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Publication date:
2021

Link:
[Link to publication in PEARL](#)

Citation for published version (APA):

Noonan, M., Frost, J., & Taylor, R. (in press). *Involving unpaid carers in a home-based self-management intervention for patients living with heart failure (REACH-HF): a quantitative analysis of the impact on patient and carer outcomes. 18th WFOT Congress, Paris 28-21 August 2022*. Paper presented at World Federation of Occupational Therapists.

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Involving unpaid carers in a home-based self-management intervention for patients living with heart failure (REACH-HF): a quantitative analysis of the impact on patient and carer outcomes

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Individuals living with heart failure (HF) frequently depend upon family or friend carers for support with HF self-management. A meta-analysis conducted in 2019 indicated no improvement in the outcomes of patients with HF when their carer was involved in self-management interventions (1). This research sought to address this uncertainty with a secondary analysis combining two randomised controlled trials (RCTs) of a home-based self-management intervention: REACH-HF.

The aim of this pooled analysis was to ascertain the following:

- 1) Does the involvement of a carer improve health related quality of life (HRQoL) of patients receiving the REACH-HF intervention.
- 2) What is the impact of the REACH-HF intervention on carer outcomes?
- 3) What are the predictors of baseline HRQoL on carer outcomes measures for carers of HF patients receiving the REACH-HF intervention?

Rehabilitation Enablement in CHronic Heart Failure (REACH-HF) is a home-based intervention programme delivered over 12-weeks by trained healthcare facilitators. Intervention components include: a Heart Failure manual, a Family and Friends Resources, a Progress Tracker, exercise DVD and a relaxation CD (**Figure 1**).



Figure 1 REACH-HF intervention components

At study entry, patients were asked to nominate if they had a carer (spouse, relative or friend), who provides unpaid support. Carers were allocated to intervention or control in accord with the random allocation of the patient. Both trials were randomised to receive the REACH-HF plus usual care (REACH-HF group) or usual care alone (control group) with primary outcome data on the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) and carer outcomes assessed at baseline (pre-randomisation) and 4 and 6-months post randomisation. Further details of the REACH-HF trials are reported in detail elsewhere (2,3,4).

In this pooled analysis, of the 266 HF trial participants, 117 (44%) involved a carer, 48% of the REACH-HF intervention group (63/132) and 40% of the control group (54/134). With the exception of the presence of atrial fibrillation (41.6% vs 55.5%), there was no statistically significant difference in the characteristics or medical history of patients with or without a carer. Carers were typically the partner (75%) of the patient and retired (68%). Compared to patients, carers were younger (mean 64 vs 70 years) and more likely to be female (78% vs 28%).

Question 1: Do patients participating in the REACH-HF intervention, achieved a better HRQoL outcome when they had a carer involved in intervention delivery?

We used multivariable linear regression analysis to compare MLwHFQ scores at follow up adjusting for trial site & baseline plasma N-terminal proB-type natriuretic peptide levels (≤ 2000 vs. >2000 pg/ml) & atrial fibrillation. To assess the impact of carer involvement, secondary analysis incorporated an interaction term (carer present vs no carer present x REACH-HF vs control group) to this regression model. 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.

At 4-months follow-up, greater improvement was seen in the mean total MLwHFQ score with the REACH-HF intervention in patients with a carer (-12.2, 95% CI = -5.6 to -18.8) than without (-1.9, 95% CI: 3.0 to -6.8) with evidence of an interaction effect (-10.15, 95% CI: -2.01 to -18.30, $p = 0.015$). An interaction effect in favour of carer involvement was also seen for both the MLwHFQ physical (-4.79, -0.95 to -8.63, $p = 0.015$) and emotional sub-scores (-3.28, 95% CI: -0.73 to -5.83, $p = 0.012$). The trend was not statistically significant at 6-months follow-up (**Table 1**).

Table 1 Comparison of REACH-HF vs control group treatment effect on MLwHFQ score in patients with and without a carer

	REACH-HF vs control group treatment effect*		Interaction Mean (95% CI) N, p-value
	<u>Without a carer</u>	<u>With a carer</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, $p = 0.142$

*between group difference adjusted for baseline score and stratification variables (trial site & baseline plasma N-terminal proB-type natriuretic peptide levels (≤ 2000 vs. >2000 pg/ml), atrial fibrillation)

Question 2 What is the impact of the REACH-HF intervention on carer outcomes (Table 2)?

Baseline characteristics of patients and carers in REACH-HF vs control groups were compared using t-tests for continuous variables and chi-square analyses for binary variables.

At 6 months follow-up REACH-HF demonstrated a statistically significant impact on:

Anxiety (HADS) (-0.9 point reduction, $p = 0.036$)

Social burden (CBQ) (-0.6 point reduction, $p = 0.038$)

Lifestyle burden (CBQ) (-1.7 point reduction, $p = 0.001$)

However, overall carer outcomes (**Table 2**) were inconsistent at 4 and 6 months follow-up.

Table 2 Carer Outcome Measures

Hospital Anxiety and Depression Scale (HADS)	Higher scores = Higher anxiety and Depression
Family Quality of Life Scale (FAMQoL)	Higher scores = Better quality of life
EQ-5D-5L	Higher scores = Better quality of life
Caregiver burden questionnaire (CBQ)	Higher scores = Increased burden

Question 3: What are the predictors of baseline HRQoL on carer outcome measures (Table 2) for carers of HF patients receiving the REACH-HF intervention?

Multivariate regression analysis was conducted adjusting for baseline patient and carer characteristics identified as potential confounders:

(NYHA, years of diagnosis, comorbidities, trial (HFPEF or HFREF), age, gender, main daily activity (employed, unemployed or unpaid occupation) continued education (beyond minimum school leaving age of 16), educated to degree level (or equivalent professional qualification), living alone).

Patient NYHA status was a predictor of carer anxiety, quality of life and burden ($p < 0.05$).

Carers of patients with a higher NYHA status (i.e. increasing illness severity) scored:

- A mean of 1.5 points higher on the **anxiety** subsection of the HADS scale (1.5, -0.3 to 2.6, $p = 0.013$)
- A mean of 4.6 points less on the **FAMQoL** overall (-4.6, -7.4 to 1.8, $p = 0.002$)
- A mean of -0.1 points less on the **EQ5D5L** (-0.1, -0.1 to 0.0, $p = 0.002$).
- A mean increase of 5.9 (emotional burden), 0.5 (social burden) and 1.3 (lifestyle burden) on the **CBQ**

Conclusion

Our results support the value of actively engaging carers in self-management interventions for HF patients. Involvement of carers with the COVID-19 pandemic has become even more important as HF patients may be required to socially distance to minimise the risk of infection limiting their access to healthcare.

Understanding the impact of carers in their role, and the needs of carers, in particular, carers of patients with increasing illness severity is imperative. Occupational Therapists are well placed to advocate for carers, identify their needs and promote carer health and wellbeing. Further evidence is required to confirm the benefits of actively involving carers in the development and delivery of rehabilitation and self-management interventions for HF.

Funding Acknowledgements

This research was conducted as part of a PhD studentship funded by University of Exeter

The REACH-HF trial was funded by the National Institute of Health and Research (Reference Number RP-PG-1210-12004)

With thanks to Elizabeth Casson Trust and University of Plymouth who have funded attendance at WFOT

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