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

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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

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

7 Our analysis demonstrated that presence of a caregiver enhanced the HRQoL of
8 patients participating in a CR intervention. We believe this benefit reflects both the
9 design and delivery of the REACH-HF intervention. We included caregivers in the
10 development of the intervention including the Family and Friends Resource and we
11 emphasised the importance of actively involving caregivers in the facilitator training of
12 healthcare staff (6). A key strength of our analysis is that it is based on pooled individual
13 patient data analysis of two randomised trials of the REACH-HF home-based CR
14 intervention in both HFrEF and HFpEF patients. However, we need to acknowledge
15 some potential limitations of our analysis. First, this comparison of patient outcomes
16 between those with and without an identified caregiver is effectively observational and
17 therefore subject to bias and confounding. However, as reported above, there was little
18 difference in characteristics of patients with and without a caregiver and we adjusted for
19 previous atrial fibrillation/flutter (see Table 2). Second, as this is a multi-component
20 intervention it is likely that the intervention was tailored to the needs of each patient-
21 caregiver dyad. Third, this analysis focused on disease-specific HRQoL and not other
22 secondary outcomes collected in the primary trials including patient's physical activity,
23 stress and anxiety. Fourth, this analysis was not pre-specified but rather driven by the
24 findings of our previous systematic review and meta-analysis (2). Finally, it is interesting
25 to note that although more than a half of trial patients (149 of 266, 56%) participated
26 with a caregiver, a substantial proportion of patients without an identified caregiver
27 participating in the trial, were married, in a civil partnership or living with another. These
28 later patients may therefore have received some form of caregiver support albeit without
29 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.

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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.

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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 |
|-------------------------|---|----------------------------|---|
| | <u>Without a caregiver</u> | <u>With a caregiver</u> | |
| | 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

Caregiver presence in a home-based cardiac rehabilitation programme



12 week intervention



Facilitated home visits



Exercise programme



Self-management resource



Guided relaxation

Pooled analysis of two randomised controlled trials: REACH-HF multi-centre trial (HFrEF patients) and REACH-HF pilot trial (HFpEF)



149

Patients **with** a caregiver



117

Patients **without** a caregiver

Outcome Measure:
Minnesota Living with Heart
Failure Questionnaire*

*reduction in score: improvement
in health related quality of life

Compared to controls
REACH-HF group patients
with a recruited caregiver
had greater gain in health
related quality of life

4 months

MLHFQ score:
A reduction of 10.15
points, $p = 0.015$

6 months

MLHFQ Score:
A reduction of
8.04 points, $p = 0.066$



These results support the value of recruiting caregivers to participate
in rehabilitation interventions for HF patients in the short-term

Graphical Abstract
180x120 mm (.43 x DPI)