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Long-Term Compliance with Non-Pharmacological Treatment of Patients with Heart Failure

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Abstract

The aim of this study was to examine long-term compliance with non-pharmacological treatment of patients with heart failure (HF) and its associated variables. Data of 648 hospitalized HF patients (mean age 69±12 years; 38% female; mean left ventricular ejection fraction [LVEF] 33±14%) were analyzed. Compliance was assessed by means of self-report at baseline and 1, 6, 12, and 18 months after discharge. Patients completed questionnaires on depressive symptoms, HF knowledge, and physical functioning at baseline. Logistic regression analyses were performed to examine independent associations with low long-term compliance. From baseline to 18 months at follow-up, long-term compliance with diet and fluid restriction ranged from 77%-91% and 72%-89% respectively. In contrast, compliance with daily weighing (34%-85%) and exercise (48%-64%) was lower. Patients who were in New York Heart Association [NYHA]-class II were more often noncompliant with fluid restriction (odds ratio [OR] 1.97, 95% confidence interval [CI] 1.25-3.08). Lower level of knowledge on HF was independently associated with low compliance with fluid restriction (OR 0.78, 95% CI 0.71-0.86) and daily weighing (OR 0.86, 95% CI 0.79-0.94). Educational support improved compliance with these recommendations. Female sex (OR 1.91, 95% CI 1.26-2.90), LVEF ≥40% (OR 1.55, 95% CI 1.03-2.34), a history of stroke (OR 3.55, 95% CI 1.54-8.16), and less physical functioning (OR 0.99, 95% CI 0.98-0.99) were associated with low compliance with exercise. In conclusion, long-term compliance with exercise and daily weighing was lower than long-term compliance with advice on diet and fluid restriction. Although knowledge on HF and being offered educational support positively affected compliance with weighing and fluid restriction, these variables were not related to compliance with exercise. Therefore, new approaches to help HF patients stay physically active are needed.

Key-words: Adherence; Compliance; Heart Failure; Non-Pharmacological Treatment.

Although it has been well established, most studies on determinants of compliance in patients with heart failure (HF) are cross-sectional, or focus solely on compliance with 1 specific non-pharmacological recommendation. Data on temporal trends in compliance with cardiovascular medication have been reported previously [1], but little is known about long-term compliance with non-pharmacological treatment (i.e., sodium-restricted diet, fluid restriction, daily weighing, and exercise) and its determinants. Noncompliance with non-pharmacological treatment is related to adverse outcomes [2] and lower quality of life.[3] It is therefore vital to identify those patients who are at risk for noncompliance over a longer period of time, especially since studies have shown that noncompliance is a problem in the HF population.[4] It has been suggested that compliance with a specific recommendation might be a marker for compliance with other recommendations or lifestyle changes.[5] Unfortunately, direct comparisons of compliance with different recommendations in the same study population are not available. The present study aims to address this gap by examining long-term compliance with non-pharmacological recommendations and by assessing variables associated with long-term compliance.

Methods

The study employed a descriptive, prospective design and used data from the COACH (Coordinating study evaluating Outcomes of Advising and Counseling in Heart failure) study. COACH was a randomized, multi-center, controlled study in which 1023 HF patients were included between November 2002 and February 2005.[6, 7] Inclusion criteria were an admission for HF, evidence of a structural underlying heart disease, and ≥18 years of age. Exclusion

criteria were participation in another study, a planned or recent invasive cardiac intervention, or inability to complete questionnaires. COACH was designed to evaluate the effect of education and counseling by an HF nurse on clinical outcomes in HF patients. Patients were randomized to either a control group (‘care as usual’, with routine management by a cardiologist) or to 1 of the intervention groups (‘basic support’ or ‘intensive support’). Along with routine management by a cardiologist, patients in both intervention groups received additional care from a HF nurse. This additional care was provided both during hospitalization and after discharge according to protocol and consisted of comprehensive education and counseling about HF and the HF regimen. Patients in the intensive group had more contact moments with the HF nurse, including 1 or more home visits. Multidisciplinary advice was also part of the intensive intervention.

The study complied with the Declaration of Helsinki and the Medical Ethics Committee granted approval for the protocol. All patients provided written informed consent and were enrolled and examined during a fixed period of 18 months after discharge from the hospital. Assessments, conducted by an independent data-collector, took place at index hospitalization (baseline) and 1, 6, 12 and 18 months after discharge (follow-up) at the patients’ home. Patients completed questionnaires on compliance, HF knowledge, and quality of life. The presence of depressive symptoms was assessed at baseline and 12 and 18 months after discharge. When patients were not able to complete the questionnaires by themselves, the data collector guided the patients through the questionnaires by reading them the questionnaires. At baseline, clinical variables were retrieved from the patients’ medical records and by means of structured interviews. Data on left ventricular function were obtained by standard trans- thoracic echocardiography. Patients were included in this study on long-term compliance when they completed the compliance questionnaire during at least 4 out of 5 assessment moments. Only one missing value on each separate recommendation was permitted. When patients had 1 missing value on a specific recommendation during the total follow-up period, this missing

value was substituted by the lowest compliance score for that specific recommendation on all other assessments.

The Center for Epidemiological Studies Depression scale (CES-D) was used to measure the presence of depressive symptoms.[8] This scale consists of 20 items and measures the presence of depressive feelings and behaviors. A score of ≥16 indicates the presence of depressive symptoms. To differentiate between patients with moderate or severe depressive symptoms, the following cut-off scores of the CES-D were used: 0-15 (no depressive symptoms), 16-23 (moderate depressive symptoms), and ≥24 (severe depressive symptoms).[9]

Compliance with recommendations on a sodium-restricted diet, fluid restriction, exercise, and daily weighing was measured using the Revised Heart Failure Compliance Scale.[10] Compliance was measured on a 5-point scale (0 = never; 1 = seldom; 2 = half of the time; 3 = mostly; 4 = always). Two HF nurses, experienced in the field of compliance, assessed face validity of the Dutch version of the scale. Patients were defined as compliant with diet, fluid restriction, or exercise when they followed the recommendations ‘always’ or ‘mostly’ during the previous week. They were compliant with weighing when they weighed ‘daily’ or ‘at least 3 times a week’ during the previous month. When a patient reported to be compliant with a specific recommendation, a score of 1 point was assigned. Since compliance was measured at 5 different assessment moments (baseline and 1, 6, 12 and 18 months during follow-up), the compliance score for each recommendation could range from 0 to 5 points. This long-term compliance score was categorized into either low or high, with a score of 3 or less being defined as ‘low long-term compliance’. ‘High long-term compliance’ indicated compliance at 4 or all 5 assessment moments.

HF knowledge was measured with the Dutch HF knowledge Scale, which consists of 15 multiple choice items (range 0-15), with higher score indicating a higher level of HF knowledge.

This scale is a reliable and valid instrument for measuring knowledge on HF in general, symptom recognition, and the HF regimen.[11]

Perceived health and physical functioning were assessed using the RAND-36, a self-report questionnaire of the general health status similar to the Medical Outcome Study 36-item General Health Survey.[12, 13] Patients were asked to score their general health on a 5-point scale (1 = excellent to 5 = bad). Next, patients were divided into two groups: patients who perceived their general health as 'good-excellent' and 'fair-bad'. The subscale 'Physical functioning' consists of 10 items on limitations experienced when performing daily physical activities due to health problems. The total score of the subscale ranges from 0 to 100, with a higher score indicating better functioning.

Descriptive statistics were used to characterize the study population and to examine long-term compliance with the recommendations. For this study, data of the COACH-study were used. Compliance with each recommendation was therefore also described separately for patients in the control group and for patients who were assigned to 1 of the intervention groups. Since examining differences in compliance between both intervention groups was not the main focus of the present study, data were pooled for the 2 intervention groups and compared with the control group. To assess which baseline variables were independently associated with low long-term compliance, logistic regression analyses were performed. Low long-term compliance was used as the dependent variable; an odds ratio >1 indicates a higher probability of being low long-term compliant, whereas an odds ratio <1 indicates a lower probability of being low long-term compliant. First, univariable regression analyses were performed to explore which baseline variables were individually associated with low long-term compliance. All theoretically relevant variables for which the Wald test of no association with low long-term compliance had a p value < 0.10 were subsequently inserted in a multivariable regression model to determine whether these variables were also independently associated with low long-term compliance. This

procedure was conducted for all 4 recommendations. SPSS 16.0 statistical software (SPSS Inc, Chicago, IL) was used to perform the statistical analyses.

Results

Of the 1023 patients participating in COACH, 648 were included in this substudy. A total of 375 (1023-648) patients were excluded: 272 patients died during follow-up period of 18 months and 103 patients did not complete the compliance questionnaires on at least 4 assessment moments, or had more than 1 missing value on a specific recommendation. Compared with included patients, excluded patients were significantly older (74 vs. 69 years, $p < 0.001$), more often lived alone (44% vs. 36%, $p = 0.015$), were more often in New York Heart Association (NYHA)-functional class III-IV at discharge (58% vs. 44%, $p < 0.001$), and more often had an ischemic origin of HF (48% vs. 39%, $p = 0.008$).

The baseline characteristics of the study population are summarized in Table 1. The mean age of the study population ($n = 648$) was 69 ± 12 years, 38% were female, and 44% were in NYHA-class III-IV at discharge with a mean LVEF of 33 ± 14% (Table 1). The mean length of HF symptoms was 26 ± 48 months. Of all patients, 18% had moderate and 20% had severe depressive symptoms. In total, 31% of the patients were in the 'care as usual' group and 69% were in 1 of the 2 intervention groups.

Compliance with daily weighing (ranging from 34%-85% at the 5 assessment moments) and compliance with exercise (range 48%-64%) was lower compared with compliance with a sodium-restricted diet (range 77%-91%) and fluid restriction (range 72%-89%) (Figure 1). Compliance with diet at 1 month after discharge from the index hospitalization increased from

77% to 91% and remained stable afterwards. A similar trend was found for compliance with fluid restriction. Compliance with daily weighing increased from 34% to 85% at 1 month, but decreased over time to 67% at 18 months. Although compliance with exercise increased at 1 month, it remained at ~60% during follow up (Figure 1). Compliance was also examined separately for patients in the control group and for patients in the intervention groups. In both groups, percentages of compliance were also lower for daily weighing and exercise when compared with diet and fluid restriction. Compliance with fluid restriction, and, in particular daily weighing, was higher in the intervention groups (Figure 2 and Figure 3).

Subsequently, low long-term compliance (defined as being compliant at ≤ 3 out of 5 assessment points during baseline and follow-up) with each separate recommendation was examined. Of all patients, 16% demonstrated low compliance on the long term with a sodium-restricted diet and 21% with fluid restriction. In contrast, 41% and 54% respectively showed low compliance with daily weighing and exercise. Of all patients who showed low compliance with diet (n = 104), 54% showed low compliance with fluid restriction, 61% with daily weighing, and 82% with exercise. These percentages indicate that low compliance with 1 recommendation does not automatically indicate low compliance with other recommendations on the long term. Similar results were found for low long-term compliance with fluid restriction, weighing, and exercise (Table 2).

In a multivariable analysis, being in NYHA class II was independently associated with low compliance with fluid restriction. Having more knowledge about HF and being assigned to basic- or intensive support were inversely associated with low compliance with fluid restriction, and also with low compliance with daily weighing. This indicates that patients with more knowledge or patients who received additional support were more often compliant over a longer period of time. Women and patients with a LVEF of ≥40% were more likely to have low compliance with exercise. In addition, a history of stroke and poor physical functioning due to

health problems were associated with low long-term compliance with exercise. No significant associations in univariable or in multivariable analyses were found between compliance with a sodium-restricted diet and possible relevant variables (Table 3).

Discussion

This is the first study to examine long-term compliance with all aspects of non-pharmacological treatment in HF patients. The main finding of this study is that it appears to be more challenging for patients to become and to maintain compliant with daily weighing and exercise than with a sodium-restricted diet and fluid restriction. Providing education and counseling improved compliance with fluid restriction and daily weighing on the long term, but did not improve compliance with exercise.

Low compliance with daily weighing and exercise has also been demonstrated in previous studies.[10, 14-16] In addition, our study showed that long-term compliance with a particular recommendation does not automatically indicate compliance with other recommendations. This suggests that compliance with the different lifestyle recommendations require different skills from patients. Furthermore, different factors were found to be associated with low compliance after examining all 4 separate recommendations. Our data, however, could not identify factors associated with low compliance with a sodium-restricted diet. This is probably caused by the lack of variance in compliance.

Patients with more HF knowledge and patients who received additional support from the HF nurse during follow-up were more likely to comply with daily weighing over a longer period of time. After 1 month of follow-up, compliance with daily weighing increased both in patients

who received educational support and in patients who received care as usual. However, compliance with weighing remained high during follow-up in the intervention groups, while compliance decreased in the care as usual group. Although knowledge alone does not ensure compliance [16], it has nevertheless been confirmed as an important determinant of compliance in the HF literature.[17-20] An explanation for low compliance with weighing could be that many HF patients do not recognize the importance of daily weighing to check for fluid retention.[16] Also, having a stable weight over a longer period of time is another reason why patients weigh themselves less often.[21] Our study showed that providing adequate education on the importance of daily weighing is effective on increasing and maintaining compliance.

Patients with more knowledge about HF and patients who received educational support during follow-up were also more likely to comply with fluid restriction on the long term. In contrast, patients in NYHA class II more often had low long-term compliance with fluid restriction when compared with patients in NYHA class III-IV. A possible explanation for this difference could be that patients in a lower NYHA class are less motivated to comply with the recommendations on fluid intake because they do not experience many of the symptoms associated with HF.

Besides low compliance with daily weighing, we also confirmed low long-term compliance with recommendations on exercise.[22] Compliance with exercise also influenced the results of the HF-ACTION trial. Patients who fully complied with the exercise intervention had better outcomes, but only 30% of the patients actually did. Consequently, low compliance with the training regimen may have led to a demise in detecting a significant effect of exercise training on primary outcomes.[22] Our study showed that less physical functioning and a history of stroke, resulting in physical impairment, were independently associated with low long-term compliance with exercise. Additionally, older patients tended to be more often noncompliant, which suggests that older patients may have less energy or experience more physical symptoms,

which in turn might affect their ability to comply.[10, 20] HF symptoms and NYHA class were not associated with compliance with exercise. This indicates that physical symptoms and limitations related to factors such as older age and comorbidity possibly play a larger role in noncompliance with exercise than physical limitations related to HF itself. Health care providers should take these possible physical limitations into consideration, and should try to tailor recommendations on exercise to the specific needs of individual patients.

In contrast with compliance with daily weighing, which improved in patients who received education and counseling according to the COACH-study intervention, this intervention was not effective in increasing compliance with exercise. This suggests that other interventions are needed to improve compliance on the long term. Although it is known that motivational strategies, such as setting goals, giving feedback and solving problems might be effective in the short term, further research is needed to formulate strategies in order to sustain physical activity in HF patients.[23]

Our study has some limitations. Firstly, we used an arbitrary cut-off score to differentiate between patients with low and high long-term compliance. Secondly, data were collected by means of self-report, which may be susceptible to social desirability bias. Patients either completed questionnaires by themselves, or the data collector read them the questionnaires, which may have affected responses of the patients. Since it is not known which patients received assistance with completing the questionnaires, possible mode effects could not be assessed. Nevertheless, all data collectors were independent and trained according to protocol. A final limitation concerns the exclusion of patients who died during follow-up or who had more than 1 missing value on compliance data. This may have biased our data on long-term compliance, since mortality or not completing questionnaires might be due to noncompliance with non-pharmacological treatment.

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Figure Legends

Figure 1. Long-term compliance with non-pharmacological treatment (n = 648).

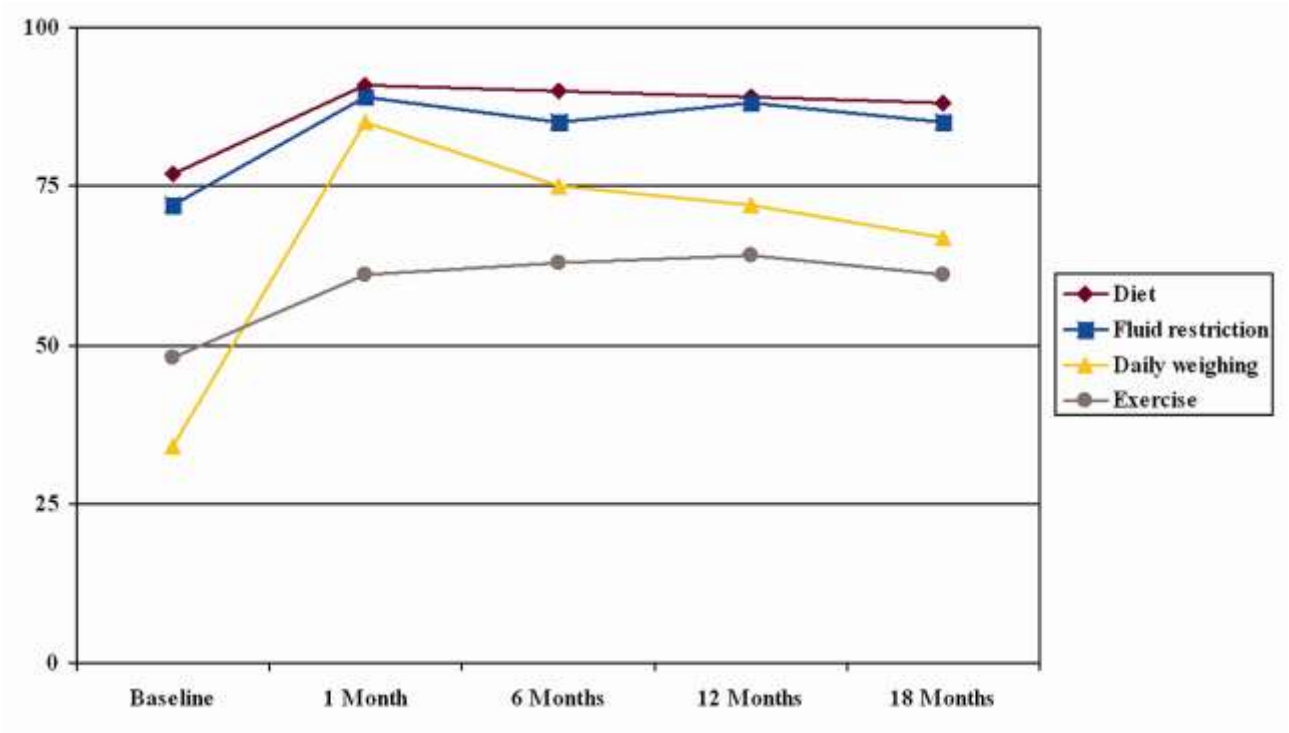
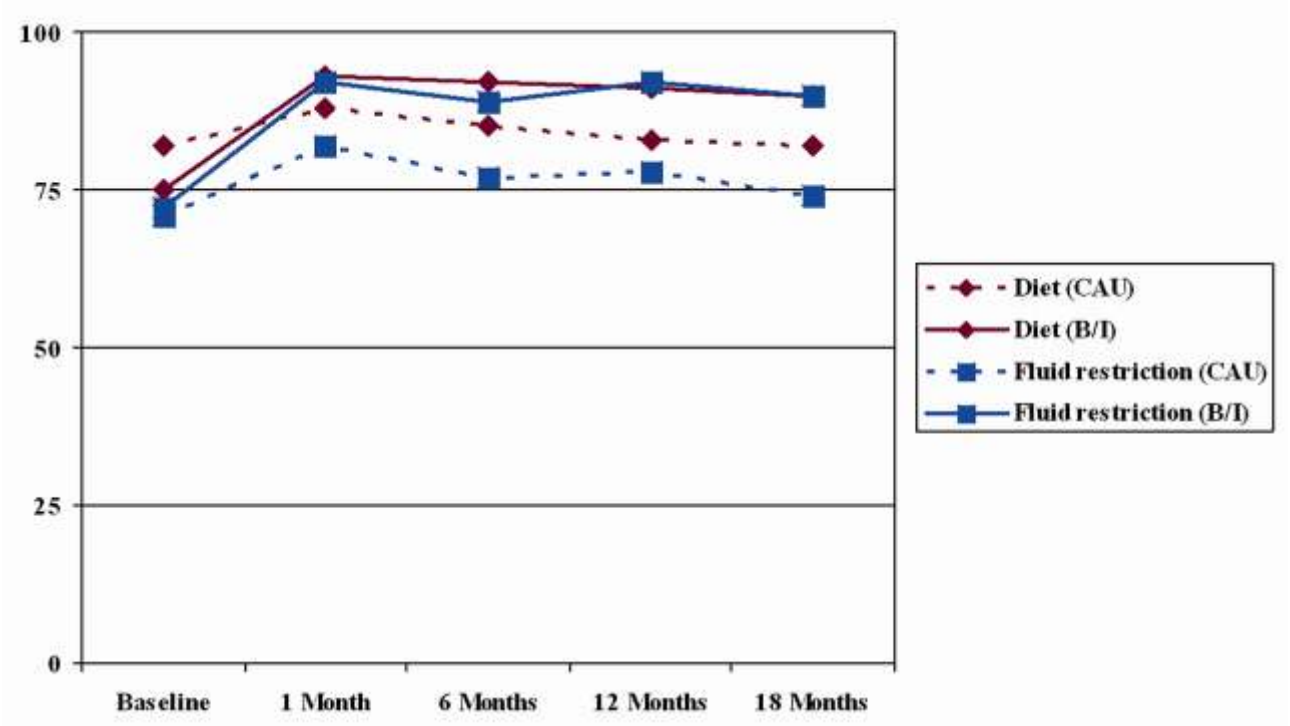
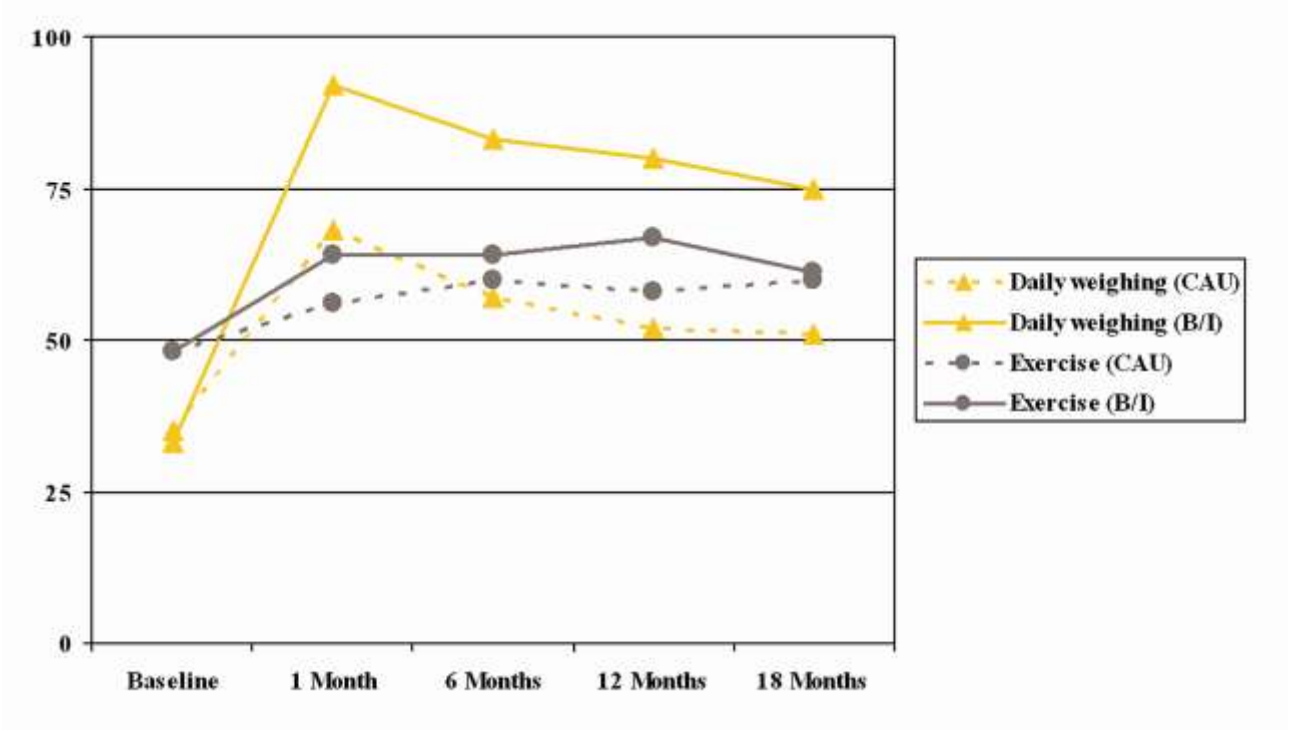


Figure 2. Long-term compliance with a sodium-restricted diet and fluid restriction; 'Care as usual' (n = 199) vs. 'Basic/Intensive support' (n = 449).



Abbreviations: B/I- Basic/Intensive; CAU- Care as usual.

Figure 3. Long-term compliance with daily weighing and exercise; 'Care as usual' (n = 199) vs. 'Basic/Intensive support' (n = 449).



Abbreviations: B/I- Basic/Intensive; CAU- Care as usual.

Table 1

Baseline characteristics (n = 648)

Age (years)	69 ± 12
Women	244 (38%)
Living alone	233 (36%)
Educational level (high)	74 (11%)
Left ventricular ejection fraction (%)	33 ± 14%
Left ventricular ejection fraction ≥40%	187 (32%)
New York Heart Association-class (III-IV) at discharge	281 (44%)
Ischemic origin of heart failure	255 (39%)
Length of heart failure (months)	26.3 ± 48.3
Previous heart failure admission	183 (28%)
Depressive symptoms:	
Moderate	112 (18%)
Severe	120 (20%)
Diabetes mellitus	153 (24%)
Chronic obstructive pulmonary disease	160 (25%)
Stroke	49 (8%)
RAND-36	
Perceived Health, 'Fair-Bad'	400 (64%)
Physical Functioning	39 ± 27
Dutch heart failure knowledge scale	
Total score	11.3 ± 2.3

Variables are reported as mean ± SD or number (percentage)

Table 2
Low long-term compliance with a particular recommendation related to other recommendations

	Diet	Fluid restriction	Daily weighing	Exercise
Diet (n = 104)		54% (n = 56)	61% (n = 63)	82% (n = 85)
Fluid restriction (n = 138)	41% (n = 56)		65% (n = 89)	79% (n = 109)
Daily weighing (n = 267)	24% (n = 63)	33% (n = 89)		69% (n = 184)
Exercise (n = 352)	24% (n = 85)	31% (n = 109)	52% (n = 184)	

This table shows how many patients with low long-term compliance with a specific recommendation also had low compliance with the other recommendations.

Table 3
Univariable (p value <0.10) and multivariable associations with low long-term compliance

Variable	Unadjusted OR (95% CI)	p Value	Adjusted OR (95% CI)*	p Value	Nagelkerke r square	c-statistic
Low compliance, sodium restriction					0.019	0.582
Chronic obstructive pulmonary disease	0.59 (0.34-1.02)	0.06	0.60 (0.35-1.03)	0.06		
Basic/intensive support	0.66 (0.43-1.02)	0.06	0.66 (0.42-1.03)	0.07		
Low compliance, fluid restriction					0.137	0.685
Left ventricular ejection fraction (≥40%)	1.54 (1.02-2.32)	0.038	1.19 (0.76-1.86)	0.44		
New York Heart Association (class II)	1.68 (1.13-2.50)	0.010	1.97 (1.25-3.08)	0.003		
Stroke	2.10 (1.13-3.91)	0.019	1.57 (0.77-3.21)	0.22		
Heart failure knowledge	0.77 (0.71-0.84)	<0.001	0.78 (0.71-0.86)	<0.001		
Basic/intervention support	0.47 (0.32-0.69)	<0.001	0.50 (0.32-0.77)	0.002		
Low compliance, daily weighing					0.150	0.688
Age (years)	1.03 (1.01-1.04)	<0.001	1.01 (0.99-1.03)	0.19		
Living alone	1.49 (1.07-2.06)	0.017	1.26 (0.86-1.83)	0.24		
Educational level (high)	0.61 (0.36-1.03)	0.06	0.81 (0.45-1.44)	0.47		
Left ventricular ejection fraction (≥40%)	1.77 (1.25-2.52)	0.001	1.44 (0.98-2.11)	0.06		
Heart failure knowledge	0.85 (0.79-0.91)	<0.001	0.86 (0.79-0.94)	0.001		
Basic/intervention support	0.32 (0.23-0.45)	<0.001	0.32 (0.21-0.46)	<0.001		
Low compliance, exercise					0.180	0.716
Age (years)	1.03 (1.01-1.04)	<0.001	1.02 (0.99-1.04)	0.06		
Women	1.83 (1.32-2.53)	<0.001	1.91 (1.26-2.90)	0.002		
Living alone	1.36 (0.98-1.88)	0.07	0.82 (0.54-1.24)	0.34		
Left ventricular ejection fraction (≥40%)	1.57 (1.10-2.23)	0.013	1.55 (1.03-2.34)	0.036		
New York Heart Association (class II)	0.63 (0.46-0.86)	0.004	0.90 (0.60-1.35)	0.61		
Previous heart failure admission	1.35 (0.95-1.90)	0.09	1.30 (0.83-2.03)	0.25		
Diabetes Mellitus	1.41 (0.98-2.04)	0.07	1.09 (0.69-1.73)	0.72		
Stroke	3.56 (1.75-7.27)	<0.001	3.55 (1.54-8.16)	0.003		
Depressive symptoms						
No symptoms	1.00 (reference)		1.00 (reference)			
Moderate symptoms	1.80 (1.16-2.77)	0.008	1.47 (0.88-2.46)	0.14		
Severe symptoms	1.73 (1.14-2.63)	0.011	1.04 (0.61-1.75)	0.89		
Total heart failure symptoms	1.10 (1.02-1.17)	0.010	1.01 (0.92-1.11)	0.78		
Perceived health (fair-bad)	1.93 (1.39-2.68)	<0.001	1.28 (0.84-1.94)	0.25		
Physical functioning	0.98 (0.98-0.99)	<0.001	0.99 (0.98-0.99)	0.006		
Heart failure knowledge	0.86 (0.80-0.93)	<0.001	0.93 (0.85-1.02)	0.14		

* Multivariable model includes all variables listed. CI = confidence interval; OR = odds ratio