2023-03-07

Caregiver presence in a home-based cardiac rehabilitation programme improves the health-related quality of life of patients with heart failure

Noonan, Miriam

10.1093/eurjcn/zvad031
European Journal of Cardiovascular Nursing
Oxford University Press (OUP)

European Journal of Cardiovascular Nursing

Caregiver presence in a home-based cardiac rehabilitation programme improves the health-related quality of life of patients with heart failure

Authors Miriam C. Noonan[1], Julia Frost[2], Hasnain M Dalal[2,3], Rod S Taylor[4]

1. Occupational Therapy, School of Health Professions, University of Plymouth, Devon, United Kingdom

2. Institute of Health Research, University of Exeter, Devon, United Kingdom

3. Royal Cornwall Hospitals Trust, Cornwall, United Kingdom

4. Social & Public Health Institute, Institute of Health and Wellbeing, University of Glasgow, United Kingdom

Short Title: Caregiver participation in REACH-HF

Abstract

Rehabilitation Enablement in CHronic Heart Failure (REACH-HF) is a home-based cardiac rehabilitation intervention designed for patients with heart failure and their caregivers. We present a pooled analysis of patients > 18 years with a confirmed diagnosis of HF recruited to two REACH-HF randomised controlled trials. Where identified by patients and they consented to participate, caregivers were randomly assigned with patients to receive the REACH-HF intervention plus usual care or usual care alone. Our analysis demonstrated that compared to control group, the REACH-HF group had a greater gain in their disease-specific health related quality of life at follow up.

Novelty

- Involvement of caregivers (such as a family member or friend) alongside patients in a cardiac rehabilitation programme can enhance patient's gain in health-related quality of life.

- Understanding the significance of the caregiver role and the impact of including caregivers, can inform how we design and deliver interventions in heart failure.

Individuals living with heart failure (HF) frequently depend upon family or friend caregivers for support with managing their illness (1). Our 2019 meta-analysis of randomised trials indicated no additional benefit in the outcomes of patients with HF when their caregivers were formally involved in self-management interventions (2). However, our review noted the limited quality and quantity of evidence addressing the value of caregiver involvement in HF care. This research letter seeks to address this uncertainty by reporting a secondary analysis combining two randomised controlled trials (RCTs) (3,4) of a home-based cardiac rehabilitation (CR) programme on the health-related quality of life (HRQoL) of HF patients according to whether the patient was supported by a caregiver or not.

Rehabilitation Enablement in CHronic Heart Failure (REACH-HF) is a home-based CR programme delivered over 12-weeks by trained healthcare facilitators. Components of the intervention include: a Heart Failure Manual for patients, Family and Friends Resource for caregivers, progress tracker, exercise DVD, and relaxation CD. The REACH-HF intervention was evaluated in two separate trials: a multicentre trial (across 4 UK sites) that recruited 216 HF patients with reduced ejection fraction (HFrEF, left ventricular ejection fraction <45%) and a single centre pilot trial that recruited 50 HF patients with preserved ejection fraction (HFpEF, left ventricular ejection fraction ≥45%). Further details of the REACH-HF intervention and the participants and outcome findings of both trials are reported in detail elsewhere (3, 4, 5). At study entry, patients were asked to nominate if they had a caregiver, i.e., a family member or friend, who provides unpaid support. Where identified by patients and consented to participate, caregivers were randomly assigned with patients to receive the REACH-HF intervention plus usual care (REACH-HF group) or usual care alone (control group). The expectation of involving caregivers in the REACH-HF intervention was to develop knowledge about self-management in heart failure and how to maintain their own health and wellbeing and to support patients' engagement with the intervention (5).

The two trials randomised patients to receive either REACH-HF plus usual care (REACH-HF group) or usual care alone i.e., no CR and a medical management approach (control group) (3, 4) and assessed the primary outcome of the Minnesota Living with Heart Failure Questionnaire (MLwHFQ). This was assessed at baseline (pre-randomisation) and 4 and 6-months post randomisation. Pooling the individual patient MLwHFQ data across trials, we sought to address the question of whether patients (n = 266) participating in the REACH-HF intervention, achieved a better outcome when they had caregiver support (n =117). MLwHFQ scores at follow up between REACH-HF versus control groups were compared using multivariable linear regression analysis for comparison adjusting for baseline score and stratification variables (trial site & baseline plasma N-terminal proB-type natriuretic peptide levels (≤2000 vs. >2000 pg/ml), and previous atrial fibrillation/atrial flutter (as shown to be different between groups, see Table 1). To assess the impact of caregiver involvement, we incorporated an interaction term (caregiver present vs no caregiver present x REACH-HF vs control group). Separate analyses were conducted for MLwHFQ total score and MLwHFQ physical and emotional sub-scores at both 4- and 6-months follow-up. An interaction term p-value of ≤0.05 was pre-determined to indicate statistical significance.

Of the 266 HF trial participants, 117 (44%) caregivers were identified and consented to participate with the patient, 48% in the REACH-HF intervention group (63/132) and 40% in the control group (54/134). With the exception of the presence of previous atrial fibrillation/atrial flutter (41.6% vs 55.5%), there was no significant difference in the characteristics or medical history of patients with or without a caregiver. Caregivers were typically the partner (75%) of the patient and retired (68%). Compared to patients, caregivers were younger (mean 64 vs 70 years) and more likely to be female (78% vs 28%) (Table 1).

At 4-months follow-up, a greater improvement (p =0.015) in treatment effect (i.e. REACH-HF group vs control group) in HRQoL was seen in those patients with a caregiver (mean total MLwHFQ score: -12.2, 95% CI = -5.6 to -18.8) compared to patients without a caregiver (mean total MLwHFQ score: -1.9, 95% CI: 3.0 to -6.8) (Table 2). This HRQoL effect in favour of caregiver participation was also seen for both

the MLwHFQ physical and emotional sub-scores. A similar direction of effect was also seen at 6-months follow-up but not statistically significant (Table 2). A summary of patient MLwHFQ scores (total and sub-score) in REACH-HF and control group by caregiver recruitment at baseline, 4 and 6-months follow-up can be viewed as an online supplementary table and demonstrates greater improvements within the intervention group on the MLwHFQ.

Our analysis demonstrated that presence of a caregiver enhanced the HRQoL of patients participating in a CR intervention. We believe this benefit reflects both the design and delivery of the REACH-HF intervention. We included caregivers in the development of the intervention including the Family and Friends Resource and we emphasised the importance of actively involving caregivers in the facilitator training of healthcare staff (6). A key strength of our analysis is that it is based on pooled individual patient data analysis of two randomised trials of the REACH-HF home-based CR intervention in both HFrEF and HFpEF patients. However, we need to acknowledge some potential limitations of our analysis. First, this comparison of patient outcomes between those with and without an identified caregiver is effectively observational and therefore subject to bias and confounding. However, as reported above, there was little difference in characteristics of patients with and without a caregiver and we adjusted for previous atrial fibrillation/flutter (see Table 2). Second, as this is a multi-component intervention it is likely that the intervention was tailored to the needs of each patient-caregiver dyad. Third, this analysis focused on disease-specific HRQoL and not other secondary outcomes collected in the primary trials including patient's physical activity, stress and anxiety. Fourth, this analysis was not pre-specified but rather driven by the findings of our previous systematic review and meta-analysis (2). Finally, it is interesting to note that although more than a half of trial patients (149 of 266, 56%) participated with a caregiver, a substantial proportion of patients without an identified caregiver participating in the trial, were married, in a civil partnership or living with another. These later patients may therefore have received some form of caregiver support albeit without the formal context of the REACH-HF intervention. This also may indicate the need for

greater understanding amongst healthcare professionals about how caregivers can be engaged in self-management interventions.

In conclusion, our results support the value of identifying caregivers to participate in rehabilitation interventions for HF patients in the short-term. Involvement of caregivers following the COVID-19 pandemic has become even more important with growing pressures on healthcare systems to deliver self-management services as well as ongoing requirement for some patients to continue to socially distance to minimise the risk of infection limiting their access to healthcare. Further evidence from appropriately designed trials is required to confirm the benefits of involving caregivers in the development and delivery of rehabilitation and self-management interventions for HF.

Funding
The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was supported by a University of Exeter Postgraduate Studentship Grant.
The data collection for the data for the two REACH-HF trials reanalysed in this article was originally funded by was supported by the United Kingdom's National Institute for Health Research (NIHR) Programme
Grants for Applied Research (grant number RP-PG-1210-12004).

Data availability statement
The data underlying this article will be shared on reasonable request to the corresponding author.

Declaration of conflicting interests
RST was co-chief investigator for the REACH-HF trials.
RST is a member of the ACNAP Scientific Committee.

References

1. Wingham J, Frost J, Britten N, Jolly K, Greaves C, Abraham C, et al. Needs of caregivers in heart failure management: a qualitative study. Chronic Illn. 2015;11:304–319.

2. Noonan MC, Wingham J, Dalal HM, Taylor RS. Involving caregivers in self-management interventions for patients with heart failure and chronic obstructive pulmonary disease. A systematic review and meta-analysis. J Adv Nurs. 2019;75:3331-3345.

3. Dalal HM, Taylor RS, Jolly K, Davis RC, Doherty P, Miles J, et al. The effects and costs of home-based rehabilitation for heart failure with reduced ejection fraction: The REACH-HF multicentre randomized controlled trial. Eur J Prevent Cardiol. 2019;26:262-72.

4. Lang CC, Smith K, Wingham J, Eyre V, Greaves CJ, Warren FC, et al. A randomised controlled trial of a facilitated home-based rehabilitation intervention in patients with heart failure with preserved ejection fraction and their caregivers: the REACH-HFpEF Pilot Study. BMJ Open. 2018;8:e019649.

5. Wingham J, Frost J, Britten N, Greaves C, Abraham C, Warren FC, et al. Caregiver outcomes of the REACH-HF multicentre randomized controlled trial of home-based rehabilitation for heart failure with reduced ejection fraction. Eur J Cardiovasc Nurs.: 2019;18(7):611-20.

6. Greaves CJ, Wingham J, Deighan C, Doherty P, Elliott J, Armitage W, et al. Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping. Pilot feasibility stud. 2016;2:37.

1 **Table 1. Characteristics of patients by caregiver recruitment**

Patients (n = 266)	**Patient without a caregiver recruited n (%) N = 149**	**Patient with a caregiver recruited n (%) N = 117**	**P-value**	**Total** N=266
Gender n (%)				
Male	109 (73.1)	83 (70.9)	0.149	192 (72.18)
Age (years) Mean (SD)	70.6 (10.9)	70.6 (10.1)	0.475	70.56 (0.65)
Ethnic group: white	138 (92.6)	116 (99.1)	0.492	254 (95.49)
Relationship status n (%)			0.639	
Single	22 (14.7)	9 (7.6)		31 (11.65)
Civil partnership	2 (1.3)	1 (0.8)		3 (1.13)
Widowed/surviving civil partner	35 (23.4)	11 (9.4)		46 (17.29)
Married	74 (49.6)	92 (78.6)		166 (62.41)
Divorced/civil partnership dissolved	16 (10.7)	4 (3.4)		20 (7.52)
Domestic residence n (%)				
Lives alone	58 (38.9)	15 (12.8)	0.832	73 (27.44)
Live with another	91 (61)	102 (87.1)		193 (72.56)
HFpEF diagnosis n (%)	25 (18.94)	25 (18.66)	0.953	50 (18.80)
NYHA Status:			0.621	
NYHA I	26 (17.4)	19 (16.2)		45 (16.92)
NYHA II	92 (61.7)	65 (55.5)		157 (59.02)
NYHA III	30 (20.1)	33 (28.2)		63 (23.68)
NYHA IV	1 (0.6)	-		1 (0.38)
Cause of heart failure* n (%)			0.283	
Ischaemic	64 (42.9)	58 (49.5)		122 (45.86)
Non-ischaemic	71 (47.6)	55 (47)		126 (47.37)
Unknown	5 (3.3)	3 (2.5)		8 (3.01)
Not Classified	9 (6)	1 (0.8)		10 (3.76)
Number of comorbidities n (%)			0.667	
0	82 (55)	56 (47.8)		138 (51.88)
1	45 (30.2)	45 (38.4)		90 (33.83)
2	14 (9.4)	12 (10.2)		26 (9.77)
3	8 (5.3)	2 (1.7)		10 (3.76)
4	-	2 (1.7)		2 (0.75)

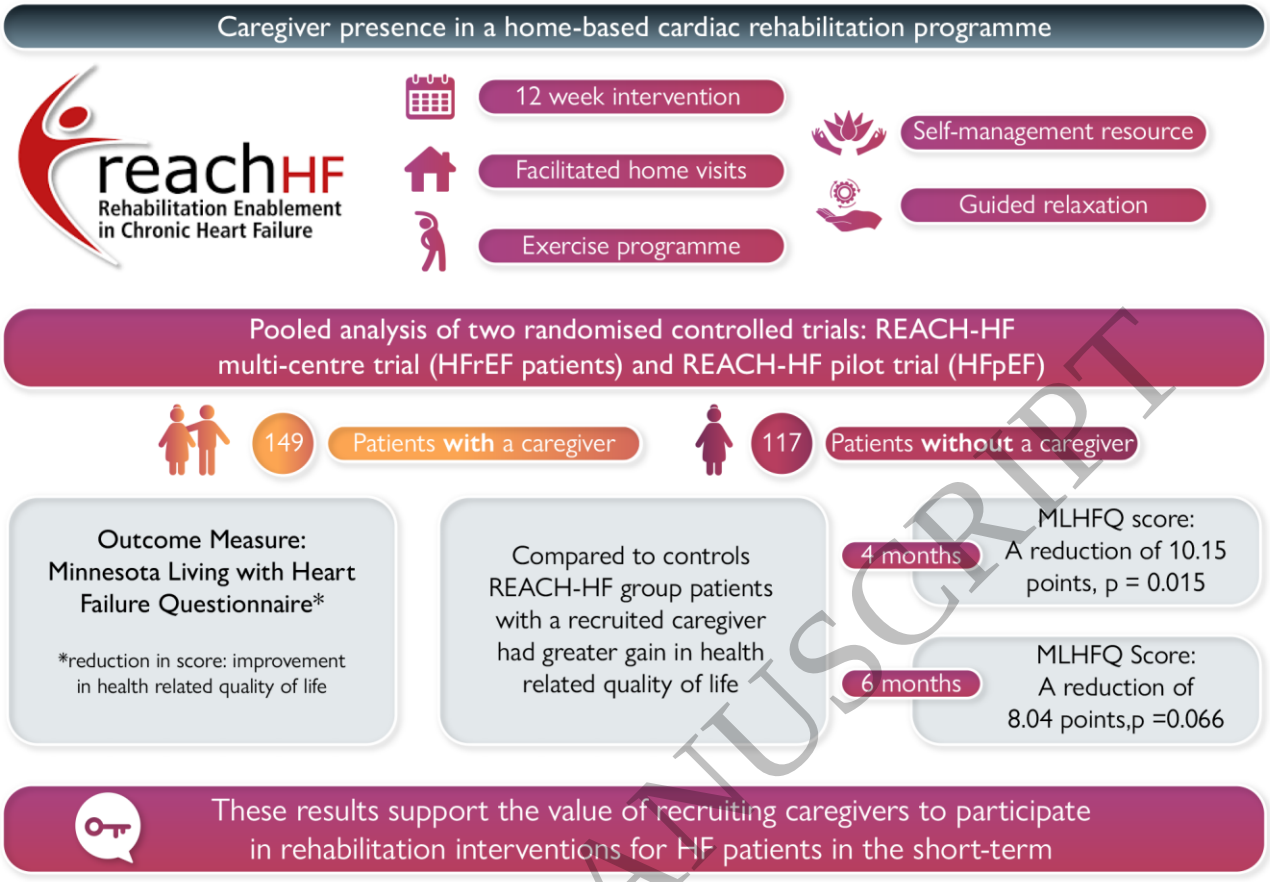
Previous myocardial infarction	34 (22.8)	42 (35.9)	0.202	76 (28.57)
Previous atrial fibrillation/atrial flutter	62 (41.6)	65 (55.5)	**0.026***	127 (47.74)
Hypertension	64 (42.9)	55 (47)	0.332	119 (44.74)
Diabetes mellitus	45 (30.2)	30 (25.6)	0.628	75 (28.20)
Chronic renal impairment	27 (18.1)	19 (16.2)	0.320	46 (17.29)
Time since diagnosis of heart failure (years)			0.941	
<1	40 (26.8)	33 (28.2)		79 (29.69)
1 to 2	30 (20.1)	18 (15.3)		48 (18.04)
>2	70 (53)	66 (56.4)		136 (51.12)
Main activity n (%)			0.808	
In employment or self-employment	26 (17.4)	11 (9.4)		37 (13.91)
Unemployed	5 (3.4)	5 (4.3)		10 (3.76)
Unpaid Occupation (carer, housework, student)	1 (0.7)	1 (0.8)		2 (0.75)
Retired (medical/disability/age)	117 (78.5)	100 (85.5)		217 (81.58)
Education n (%)				
Post-school	68 (45.6)	59 (50.4)	0.459	127 (47.74)
Degree	36 (24.2)	35 (29.9)	0.372	71 (26.69)
Pro-BNP levels n(%)				
≤2000 pg/mL	120 (80.5)	95 (81.2)	0.923	215 (80.83)
>2000 pg/mL	29 (19.5)	22 (18.8)	0.923	51 (19.17)

*significant difference between patients without a caregiver and patients with a caregiver

Table 2 Comparison of REACH-HF vs control group treatment effect on MLwHFQ score in patients without and with a caregiver

	REACH-HF vs control group treatment effect* Mean (95% CI) N patients		Interaction** Mean (95% CI) N, p-value
	Without a caregiver	**With a caregiver**	
	4-months follow up		
MLwHFQ Total	-1.9 (3.0 to -6.8) 132	-12.2 (-5.6 to -18.8) 108	-10.15 (-2.01 to -18.30) 240, 0.015
MLwHFQ Physical	-0.9 (1.4 to -3.4) 133	-6.0 (-3.0 to -9.0) 108	-4.79 (-0.95 to -8.63) 241, 0.015
MLwHFQ Emotional	-0.5 (1.0 to -2.0) 133	-3.7 (-1.6 to -5.7) 108	-3.28 (-0.73 to -5.83) 241, 0.012
	6-months follow up		
MLwHFQ Total	-0.1 (5.5 to -5.8), 122	-10.7 (-4.1 to -17.2), 105	-8.04 (0.54 to -16.64) 227, 0.066
MLwHFQ Physical	0.4 (3.4 to -2.6) 123	-4.3 (-1.1 to -7.5) 105	-3.33 (1.01 to -7.67) 228, 0.132
MLwHFQ Emotional	-0.3 (1.3 to -2.1), 123	-3.0 (-0.9 to -5.2) 105	-2.04 (0.69 to -4.77) 228, p = 0.142

*REACH-HF vs control group difference adjusted for MLwHFQ baseline score and stratification variables (trial site & baseline plasma N-terminal proB-type natriuretic peptide levels (≤2000 vs. >2000 pg/ml), and adjusted for atrial fibrillation/atrial flutter.
**interaction effect and P-value is the comparison of treatment effect (i.e. REACH group vs control group) of patients with a recruited caregiver vs. patients with no caregiver.
Note: the lower the MLwHFQ score the higher the HRQoL



Graphical Abstarct
180x120 mm (.43 x DPI)