

A randomized trial of a nurse-led educational intervention in patients with heart failure and their caregivers: impact on caregiver outcomes

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Aims

Psychoeducational interventions focusing on self-management of heart failure (HF) patients may improve patient health knowledge and reduce hospitalizations, but data regarding the effects on caregiver outcomes are inconclusive.

Methods and results

We conducted a single-centre, randomized controlled study to evaluate the effect of a nurse-led educational intervention in dyads of recently hospitalized HF patients and their caregivers on caregiver burden, feelings of guilt and health-related quality of life (HR-QoL). Dyads were randomized to usual care plus intervention group 1 (IG-1) or 2 (IG-2) or usual care only (control group, CG). Educational sessions in IG-1 and IG-2 were initiated before hospital discharge and continued with combination of home visits and telephone sessions in IG-1, or telephone sessions only in IG-2, delivered on regular intervals for 6 months. Caregiver burden was assessed by Heart Failure Caregiver Questionnaire (HF-CQ v5.0), guilt by Caregiver Guilt Questionnaire (CGQ), and QoL by EuroQol EQ-5D. Fifty-seven patient/caregiver dyads were included: 12 in IG-1, 18 in IG-2, and 27 in CG, of whom 11, 16, and 20, respectively, completed the study. All domains of HF-CQ and CGQ improved in IG-1 and IG-2 at 6 months, whereas deteriorated in CG (all $P < 0.01$). EQ-5D improved in IG-1 and IG-2 only in visual analogue scale part ($P = 0.002$), but not in the descriptive part.

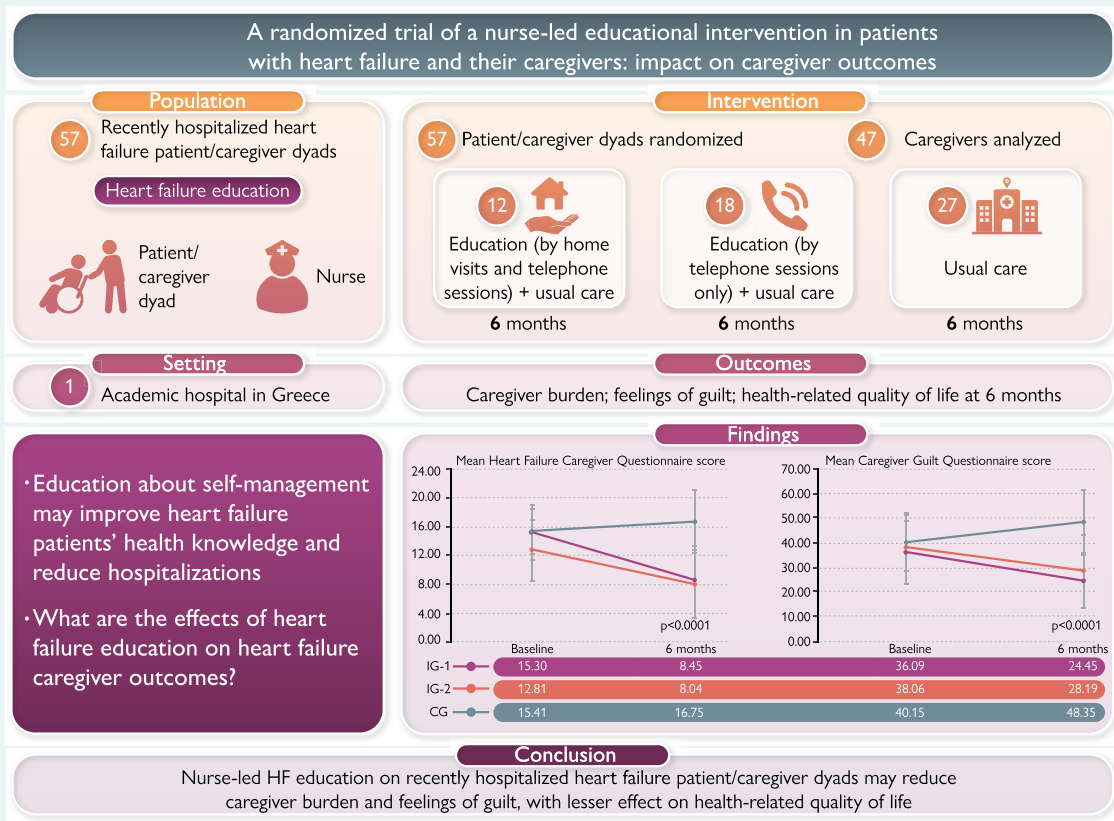
Conclusion

A nurse-led, 6-month educational intervention on recently hospitalized HF patients/caregiver dyads, delivered through either combined home visits and telephone sessions or telephone sessions only, reduced caregiver burden and feelings of guilt, with lesser effect on HR-QoL.

Registration

ClinicalTrials.gov: NCT05480969

Graphical Abstract



Keywords

Heart failure education • Patient–caregiver dyads • Caregiver burden • Caregiver guilt

Novelty

- Nurse-led dyadic education of recently hospitalized heart failure (HF) patients and their caregivers may reduce caregivers' burden and feelings of guilt.
- Delivery of education either by combined home visits and telephone sessions or telephone sessions only may be similarly efficacious in improving caregiver outcomes.
- Feeling of guilt—a potential contributor to mental distress—is experienced in a substantial degree by HF caregivers. There is a need to further explore mental distress and factors contributing to it in this population.

Introduction

Heart failure (HF) is a chronic syndrome requiring strict adherence to therapies, frequent clinic visits and self-care management, including self-monitoring activities. An important factor contributing to adequate self-care is the involvement of the informal caregiver.¹ Informal caregivers are considered as unpaid relatives or friends who provide care for patients with chronic diseases.² High-quality caregiver support may improve HF patient outcomes.³ Although caregiving may enhance self-esteem and provide gratification to providers, it can also impose significant burden.^{4,5} Increased burden may aggravate mental health problems and deteriorate quality of life (QoL) of HF caregivers.⁶

Recently, a dyadic patient/caregiver approach has been used to study self-care in HF realizing that patients and their caregivers are an

interdependent team and the way they appraise illness as a team influences management of the disease itself and related comorbidities.¹ HF nurses have a central role in the multidisciplinary HF care model, providing education to patients and their family regarding self-care, lifestyle modifications, diet and fluid restrictions and adherence to medication.⁷ Previous studies have shown improved patients' health knowledge and perceived health control with psychoeducational programmes,^{8,9} but data regarding the effect on caregiver burden are inconclusive.^{10,11} We conducted a randomized controlled study to examine the effect of a nurse-led, educational intervention delivered through either combined home/telephone sessions or telephone-only sessions in recently hospitalized HF patients and their caregivers on outcomes of patients and caregivers. Here, we report the effect on caregiver outcomes, including burden, feelings of guilt and health-related (HR)-QoL.

Methods

Study design

A single-centre, single-blind, randomized, parallel controlled study was performed to evaluate the effects of a nurse-led 6-month educational intervention in recently hospitalized HF patients and their caregivers on patients' and caregivers' outcomes. Adult patients who were recently hospitalized for HF were eligible for the study. Patients were excluded if they had severe cognitive dysfunction or psychiatric disease that precluded education. Among enrolled patients, those who reported that they had a caregiver living in the same household were enrolled and randomized in the study along with their caregiver (patient/caregiver dyads). Randomization was performed before hospital discharge to usual care plus intervention groups 1 or 2 (IG-1 or IG-2) or to usual care only (control group, CG) at 1:1:1 ratio, using simple randomization facilitated by a computer software tool (sealed envelope technique). Randomization was performed by a different researcher (PN) from the nurse who enrolled participants and assigned them to the intervention groups (MT). Due to the nature of the intervention, it was not possible to blind participants or the nurse who provided the education (MT). However, the researcher who performed assessment of caregiver outcomes and statistical analysis (VB) was blinded to minimize potential bias. Dyads in the intervention groups received personal educational sessions by a HF-trained nurse that were initiated before hospital discharge and continued thereafter by either combined home visits and telephone sessions (IG-1) or telephone sessions only (IG-2), both delivered at regular time intervals for a total period of 6 months. All patients received medical management for HF according to current guidelines and were followed at the HF outpatient clinic of the recruiting hospital.¹² The study was conducted in a university hospital in Greece and was approved by the local Ethics Committee (EC 28/18-01-2019), (ClinicalTrials.gov trials number, NCT05480969). All patients and caregivers provided written informed consent before enrolment.

Patient/caregiver recruitment was interrupted earlier than originally planned due to COVID-19 pandemic restrictions, which affected implementation of the intervention. More specifically, pre-discharge face-to-face dyads' education as well as home visits could not be performed due to restrictions for hospital visitors and social distancing.

Intervention

Patient/caregiver dyads who were randomized to IG-1 or IG-2 received a face-to-face educational session by a HF-trained nurse before hospital discharge and outpatient education re-enforcement sessions on regular intervals for a total period of 6 months. In patients randomized to IG-1, two home-based sessions were provided, on months 1 and 3 after discharge. These were combined with telephone sessions that were performed weekly during month 1 and every 2 weeks during months 2–6 after discharge. In patients randomized to IG-2, only telephone sessions were provided after hospital discharge using the same schedule as the telephone sessions provided in IG-1. The pre-discharge educational session, which was provided to patient/caregiver dyads, addressed topics such as daily self-care, self-monitoring and health awareness as described in the European Society of Cardiology (ESC) guidelines for HF diagnosis and management.¹² More specifically, topics addressed included: adherence to pharmacological therapies; non-pharmacological lifestyle interventions including diet, exercise and activities; advice on fatigue, stress management and relaxation; and performing daily self-care activities such as assessment and recording of body weight, blood pressure and heart rate. Education was provided by in-person discussion and through printed educational and self-management supporting material (including warning indications table; medications diagram; diary of vital signs and symptoms; and timetable of future clinic visits). In case that participants experienced learning difficulties, the educational strategy was adapted according to their educational level and age.¹³ Caregiver education included understanding HF syndrome and provision of advice on how to practically and emotionally support the patient, how to manage their own health and well-being and when and how to get help when needed. Outpatient sessions, also performed by the HF nurse, included repeated discussion and education on the topics discussed during the pre-discharge session;

evaluation of implementation of self-care activities by assessing patient-filled recording forms (including vital signs diary, symptoms diary and medications intake diary); discussion of difficulties limiting adherence to recommendations and self-care activities; and teaching problem-solving strategies.

Caregiver outcomes

Caregiver outcomes included caregiving burden, feelings of guilt and HR-QoL. Assessments were performed at baseline and at month 6, after completion of the intervention. Demographics, societal, family and personal health characteristics of caregivers were collected at baseline. Caregiving burden was assessed using the Heart Failure Caregiver Questionnaire (HF-CQ version 5.0), which consists of 21 items assessing three domains: physical, emotional/psychological and lifestyle. Items were scored on a burden severity response scale ranging from 0 (= Not at all) to 4 (= A lot). The score of each domain was then calculated as: (sum of scores for items answered/total possible score for items answered) × 100, after reversing scoring of item 15 because it is positively worded. Total score was calculated as the average of the sum of the three domain scores and ranges between 0 and 100.¹⁴

Caregivers' feeling of guilt was assessed using the Caregiver Guilt Questionnaire (CGQ). CGQ consists of 22 items that are scored on a five-point severity response scale from 0 (never) to 4 (always), with total scores ranging from 0 to 88. CGQ analyses five dimensions of guilt: guilt about doing wrong by the care recipient, guilt about failing to meet the challenges of caregiving, guilt about self-care, guilt about neglecting other relatives and guilt about having negative feelings towards other people.¹⁵

Caregivers' HR-QoL was assessed using the EuroQol Health-Related Quality of Life Questionnaire EQ-5D three-level version (EQ-5D-3L). EQ-5D-3L is a generic tool for measuring HR-QoL that consists of two parts: a descriptive part and a visual analogue scale (VAS). The descriptive part has five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems and extreme problems (labelled 1–3). The VAS records the respondent's self-rated health on a vertical scale that ranges from 0 to 100. Zero is labelled as 'The worst health you can imagine' and 100 as 'The best health you can imagine' and the participant is asked to draw a line to the point of the scale that represents their health state as perceived by themselves.¹⁶

Statistical analysis

Statistical analysis was performed using SPSS version 26 (SPSS Inc., Chicago, IL, USA). Categorical variables are presented as frequencies and percentages. Continuous variables are expressed as mean ± SD or median (IQR), for normally and not normally distributed variables, respectively. Normality was tested with Shapiro–Wilk's test. Differences between baseline variables of caregiver or patient groups were compared using the Chi-squared test for categorical variables and one-way ANOVA for continuous variables. Analysis of covariance (ANCOVA) was used to assess differences in changes of caregiver questionnaires between caregiver groups at 6 months compared to baseline, with caregiver group as fixed factor and baseline value of the tested variable (HF-CQ, CGQ and EQ-5D-VAS) as covariate. Because of baseline differences in age between caregiver groups, additional ANCOVA analyses after adjustment for caregiver age were performed. Statistical significance was defined by a *P*-value of <0.05.

Study sample size was calculated based on previous literature regarding educational interventions on HF patients showing improvement in the patient primary outcome measure (Kansas City Cardiomyopathy Questionnaire) in the intervention vs. the usual care group with an effect size of 0.26 and a standard deviation of 20.¹⁷ Hence, accounting for 10% attrition rate, we estimated that a total sample size of 162 patients (54 in each group) were required in order to detect this difference with a power of 80% and a significance level (alpha) of 0.05. Power analysis was performed using G*Power v3.1. There was no formal sample size calculation for the number of caregivers enrolled in the study. Post hoc power calculation showed that the study had a 99% power to detect the observed difference in caregiver HF-CQ total score at an alpha level of 0.05.

Results

Study cohort

From April 2019 to March 2020, 83 hospitalized HF patients were screened for study enrolment, of whom 73 were randomized into the three study arms (Figure 1). Among randomized patients, a total of 57 patients were randomized along with their caregivers as dyads: 12 in the IG-1, 18 in the IG-2 and 27 in the CG. No significant differences were observed in baseline characteristics of patients who had vs. those who did not have a caregiver, except from family status as the majority of patients in the dyadic group were married (77.2%) whereas in the non-dyadic group were either divorced (50%) or widowed (37.5%) ($P < 0.001$), and a higher frequency of coronary artery disease in the non-dyadic group ($P = 0.022$). In the dyadic cohort, six patients died during the study period (one in the IG-2 and six in the CG) and their caregivers did not perform the caregiver questionnaires at 6 months. In addition, four patients and their caregivers were lost to follow-up (one in the IG-1, one in the IG-2 and two in the CG), resulting in 47 caregivers being included in the caregiver outcomes analysis.

Baseline characteristics of patients and their caregivers in the dyadic cohort are shown in Tables 1 and 2, respectively. Patients were in their majority males (84.2%), with symptomatic HF of NYHA class II or III (98.2% overall), and reduced ejection fraction (75.4%). Most frequent comorbidities were arterial hypertension (66.7%), dyslipidemia (70.2%), anaemia (56.1%), atrial fibrillation (47.4%), and diabetes mellitus

(40.4%). Patients included in the three management arms were well-balanced with respect to their baseline characteristics except from age as those included in the IG-2 were younger as compared to the CG ($P = 0.039$).

Caregivers were in the majority females (84.2%), spouses (75.4%), living with the patient (89.5%) and providing >15 h of daily caregiving (64.9%). Social and caregiving-related characteristics were generally well-balanced among caregiver groups. However, caregivers of patients enrolled in the IG-2 were younger ($P = 0.003$) and more frequently apparently healthy than in the other groups ($P = 0.032$).

Assessment of caregiver burden, feeling of guilt and quality of life

Tables 3–5 present the baseline and follow-up scores as well as their respective changes over 6 months of the HF-CQ, CGQ and EQ-5D questionnaires in the IG-1 and IG-2 vs. the CG, respectively. At baseline, there were no significant differences between IG-1 and IG-2 vs. CG for all three questionnaires. As shown in Table 3, all domains of caregiver burden HF-CQ questionnaire including emotional well-being, physical well-being and lifestyle, improved in the IG-1 and IG-2, while they deteriorated or remained unchanged in the CG. Changes in the total HF-CQ score were -6.85 (4.19), -4.77 (4.36), and 1.33 (5.32) in the IG-1, IG-2, and CG, respectively ($P < 0.0001$) (Figure 2). Similarly, all domains of the CGQ score improved in the IG-1 and IG-2 at 6 months, whereas they deteriorated in the CG (Table 4). Changes in the total

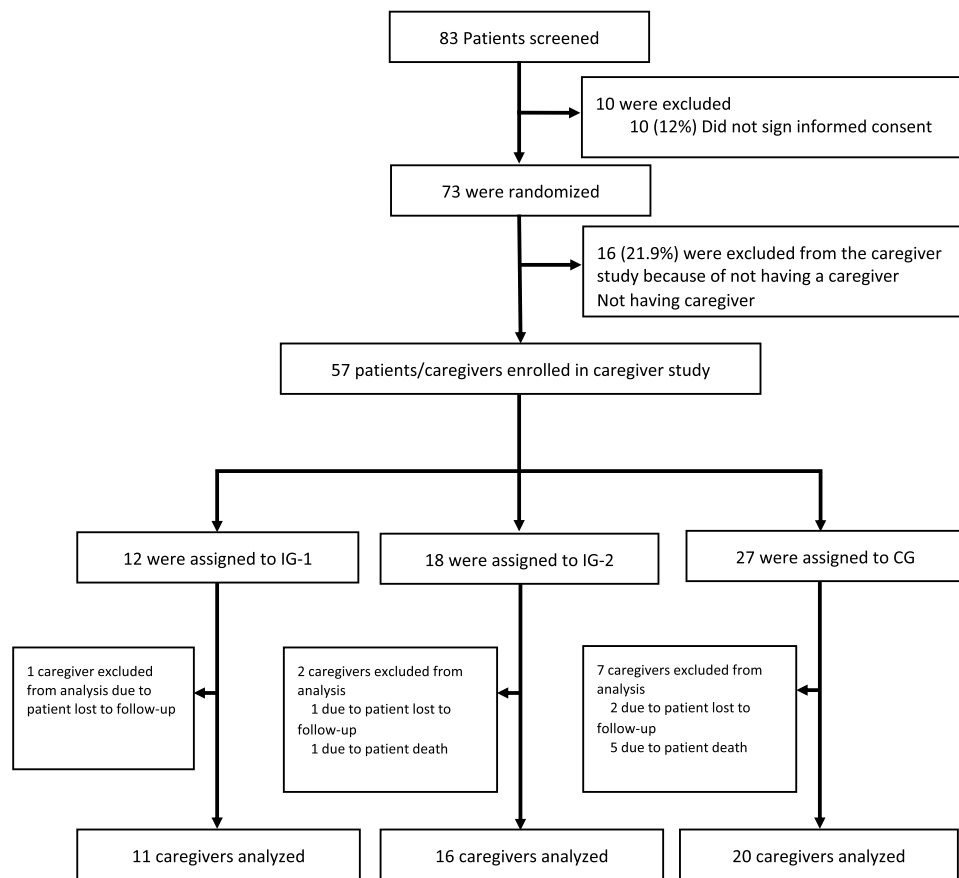


Figure 1 Study flow diagram.

Table 1 Baseline characteristics of patients enrolled in the caregiver study

	All patients, n = 57	IG-1, n = 12	IG-2, n = 18	CG, n = 27	P-value
Age, years	67.5 ± 11.2	68.8 ± 12.8	62.2 ± 10.6*	70.5 ± 9.7*	0.039*
Sex (male), %	84.2	91.7	77.8	85.2	0.615
Primary cause of HF					0.334
Ischaemic	43.9	50.0	33.3	48.1	
Non-ischaemic	50.9	50.0	50.0	51.9	
Unknown	5.3	0	16.7	0	
HF type (%)					0.605
HFrEF	75.4	53.8	77.8	81.5	
HFmrEF	14.0	33.3	11.1	7.4	
HFpEF	10.5	8.3	11.1	11.1	
Employment status (%)					0.206
Employed	29.8	41.7	38.9	18.5	
Unemployed	3.5	0	11.1	0	
Retired	66.7	58.3	50.0	81.5	
Family status (%)					0.941
Married	77.2	91.7	61.1	81.5	
Unmarried	0	0	0	0	
Divorced	8.8	0	22.2	3.7	
Widowed	14.0	8.3	16.7	14.8	
Level of education (%)					0.756
Up to and including high school	84.2	91.7	77.8	85.2	
Above high school education	15.8	8.3	22.2	14.8	
NYHA class (%)					0.726
NYHA II	42.1	50	33.3	44.4	
NYHA III	56.1	50	61.1	55.6	
NYHA IV	1.8	0	5.6	0	
LVEF	31.9 ± 10.1	36.7 ± 7.6	32.3 ± 10.4	29.6 ± 10.5	0.126
Comorbidities					
Arterial hypertension	66.7	83.3	66.7	59.3	0.615
Diabetes mellitus	40.4	58.3	27.8	40.7	0.856
Dyslipidaemia	70.2	83.3	61.1	70.4	0.756
Atrial fibrillation	47.4	33.3	38.9	59.3	0.856
Chronic renal dysfunction	28.1	33.3	16.7	33.3	0.660
Anaemia	56.1	50.0	38.9	70.4	0.497
Previous stroke	8.8	8.3	5.6	11.1	0.660
COPD	33.3	25.0	27.8	40.7	0.205
Cardiovascular medications					
RASi	64.9	91.7	66.7	51.9	0.587
Beta-blockers	77.2	83.3	72.2	77.8	0.411
MRA	57.9	66.7	61.1	51.9	0.430
Loop diuretics	64.9	66.7	55.6	70.4	0.238

*P-value for *post hoc* one-way ANOVA comparison between IG-2 and CG.

CGQ scores in the IG-1, IG-2, and CG were -11.64 (13.74), -9.87 (11.51), and 8.20 (13.86), respectively ($P < 0.0001$) (Figure 3). Assessment of caregivers' HR-QoL using EQ-5D-EL showed significant improvement of the VAS self-reported health status in the IG-1 and IG-2 as compared to the CG (changes in EQ-5D VAS: IG-1, 5.45 (5.22); IG-2, 6.56 (5.98); CG, -0.50 (6.86); $P = 0.002$). However,

percentage of patients who reported problems in the domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, did not differ among study groups at 6 months (Table 5). Analyses after adjustment for caregivers' age provided similar results and all significant differences in questionnaire changes among study groups remained significant (all $P < 0.01$).

Table 2 Baseline characteristics of caregivers

	All caregivers, n = 57	IG-1, n = 12	IG-2, n = 18	CG, n = 27	P-value
Age, years	55.5 ± 15.7	61.3 ± 14.8	45.5 ± 14.8	59.6 ± 13.8	0.003
Sex (female), %	84.2	75.0	77.8	92.6	0.253
Employment status (%)					0.136
Employed	31.6	41.7	50.0	14.8	
Unemployed	12.3	8.3	16.7	11.1	
Retired	22.8	25.0	5.6	33.3	
Housewife	33.3	25.0	27.8	40.7	
Family status (%)					0.372
Married	84.2	100	72.2	85.2	
Single	12.3	0	22.2	11.1	
Divorced	3.5	0	5.6	3.7	
Highest education level (%)					0.982
Up to and including high school	84.2	83.3	83.3	85.2	
Above high school education	15.8	16.7	16.7	14.8	
Living with patient cared for (%)	89.5	91.7	83.3	92.6	0.588
Relationship with the patient (%)					0.293
Spouse	75.4	91.7	61.1	77.8	
Child (adult)	12.3	8.3	22.2	7.4	
Other relative	12.3	0	16.7	14.8	
Daily hours of caring (%)					0.187
1–5 h	3.5	0	11.1	0	
>5–10 h	10.5	16.7	11.1	7.4	
>10–15 h	21.1	16.7	33.3	14.8	
>15 h	64.9	66.7	44.4	77.8	
Cardiovascular risk factors (%)					
Arterial hypertension	15.8	25.0	11.1	14.8	0.582
Dyslipidaemia	14.0	16.7	0	22.2	0.105
Diabetes mellitus	10.5	25.0	0	11.1	0.091
Coronary artery disease	5.3	16.7	0	3.7	0.119
Atrial fibrillation	5.3	8.3	0	7.4	0.478
Depression	3.5	0	0	7.4	0.316
Apparently healthy	63.2	8.3	55.6	37.0	0.032

Discussion

Caregiving for HF patients requires skills and coordination of actions to provide support in several activities including tasks of daily living, improving and maintaining self-care, providing psychosocial support and navigating the healthcare system.¹⁸ In addition, HF caregiving is a time-consuming task with changing caring demands through syndrome trajectory. Therefore, it imposes significant burden to providers that extends from financial costs to risks on personal psychological and physical health.^{19,20}

In the present study, we have shown that a 6-month nurse-led educational intervention in recently hospitalized HF patients and their caregivers, conducted through either combined face-to-face home visits and telephone contacts or telephone sessions only, improved caregiver burden and feelings of guilt, with a tendency to also improve their HR-QoL. Randomized studies assessing the effects of educational interventions to HF caregivers have been limited to date, while the type,

setting, duration, and intervention delivery modalities have varied. In most studies, education regarding HF awareness, self-monitoring and self-management was provided through face-to-face sessions with telephone follow-up contacts to patient/caregiver dyads, while in fewer studies delivery method was telephone sessions only.^{11,21–28} Recently, the effect of telehealth self-care assistance supportive interventions delivered through automated calls and emails to caregivers has been reported.²⁹ Caregiver outcomes examined previously have varied but most frequently have included caregiver burden, depression and anxiety, QoL, personal health status and perceived knowledge regarding HF care. Although results have been inconsistent, possibly due to the heterogeneity in terms of type and content of interventions or the mode of delivery, a number of studies have reported beneficial effects in burden and care knowledge with the use of home-based, face-to-face education.^{21,22,24,26,27,30} Our study is in alignment with these studies by showing reduction of caregiver burden in the home-

Table 3 Changes in caregiver burden questionnaire scores (HF-CQ) at 6 months compared to baseline in the interventional groups and the control group

Variable	n	IG-1			IG-2			CG			P-value		
		Baseline	6 months	Change	Baseline	6 months	Change	Baseline	6 months	Change			
<i>HF-CQ domains</i>													
Physical well-being	11	9.55 (4.39)	5.36 (4.03)	-4.18 (3.71)	16	8.00 (4.44)	4.88 (4.92)	-3.12 (4.05)	20	11.50 (4.83)	11.45 (4.32)	-0.05 (4.08)	0.001
Emotional well-being	11	28.45 (5.41)	15.82 (8.04)	-12.64 (7.16)	16	23.25 (6.55)	15.56 (6.42)	-7.69 (7.06)	20	26.85 (6.81)	29.85 (6.25)	3.00 (7.41)	<0.0001
Life style	11	8.82 (2.86)	4.18 (3.63)	-4.64 (3.17)	16	7.13 (3.40)	3.69 (3.44)	-3.44 (3.60)	20	8.45 (3.12)	10.00 (4.04)	1.55 (3.14)	<0.0001
HF-CQ Total score	11	15.30 (3.77)	8.45 (5.05)	-6.85 (4.19)	16	12.81 (4.25)	8.04 (4.76)	-4.77 (4.36)	20	15.41 (3.16)	16.75 (4.33)	1.33 (5.32)	<0.0001

Table 4 Changes in caregiver guilt questionnaire (CGQ) scores at 6 months compared to baseline in the interventional groups and the control group

Variable	n	IG-1			IG-2			CG			P-value		
		Baseline	6-Month	Change	Baseline	6-Month	Change	Baseline	6-Month	Change			
<i>CGQ domain</i>													
Guilt about doing wrong by the care recipient	11	13.18 (4.02)	8.09 (3.70)	-5.09 (4.76)	16	12.50 (4.98)	9.50 (5.50)	-3.00 (3.93)	20	13.23 (4.29)	16.35 (4.25)	2.50 (5.14)	<0.0001
Guilt about failing to meet the challenges of caregiving	11	10.82 (3.25)	8.82 (2.32)	-2.00 (3.55)	16	12.06 (3.57)	10.00 (3.39)	-2.06 (2.77)	20	12.00 (3.31)	14.80 (2.82)	2.80 (3.37)	<0.0001
Guilt about self-care	11	6.27 (3.23)	4.27 (2.94)	-2.00 (3.07)	16	8.00 (3.33)	4.94 (3.36)	-3.06 (3.15)	20	7.90 (2.57)	8.95 (3.19)	1.05 (3.38)	<0.0001
Guilt about neglecting other relatives	11	3.73 (1.85)	2.09 (1.51)	-1.64 (1.57)	16	3.44 (1.67)	2.69 (1.66)	-0.75 (1.61)	20	3.85 (1.76)	4.70 (1.63)	0.85 (1.53)	<0.0001
Guilt about having negative feelings towards other people	11	2.09 (2.07)	1.18 (1.99)	-0.91 (3.08)	16	2.69 (2.52)	1.06 (1.88)	-1.62 (2.34)	20	2.60 (2.54)	3.55 (2.28)	0.95 (3.28)	0.001
CGQ total score	11	36.09 (12.79)	24.45 (11.25)	-11.64 (13.74)	16	38.06 (14.04)	28.19 (14.86)	-9.87 (11.51)	20	40.15 (11.39)	48.35 (13.21)	8.20 (13.86)	<0.0001

Table 5 Changes in caregiver quality of life EQ-5D-3L questionnaire scores at 6 months compared to baseline in the interventional groups and the control group

Variable	IG-1 (n = 11)			IG-2 (n = 16)			CG (n = 20)			P-value (6 months)		
	Baseline	6 months	n (%)	Baseline	6 months	n (%)	Baseline	6 months	n (%)			
EQ-5D-3L descriptive part												
EQ-5D, caregivers who reported problems, n (%)												
Mobility	4 (36.4)	2 (18.2)	2 (18.2)	1 (6.3)	1 (6.3)	1 (6.3)	4 (20.0)	3 (15.0)	3 (15.0)	0.147		
Self-care	0	0	0	0	0	0	0	0	0	NA		
Daily activities	3 (27.3)	1 (9.1%)	1 (9.1%)	3 (18.8)	3 (18.8)	3 (18.8)	2 (10.0)	2 (10.0)	2 (10.0)	0.461		
Pain/discomfort	6 (54.5)	2 (18.2)	2 (18.2)	3 (18.8)	3 (18.8)	3 (18.8)	6 (30.0)	6 (30.0)	6 (30.0)	0.142		
Anxiety/depression	10 (90.9)	11 (100.0)	11 (100.0)	16 (100)	16 (100.0)	16 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	0.188		
EQ-5D-3L Visual analogue scale part												
Visual analogue scale	IG-1			IG-2			CG			P-value		
	n	Baseline	6 months	Change	n	Baseline	6 months	Change	n		Baseline	6 months
Visual analogue scale	11	61.82 (16.62)	67.27 (16.79)	5.45 (5.22)	16	64.38 (17.50)	70.94 (18.09)	6.56 (5.98)	20	60.00 (16.22)	59.50 (15.04)	-0.50 (6.86)

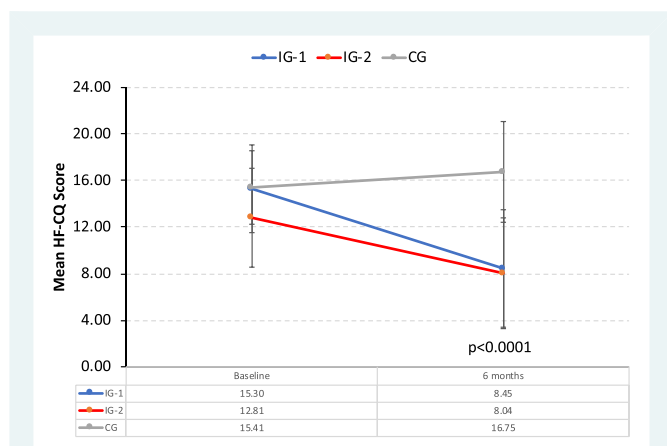


Figure 2 Total HF-CQ score. Effect of the educational intervention delivered by combined home visits/telephone sessions (IG-1) or telephone sessions only (IG-2) on total HF-CQ score over 6 months.

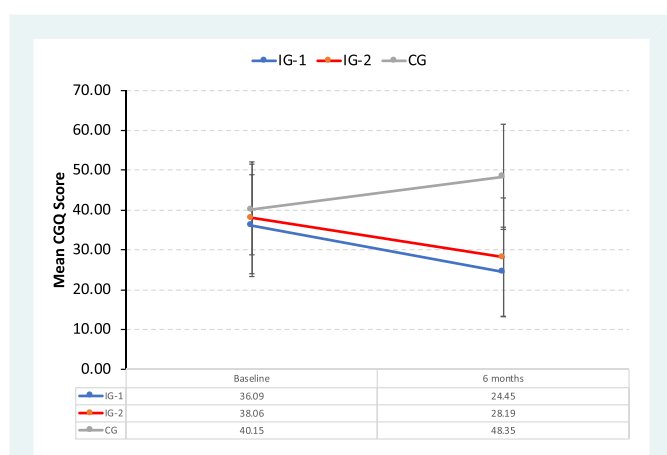


Figure 3 Total CGQ score. Effect of the educational intervention delivered by combined home visits/telephone sessions (IG-1) or telephone sessions only (IG-2) on total CGQ score over 6 months.

based arm compared to the usual care group. We have also shown a similar benefit in the telephone-based group. However, a previous study that examined a telephone-only palliative care support intervention has shown no effectiveness on several caregiver outcomes including burden, mood and QoL.²⁸ This difference could be attributed to a potentially varied effect of a remotely delivered intervention according to the point on the trajectory of HF that the targeted patient/caregiver population is positioned. For example, advanced HF patients/caregivers as the ones included in the aforementioned study may need more personalized interventions delivered through face-to-face sessions than earlier stage patients similar to our population who might also benefit from telephone or other remotely delivered interventions.

In the present study, we report for the first time to our knowledge the effect of a nurse-led HF educational intervention on caregivers' feelings of guilt. Guilt has been described as 'the dysphoric feeling associated with the recognition that one has violated a personally relevant moral or social standard'. The contribution of feelings of guilt to worse caregiver mental health has been studied in other severe chronic diseases, mostly dementia and cancer, but not in HF. Among dementia caregivers, guilt has been associated with higher rates of caregiver distress that may contribute to

the development of depression.^{31,32} The results reported herein are important for two reasons: first, because it was shown that HF caregivers experience a substantial degree of guilt, comparable at least to cancer caregivers. Second, because we have found that feelings of guilt may be reduced by a supportive educational dyadic intervention. Although our findings regarding guilt will need confirmation, they highlight the necessity to further explore mental distress of HF caregivers and the factors contributing to it including guilt and examine strategies that could alleviate it. In addition, the duration of the beneficial effects of psychoeducational interventions on HF caregiver burden and guilt should be explored in future studies, specifically addressing whether the benefit is sustained long after completion of the intervention or is observed only during the period of implementation. Further investigation is also needed to examine cost-effectiveness of nurse-led psychoeducational interventions in HF patients, as previous literature has suggested a potential cost-benefit due to reduction of HF hospitalizations.^{33,34}

Regarding the effect of educational interventions on caregiver health, a few studies have reported beneficial effects on mental health and even fewer on physical health. In our study, we have examined caregiver HR-QoL using the generic EQ-5D-3L questionnaire which primarily assesses physical HR-QoL with only one item assessing mental health. We have found a neutral effect of both intervention arms in all descriptive components of the EQ-5D questionnaire, but an improvement in the VAS component. Possible explanations for these rather neutral results on caregiver QoL might be the duration of the intervention (shorter than needed), the need to incorporate in the intervention supportive components specifically directed to caregivers and not just patient-specific educational tools or the need to assess caregivers' HR-QoL with specific instruments (e.g. the Bakas Caregiver Outcomes Scale) and not only generic ones such as the EuroQoL tool.²⁸

Our study has several limitations. First, the sample size was smaller than the intended one because the study was interrupted earlier due to COVID-19 pandemic. The small sample size might have impacted our analysis and potentially limit the generalizability of the results. Second, the premature interruption also resulted in unequal sample sizes of the study arms. However, baseline characteristics of study patients and caregivers were satisfactorily balanced except from younger age of patients and caregivers in the IG-2. However, this limitation has been addressed by the additional analysis that adjusted for caregivers' age. Third, because our study was conducted in a single HF centre of an academic hospital, results may not be generalizable everywhere. Fourth, since the majority of patients were males and their spouses had the role of their caregiver, this has resulted in the caregiver sample consisting in the majority of female subjects. This could present a gender bias, potentially limiting the generalizability of the results. Lastly, as outcomes were analysed only in caregivers who completed follow-up, this may have resulted in some selection bias.

Conclusion

We have shown that a nurse-led educational intervention in recently hospitalized HF patient/caregiver dyads, which started with a face-to-face educational session before hospital discharge and continued with either combined home visits and telephone sessions or telephone sessions only for a total duration of 6 months post-discharge, may reduce caregiver burden and feelings of guilt while it may also improve caregiver HR-QoL. Further research is needed to confirm the present results in multicentre studies that will include larger dyad samples, aiming at addressing optimal programme duration, content and methods of delivery of the educational intervention.

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Conflict of interest: V.B. reported honoraria for lectures or advisory boards from AstraZeneca, Bayer, Boehringer Ingelheim, Novartis, and Pfizer. E.L. reported honoraria from Novartis. J.P. reported honoraria for lectures from Orion Pharma, Pfizer, Servier, Astra, AOP Orphan, and Roche Diagnostics. D.F. reported lecture fees or advisory board fees from Abbott Laboratories, Bayer, Boehringer Ingelheim, Leo, Novartis, and Orion. G.F. reported honoraria from Bayer and Boehringer Ingelheim, committee membership for Medtronic, Vifor Pharma, Amgen, Servier, and Novartis, and grants from the European Commission. All other authors report no conflicts of interest.

Data availability

The data that support the findings of this study may be available from the corresponding authors, G.F. and V.B., upon reasonable request.

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