and positive change favours control group.
[h]Equal variances assumed.

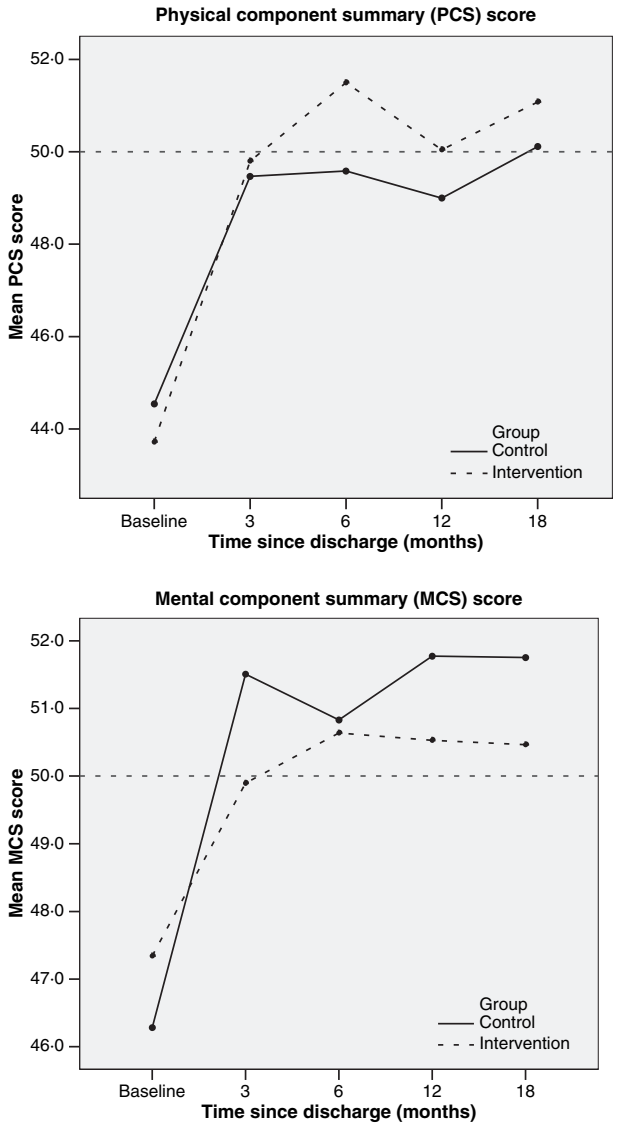

Figure 2 SF-36 PCS and MCS profiles from baseline to 18 months after discharge (n = 166) Stippled line US population norm with mean = 50 and SD = 10 (Ware & Kosinski 2001).

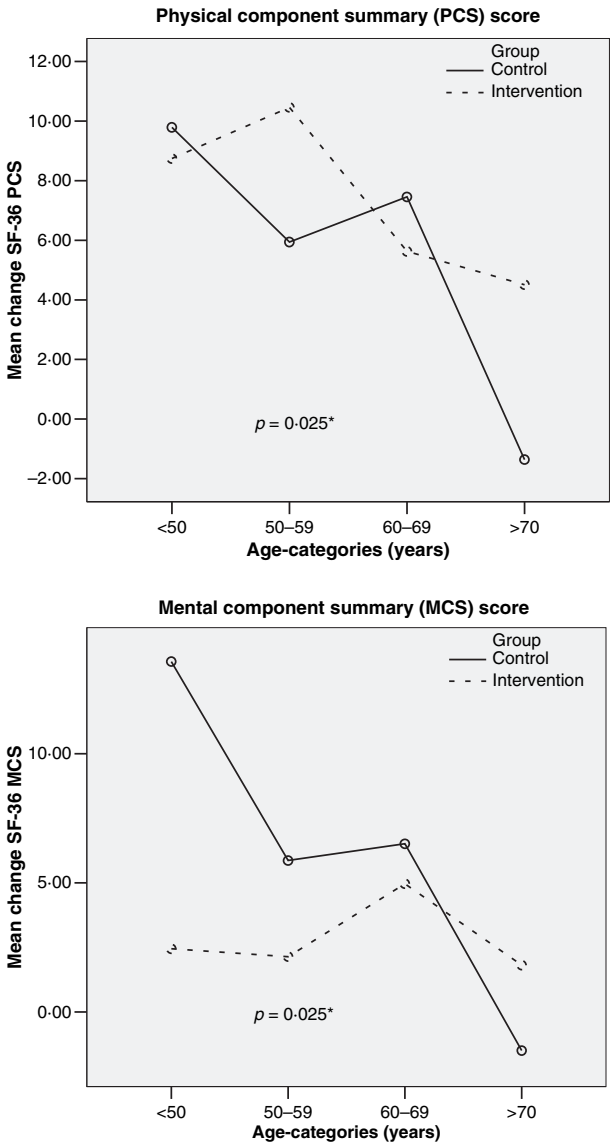

Figure 3 Change in SF-36 PCS and MCS scores from baseline to 18 months after discharge according to group and age-category. *p-value from MANOVA testing group × age–group interaction.

groups there was no significant improvement in favour of the intervention group on either the PCS or MCS scores (Table 2). When analysing the effect of time (at baseline, three, six, 12 and 18 months after discharge) and group × time effect in a repeated measures ANOVA, we found a significant effect of time (linear, quadratic and cubic) on both the MCS and PCS scores (Fig. 2), but no significant effects for group or group × time interactions. The largest improvements in both summary scores were found from baseline to three months after discharge. The repeated measure ANOVA for the time points from three months to 18 months, with baseline as a covariate, showed a significant cubic effect of time on the PCS score (p = 0·014), but no effect of time in the MCS score.

We used MANOVA to explore whether the effect of the intervention on the change in PCS and MCS from baseline to 18 months after discharge differed in various age groups (up to 50 years, 50–59 years, 60–69 years and 70 and older) and found a significant group × age group interaction (p = 0·025) (Fig. 3). There was a pattern of reduced improvement in both PCS and MCS scores over time with increasing age in the control group but not in the intervention group. Consequently, the oldest age group showed an improvement in PCS in the intervention group that was not found in the control group; hence the intervention had a significant and positive effect in patients aged 70 years or

older. In the youngest age group, we found a significant improvement in MCS score in the control group but not in the intervention group. This is most likely a spurious finding, though we cannot exclude that this finding suggests a possible unfortunate effect of the intervention on MCS score among the youngest patients.

Effect of the intervention on exercise habits and smoking cessation

After 12 months, 77·9% of patients in the intervention group and 69·4% in the control group reported exercising at least two to three times each week (Table 3). At 18 months the number exercising at least two to three times each week was 71·7% in the intervention and 73·2% in the control group. Fisher's exact test showed no significant differences in weekly exercise frequency between the intervention and control groups after 12 and 18 months.

Twelve months after discharge 73·4% in the intervention group and 71·9% in the control group were non-smokers. After 18 months the number of non-smokers was 75·0% and 75·5%, respectively (Table 4). Of those smoking at baseline, 53·3% in the intervention group and 45·5% in the control group had stopped smoking after 12 months. There were no significant differences between the intervention and control groups in smoking habits and percentage that had stopped smoking after 12 and 18 months. An analysis using a life table approach with follow-up data on 82% of those smoking at baseline, applying the times three, six, 12 and 18 months, showed a total of 52% of patients in the intervention group and 48% in the control group stopped smoking. The median time of smoking cessation in the control group was at 18 months and in the intervention group 6·7 months (log-rank test $p = 0{\cdot}350$).

Table 3 How often on average do you exercise each week?

	Control	Intervention	
Group	*n*/*N* (%)	*n*/*N* (%)	*p*-value*
12 months after discharge			
Not exercising	9/95 (9·5)	8/109 (7·3)	0·593
About once	20/95 (21·1)	16/109 (14·7)	
2–3 times	37/95 (38·9)	48/109 (44·0)	
More than 4 times	29/95 (30·5)	37/109 (33·9)	
18 months after discharge			
Not exercising	10/97 (10·3)	9/99 (9·1)	0·159
About once	16/97 (16·5)	19/99 (19·2)	
2–3 times	47/97 (48·5)	34/99 (34·3)	
More than 4 times	24/97 (24·7)	37/99 (37·4)	

*Fisher's exact test comparing control and intervention group.

Table 4 Smoking habits and change in smoking habits after 12 and 18 months

	Control	Intervention	
Group	*n*/*N* (%)	*n*/*N* (%)	*p*-value*
12 months after discharge			
Smoking habits			
Not smoking	69/96 (71·9)	80/109 (73·4)	0·880
Daily smokers	22/96 (22·9)	22/109 (20·2)	
Smoking occasionally	5/96 (5·2)	7/109 (6·4)	
Subjects who smoked at baseline			
Stopped smoking†	20/44 (45·5)	32/60 (53·3)	0·552
18 months after discharge			
Smoking habits			
Not smoking	74/98 (75·5)	75/100 (75·0)	1·000
Daily smokers	19/98 (19·4)	19/100 (19·0)	
Smoking occasionally	5/98 (5·1)	6/100 (6·0)	
Subjects who smoked at baseline			
Stopped smoking†	23/43 (53·5)	30/55 (54·5)	1·000

*Fisher's exact test comparing control and intervention group.
†Proportion and analysis restricted to those smoking at baseline.

Effect of the intervention on rehospitalisation and return to work

During the 18 months follow-up six patients in the control group and eight in the intervention group died. With respect to rehospitalisation due to chest pain, there were 58 events during follow-up; 26 events in the intervention and 32 in the control group. There were no significant differences between the groups in days before readmission to hospital (log-rank test $p = 0{\cdot}130$) or in proportion readmitted, although 16·7% of the intervention and 24·2% of the control group were readmitted due to chest pain (Fisher's exact test $p = 0{\cdot}140$). Forty-nine in the control group and 68 in the intervention group returned to work. During the 18 months follow-up the estimated median days to return to work was 91 days in both groups. There was no significant difference between the groups in estimated days before return to work (log-rank test $p = 0{\cdot}777$).

Discussion

This randomised study demonstrated that the TFI had no long-term effects on HRQOL measured with the SF-36. Further, we found no significant long-term effects of the intervention on smoking and exercise habits, return to work or rehospitalisation due to chest pain, although promising possible trends with respect to several secondary outcomes were noticed.

There were significant improvements in HRQOL scores in both groups to levels comparable to the normal population in

most of the eight dimensions of SF-36 after 18 months, providing only modest potential for improvement in the intervention group. This somewhat surprising improvement in the HRQOL scores for both groups, also noticed after six months (Hanssen *et al.* 2007), could reflect the impact of the reduction in morbidity and mortality that has been reported over the last decade, due to better medical and surgical treatments, increase in coronary interventions and reduction in risk factors particularly in western Europe (Tunstall-Pedoe *et al.* 1999, Van de Werf *et al.* 2003, Graham *et al.* 2007). Individuals' perceptions of illness could have changed as a consequence of knowledge about reduced myocardial damage, improved treatment and improved survival, thus partly explaining the improvement in HRQOL for both groups. The findings of our study resonate with the surprising (according to the authors) results of a systematic review on QOL after AMI where the majority of HRQOL domains improved to normal levels with time although physical capacity, symptoms, work status and general health perception declined after AMI (Simpson & Pilote 2003). However, others have not found this improvement in HRQOL over time after AMI (Muller-Nordhorn *et al.* 2004).

The main purpose of the intervention was to provide tailored information, education and support to discharged AMI patients in a period that is usually experienced as stressful and where many have reported an information gap (Hanssen *et al.* 2005). This is to enable patients to adhere to medication and make the lifestyle changes necessary to reduce modifiable cardiovascular risk factors. Smoking cessation after AMI is potentially the most effective of all preventive measures, however, quitting smoking is a complex and difficult process, because it is strongly addictive (De Backer *et al.* 2003, Graham *et al.* 2007). In this study, the proportion of smokers in the intervention group who stopped smoking was 53% after 12 months and 55% after 18 months. The corresponding percentages in the control group were 45% and 54%. The proportion managing to stop in the intervention group agrees with the results of a review analysing the effect of nurse-delivered smoking interventions, where approximately 50% of cardiovascular patients who smoked managed to stop smoking after 12 months (Wiggers *et al.* 2003). However, no trials were found where the effect of telephone counselling was examined and therefore our trial adds new knowledge to this area. The proportion stopping smoking in the control group was higher than expected, as previous research had reported that approximately 30% of patients receiving standard care managed to stop smoking after 12 months (Carlsson *et al.* 1997, Vestfold Heart Care Study Group 2003, Wiggers *et al.* 2003). However, the results from our study correspond to recent results from the second European Action on Secondary Prevention through Intervention to Reduce Events (EUROASPIRE) survey where 50% of smokers had stopped smoking after AMI at a median of 1·5 years (Scholte op Reimer *et al.* 2006). The lack of effect on smoking in our study, despite positive trends after six months (Hanssen *et al.* 2007), could be explained by a dilution effect on the intervention, as the control group also probably received considerable input from the hospital, general practitioners, media, family and friends about the importance of stopping smoking and adopting healthy lifestyles to reduce the risk of recurrent cardiovascular disease, as emphasised in guidelines over the last decades (De Backer *et al.* 2003).

The significant effect on physical activity in favour of the intervention group found after six months (Hanssen *et al.* 2007) did not persist after 12 and 18 months. In this study, the frequency of physical activity increased over time for both groups and after 18 months more than 70% in both groups exercised at least two to three times each week. The results are in accordance with a far more extensive intervention of 12 weeks exercise and nine months follow-up by nurses (Carlsson *et al.* 1997). However, the proportion doing exercise in our study is higher than the average for the Norwegian population, where 49% exercised twice or more each week, according to Statistics Norway (http://www.ssb.no). Only 9–10% in our control and intervention groups reported no physical activity. This is a lower proportion than in the Norwegian population and European Union (15 countries) (Petersen *et al.* 2005) where 44% and 41% respectively reported seldom or never doing physical activity. Hence, as with smoking, the possibility of a dilution of effect should be considered, as the control group also possibly received considerable input from the hospital before discharge, at the outpatient clinic, their general practitioners, media, family and friends about the importance of physical activity in reducing risk for recurrent cardiovascular disease. The strength and duration of the TFI, which lasted up to six months for the proactive part with no additional booster sessions, could also explain why there were no sustainable long-term effects of the intervention on smoking cessation and frequency of exercise. Studies with longer follow-up have demonstrated an ability to sustain effects on smoking and physical activity for up to two years (Vestfold Heartcare Study Group, 2003). However, the evidence is inconclusive, as a study of nurse-led secondary prevention clinics found sustained effects on exercise with longer follow-up (> 1 year) but no effect on smoking cessation (Murchie *et al.* 2003). Further research with longer follow-up including booster sessions is thus warranted.

In our exploratory analysis, the oldest patients in the intervention group showed significantly more improvement

in both PCS and MCS scores than those in the control group. These results indicate that older patients in particular may benefit from TFI. We can speculate that this effect might reflect the provision of less support and education to older patients in general from hospitals and general practitioners. The positive effect of the TFI in the oldest patients confirms results of studies of exercise-based cardiac rehabilitation programmes that have included older patients (Ades 2001, Williams *et al.* 2006). In the youngest age group, i.e. below 50 years, the MCS score improved more in the control group. A possible explanation could reflect an effect of the intervention from disclosure of group allocation to established baseline on MCS, in the intervention group. Knowing that they would be phoned weekly after discharge may have reduced their feeling of being left on their own after discharge (Hanssen *et al.* 2005) and thus improved the mental dimensions of HRQOL at baseline in the intervention group. The results could also partly reflect a healthy survivor effect in the control group as those lost to follow-up in the control group had poorer score than those lost in the intervention group. However, the numbers lost were too small to show any group × loss interaction in the youngest age group. One could also speculate if the improvement in MCS score may reflect a more persistent psychological denial among the youngest in the control group that persisted throughout the 18 months follow-up, leading to fewer symptoms of distress in the control group compared to the intervention group. In the intervention group, the telephone calls could have interfered with using denial as coping strategy and provoked distress. Denial in cardiac populations can reflect two different patterns of denial, avoidance and reinterpretation/optimistic coping, with opposite long-term outcomes (Kortte & Wegener 2004). Another possible explanation could be compensatory rivalry with regard to the nursing staff and control group (John Henry Effect), i.e. staff became aware of the intervention group having additional information and therefore improving the information to the control group.

Study limitations have been described previously (Hanssen *et al.* 2007). In addition to these, the principal limitation to the internal validity of the present study is the small sample size. Although the sample was larger than in the majority of previous studies on psychosocial and educational programmes for coronary heart disease patients (Dusseldorp *et al.* 1999), the lack of effect on long-term endpoints in this study could reflect low power. To reduce the possibility of type II errors in this study, we measured primary endpoints with an instrument proven to be relevant and sensitive in rehabilitation interventions and cardiac populations (Dempster & Donnelly 2000). However, possible effects may not have been detected due to low power. In addition, effects on other outcomes including dietary pattern, exercise intensity, adherence to medication, knowledge about lifestyle and risk factors were not measured in this study. The loss to follow-up of 26% in the control and 35% in the intervention group over five measurement points (six weeks, three, six, 12 and 18 months) is another limitation. To reduce dropout and missing rates one reminder was sent by mail to both groups, unless a telephone call was due within two weeks for intervention group patients. Additional reminders were not sent due to ethical constraints. Another threat to internal validity could be posed by the differences between those who dropped out of the control group and those remaining, as those who dropped out scored significantly lower on the general health scale than those remaining. Hence, the healthy attendee effect should be considered as partly explaining the lack of effect of the intervention.

Conclusion

The results from this study indicate that although TFI had positive and significant results after six months on HRQOL and frequency of exercise compared to usual care, these effects were not sustained after 12 and 18 months, as both the intervention and control group improved to normal population levels over time. The results from this study indicate a reduced morbidity after AMI after 12–18 months as HRQOL among AMI patients is similar to the normal population. Further, the results might indicate that guidelines about lifestyle recommendations are increasingly implemented in clinical practice as the proportions stopping smoking and doing exercise in both control and intervention groups were comparable to results from more intensive and costly interventions and recent results of home-based cardiac rehabilitation (Jolly *et al.* 2006). Offering AMI patients TFI encouraged lifestyle changes and improved HRQOL after six months. However, the intervention does not seem to have added effects beyond six months on HRQOL, exercise or smoking habits, return to work or on rehospitalisation due to chest pain, compared to usual care.

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Contributions

Study design: TAH, JEN, BRH; data collection and analysis: TAH, JEN, GEE and manuscript preparation: TAH, JEN, GEE, BRH.

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