Home-based cardiac rehabilitation for people with heart failure and their caregivers: a mixed-methods analysis of the roll out an evidence-based programme in Scotland (SCOT:REACH-HF study)

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Home-based cardiac rehabilitation for people with heart failure and their caregivers: a mixed-methods analysis of the roll out an evidence-based programme in Scotland (SCOT:REACH-HF study)

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ABSTRACT [250 words]

Aims:

Alternative models of cardiac rehabilitation (CR) are required to improve CR access and uptake. Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) is a comprehensive home-based rehabilitation and self-management programme, facilitated by trained health professionals, for people with heart failure (HF) and their caregivers. REACH-HF was shown to be clinically effective and cost-effective in a multicentre randomised trial. The SCOT:REACH-HF study assessed implementation of REACH-HF in routine clinical practice in NHS Scotland.

Methods & results:

A mixed-method implementation study was conducted across six regional Health Boards. Of 136 people with HF and 56 caregivers recruited, 101 people with HF and 26 caregivers provided four-month follow-up data, after participating in the 12-week programme. Compared with baseline, REACH-HF participation resulted in substantial gains in the primary outcome of health-related quality of life, as assessed by the Minnesota Living with Heart Failure Questionnaire (mean difference: -9.8, 95% CI: -13.2 to -6.4, P<0.001). Improvements were also seen in secondary outcomes (PROM-CR+; EQ-5D-5L; Self-Care of Heart Failure Index (SCHFI) domains of maintenance and symptom perception; Caregiver Contribution to Self-Care (CC-SCHFI) domains of symptom perception and management).

Twenty qualitative interviews were conducted with 11 REACH-HF facilitators, five supporting clinicians, and four national stakeholders. Interviewees were largely positive about REACH-HF,

considering it to have 'filled a gap' where centre-based CR was not an option. Key issues to support future roll-out were also identified.

Conclusion:
Our findings support wider roll-out of REACH-HF as an alternative to centre-based models, to improve CR access and uptake for people with HF.

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Keywords:
Heart failure, cardiac rehabilitation, self-management, home-based programme, caregivers, implementation study

Novelty

- Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) is a comprehensive home-based rehabilitation and self-care support programme, co-developed with key stakeholders, and drawing on relevant evidence and behaviour change theory.
- The present study uniquely provides a formal mixed-method evaluation of the implementation of REACH-HF, following demonstration of its clinical and cost-effectiveness in a recent randomised controlled trial.
- Our results show that adaptation to REACH-HF necessitated by the COVID-19 pandemic did not appear to reduce the effectiveness of the programme.
- Our findings support wider roll-out of the REACH-HF home-based programme as an alternative to traditional centre-based models of cardiac rehabilitation, which can improve rehabilitation access and uptake for people with HF and their families.

INTRODUCTION

Meta-analyses of randomised controlled trials (RCTs) show that participation in cardiac rehabilitation (CR) by people with heart failure (HF) reduces their risk of hospital admission, and results in important gains in health-related quality of life (HRQoL).[1,2] Despite these benefits - and national and international clinical guidelines consistently recommending that those living with stable, chronic HF should receive CR - access to and participation in CR remains poor.[3] While barriers to CR access are complex and interacting, they can be summarised as operating at three levels: health systems (e.g. limited funding or facilities); clinicians (e.g. lack of referral); and patients (e.g. issues with transport, convenience, conflicts with return to work).[3-5] Furthermore, some patient groups are at lower likelihood of participating in CR, including older people, those living in greater social deprivation, and people from minority ethnic groups.[5]

A key potential solution to improving CR access is more innovative, diverse models of delivery. The dominant mode of CR since its inception 50 years ago has been centre-based, typically supervised group classes delivered in a hospital outpatient setting, and focused on exercise training.[6,7] The coronavirus disease-19 (COVID-19) pandemic - and associated challenges of effectively delivering rehabilitation while following guidance on social distancing and shielding - has foregrounded the need to reframe traditional CR delivery. Calls have particularly focused on inclusion of home-based programmes, as well as use of wearable technology, and interactive online or hybrid programmes that combine centre- and home-based modes.[8] With evidence that benefits in patient-reported outcomes in home-based programmes are similar to those seen in centre-based CR,[9] leading medical bodies have advocated for this model.[10] There nevertheless remain questions around the capacity of clinical teams and responsiveness of healthcare systems to more innovative models of CR.

We sought to explore this issue in the case of the Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) intervention. REACH-HF is a comprehensive home-based rehabilitation and self-care support programme, co-developed with key stakeholders, and based on relevant evidence and behaviour change theory.[11] A multi-centre randomised trial in 216 people with

reduced ejection fraction HF (HFrEF), and their informal caregivers, found that, compared to usual care alone, participation in REACH-HF improved disease-specific HRQoL at 12-month follow-up - as measured by the Minnesota Living with Heart Failure Questionnaire (MLHF) - by a mean total score of -5.7 points (95% confidence interval: -10.6 to -0.7).[12] REACH-HF was also found to be a relatively low-cost intervention (sterling £417 per patient), and economic modelling based on the trial results showed it also be highly cost effective, with an average cost per quality adjusted life-year (QALY) of £1720 per patient.[13]

The SCOT:REACH-HF study was designed to generate understanding of organisational influences that shape implementation of REACH-HF for people living with HFrEF and their caregivers in Scotland, in order to inform potential scaled roll-out. Our specific research questions were: (1) How do 'real-world' patient and caregiver outcomes and REACH-HF costs compare with those seen in the randomised trial?; and (2) What are the service-level facilitators of and barriers to implementation of REACH-HF?

METHODS

Design and setting

We employed a mixed-method, single arm, pre-post design, collecting both quantitative and qualitative data, and drawing on UK Medical Research Council (MRC) guidance on evaluation of complex interventions.[14,15]

CR services in six (of a total of 14) NHS Scotland regional Health Boards were included as early adopter sites: NHS Ayrshire and Arran; NHS Lanarkshire; NHS Forth Valley; and NHS Highland, Orkney, and Shetland (the latter three were combined due to small patient numbers). NHS Greater Glasgow and Clyde sponsored the study, and the West of Scotland Research Ethics Service (20/WS/0038) gave ethical approval. Written informed consent was obtained from all participants.

Study population

Using existing CR referral pathways, sites recruited people who had a confirmed diagnosis of HFrEF.[14] At study entry, the person with HF was asked to nominate a friend or family member to participate as a 'caregiver' (that is, a spouse, relative, or friend who typically provided them with unpaid support).

REACH-HF intervention

A detailed account of the REACH-HF intervention has been described elsewhere,[11] and intervention components are summarised in Figure 1. As SCOT:REACH-HF was conducted during COVID-19 pandemic restrictions, several adaptations to the REACH-HF model were necessary to enable intervention delivery. These included: switching from a three-day in-person facilitator training course to a two-day online format that included a combination of pre-recorded and live presentations, and interactive sessions, hosted on Zoom; intervention adaptation to allow fully remote delivery (namely telephone or online facilitation), if face-to-face contact with the facilitator in the home or clinic was not possible. All adaptations were made in collaboration with the central REACH-HF team and our Patient and Public Involvement group. Participants with HF continued to receive 'usual' medical care, according to local and national guidelines.

Data collection

Three categories of data were collected: (a) participant (patient and caregiver) reported outcomes at baseline (pre-intervention) and four-month follow-up (post-12-week facilitated intervention period) [RQ1]; (b) economic data to allow quantification of the cost of the REACH-HF intervention to NHS Scotland [RQ1]; and (c) interviews with REACH-HF facilitators, supporting teams, and key stakeholders [RQ2]. COVID-19 restrictions also had implications for data collection: as participants completed questionnaires by post, or online via a secure web portal (rather than at clinic as initially planned).[7] It was also not possible to assess exercise capacity (incremental shuttle walk test), since lockdown measures meant participants were largely unable to attend, and services were unable to hold, research visits in a clinical setting.

Outcomes for people with HF: Sociodemographic and medical history data were collected by clinical teams from medical notes and from people with heart failure via self-complete questionnaires. Our primary outcome was disease-specific HRQoL (Minnesota Living with Heart Failure questionnaire (MLHF)).[16] Secondary outcomes included: CR-specific HRQoL (modified PROM-CR+),[17] generic HRQoL (EQ-5D-5L),[18] psychological wellbeing (Hospital Anxiety and Depression Scale (HADS)),[19] HF self-management (Self-Care in Heart Failure Index (SCHFI)),[20] and health literacy (selected sub-scales of the Health Literacy Questionnaire (HLQ)).[21] Serious adverse events (SAEs) were recorded and assessed for relatedness to the intervention. Adverse events were regarded as 'serious' if they resulted in death, were life threatening, or required hospitalisation.

Outcomes for caregivers: Generic HRQoL (EQ-5D-5L), caregiver-specific HRQoL (Family Caregiver Quality of Life Scale (FAMQoL)),[22] caregiver contribution to HF self-management (CC-SCHFI),[23] psychological well-being (HADS), and caregiver burden (Caregiver Burden Questionnaire for Heart Failure (CBQ-HF).[24] Self-reported demographic data were also collected from caregivers at baseline.

Economic data: To allow costs analysis, key implementation data were collated, including costs of training facilitators, REACH-HF consumables (such as REACH-HF manuals, DVDs), and facilitator time spent on delivering the 12-week intervention. Training coordinators (Heart Manual Department, NHS Lothian) provided teaching faculty, administration, and material costs (including REACH-HF manuals). Facilitator time was captured via self-completion logs recording the number, duration, and format (home/phone call/clinic) of every participant contact. Unit costs were applied for staff time using standard national sources.[25]

Interviews: All trained facilitators were invited to take part in a qualitative interview focused on organisational-level barriers to and facilitators of implementation. Further purposive sampling recruited supporting team members (senior clinicians) and, to provide high-level contextual data, interviews were also conducted with four key stakeholders. Normalisation Process Theory

(NPT)[26] was used as a theoretical framework to guide data production (full analysis applying NPT will be presented in a subsequent publication). All interviews were conducted by telephone, audio-recorded, transcribed verbatim and pseudonymised for analysis.

Data Analysis

Pre-specified statistical and qualitative analysis plans were developed and finalised prior to commencing data analysis.

Participant-reported outcomes: We estimated that we needed to enrol 130 people with HF to detect a pre-post change (based on MLHF total score standard deviation of 24 points, within-patient pre-post correlation (r=0.72), and attrition rate of ≤10% as seen in the randomised trial).[12] Patient and caregiver outcomes at baseline and four-month follow-up are reported descriptively. The focus of inferential analysis was a within-participant paired comparison of outcomes at baseline and four months, for those who completed follow-up. Differences are reported as mean differences, 95% confidence intervals, and P-values (P≤0.05 indicating statistical significance). We examined whether there were differences in characteristics and outcomes of participants who did not complete follow-up. Sensitivity analysis was undertaken to assess any impact where follow-up was completed outwith ±1-months window around the four-month follow-up. Statistical analysis was conducted by AP using R (R Core Team (2017), R Foundation for Statistical Computing, Vienna, Austria).

Economic analysis: An average REACH-HF programme cost per patient was calculated by totalling costs of delivering training and facilitator time, and dividing that figure by the total number of people with HF who started on the REACH-HF programme during the study. Costs are reported in pounds sterling (£) for 2021.

Qualitative interviews: Analysis was undertaken by CP using NVivo 12 software (QSR International Pty Ltd. (2020), Melbourne, Australia) to facilitate data management, and taking an approach informed by the Framework method.[27] Combining inductive and deductive

elements, a coding framework was developed based on relevant literature, learning from the REACH-HF randomised trial,[12] and on the key research questions, while also allowing for emergence of unanticipated issues. Following an initial categorising stage, a further interpretive stage explored commonalities, differences, and comparison across sites. This facilitated understanding of contextual factors shaping implementation and development of potential explanations for aspects of our quantitative results.

Public and Patient involvement

A patient and public involvement (PPI) group of 14 patients and caregivers, chaired by TI, was established to provide direction to the research team. The group met remotely on five occasions over the study duration, and its activities included: review of all participant-facing documents; advice on recruitment strategies; review of outcome and interview data; and guidance on dissemination plans.

RESULTS

Study recruitment and sample

Between 4th March and 22nd October 2021, a total of 136 HF people with heart failure and 56 caregivers were recruited (221 eligible people having been initially approached about participating in the study). Of these, 124 patients and 46 caregivers (91% and 82%, respectively, of those initially consenting) provided baseline data. 101 patients and 26 caregivers (81% and 57%, respectively, of those completing baseline assessment) completed four-month follow-up at the end of the 12-week programme (see Figure 2 & Supplementary File A).

Participant baseline characteristics

Most participants with HF were men (72%), NYHA class II-III (94%), with a mean age of 68 years, and left ventricular ejection fraction of 31% (see Table 1). Co-morbidities included atrial fibrillation (48%), hypertension (48%), and myocardial infarction (34%). Pharmacological therapy for HF included angiotensin-converting enzyme (ACE) inhibitor (36%), aldosterone receptor antagonist (MRA) (69%), beta blockers (90%), angiotensin receptor II blocker neprilysin

inhibitor (ARNI) (57%), sodium-glucose co-transporter 2 (SGLT-2) inhibitor (42%), and loop diuretics (69%). Caregivers were typically the spouse/partner (65%), predominantly women (76%), with a mean age of 62 years (see Supplementary file B). All participants were of white ethnicity.

REACH-HF delivery

Facilitator logs of REACH-HF contacts were returned for 104 participants. Patients had a median of five contacts with their facilitator, with a median total contact time of four hours and 50 minutes. There was evidence of some variation in contacts across study sites (see Supplementary File C). Only two sites were able to provide any home-based face-to-face REACH-HF contacts, with face-to-face contacts in other sites taking place at clinic.

Outcomes for people with HF

At four-month follow-up, MLHF total scores improved compared to baseline (mean within-group difference of -9.8 (95% CI: -13.2 to -6.4, P<0.0001, Table 2)), with 62 of 98 participants (63%) having a change that met the minimally important clinical difference of ≥5 points (). Figure 3 shows a negative relationship between individual patients' total MLHF baseline scores and the magnitude of reduction in pre-post MLHF scores (Pearson's correlation coefficient, -0.40, P<0.0001). That is to say, participants with the poorest HRQoL at baseline experienced the largest HRQoL gains with REACH-HF. Although there was some variation in the average magnitude of the improvement in in total MLHF scores across the four study sites, after adjustment for patient baseline MLHF score, these across-site differences were not found to be statistically significant (P=0.40, data not presented). Both physical and emotional MLHF component scores improved. A sensitivity analysis limited to those 74 patients who were assessed within the ±1-month window at follow-up showed a similar inference in pre-post comparisons of MLHF total scores (-10.5, 95%CI: -14.1 to -6.9, p-value < 0.0001).

Pre-post improvements (P≤0.05) were also observed for: the EQ-5D-5L; SCHFI self-care maintenance and symptom perception sub-scales; HLQ 'actively managing my health' sub-scale; and all PROM-CR+ sub-scales. Non-significant improvement (P>0.05) was seen in: the SCHFI

self-care management sub-scale; three HLQ sub-scales ('feeling understood and supported by healthcare providers', 'ability to actively engage with healthcare providers', 'understand health information enough to know what do to'); or in the HADS depression and anxiety sub-scales.

There was no significant difference (P>0.05) in the demographics, medical history, or baseline outcome scores of withdrawals compared with those who completed follow-up, with the exception that people with HF who withdrew were less likely to report having a degree or equivalent education (30% vs. 44%), less likely to have received ACE inhibitors (43% vs. 69%) and reported higher depression scores (mean HADS-D 8.6 vs. 6.3).

Four participants experienced SAEs in the 4-month follow-up period, all of which comprised hospital admissions (for lethargy, epistaxis, chest pain/dyspnoea, and pacemaker removal). All SAEs were reported to the project management and advisory groups. None were judged to be REACH-HF related. There were no deaths during the study.

Outcomes for caregivers

Although there was a trend to benefit for several caregiver outcomes (see Supplementary file D), this was only statistically significant for the CC-SCHFI management and symptom perception sub-scores. Caregivers who withdrew compared to those with complete follow up were more likely to be male (50% vs. 4%) and reported higher levels of depression (mean HADS-D 6.5 vs.3.5).

REACH-HF costs

Including facilitator training, REACH-HF material costs, and average facilitator total REACH-HF delivery time, the average cost for delivery of the REACH-HF intervention was estimated at £397.22 per patient (see Table 3).

Qualitative interviews

Semi-structured interviews were conducted with 11 trained REACH-HF facilitators (three cardiac physiotherapists, three heart failure and five cardiology specialist nurses), five

supporting senior clinicians (three consultant/lead cardiology nurses, two consultant cardiologists), and four national stakeholders (with clinical backgrounds and current strategic national roles relating to policy, service delivery and workforce development). Analysis highlighted general views on REACH-HF, and key barriers to and facilitators of implementation. The narrative summary of these themes presented below is supported by illustrative quotes in Supplementary File E.

General views on REACH-HF

Interviewees were broadly positive about the programme, with around half expressing fully positive views, and half describing positive views mixed with some reservations or negative experiences. Facilitators highlighted the "educational" benefit to their own practice, and perceived value for patients who were otherwise being "missed". Less positive experiences predominantly related to: the pandemic context and associated work pressures; familiarity with their work role; and reservations about capacity when already under-resourced services returned to 'normal'.

Barriers to implementation

The online facilitator training was viewed as adequate while no alternative was possible, but most said the online format reduced opportunities for interaction and network-building to support future implementation, and that face-to-face was preferable. The time required for one-to-one facilitation – versus group CR, which had been the norm in all services – was seen as a potential barrier. While not insurmountable, this was presented as requiring a shift in thinking and re-allocation of resources. There was also a general view that HF nurses' already challenging caseload was further strained by the pandemic, meaning they may not be best placed to deliver the programme.

The programme's suitability was perceived as uncertain for some patients, particularly those with a longer history of HF, and younger participants (some of whom reportedly found the exercise programmes insufficiently challenging). Interviewees expressed concerns with "targeting the right patients", and timing introduction of the programme appropriately.

Technological constraints included lack of access to DVD players and limited confidence using the internet. Some described an initial view of the programme as "all exercise", as opposed to the broader goal of self-management. Some interviewees felt this may have acted as a barrier to recruitment and indicated that it took some time to grasp REACH-HF's "actual purpose".

Facilitators of implementation

Factors appearing to aid implementation included: support and collaboration; familiarity with self-management; and perceptions of the programme's value and fit.

Clear lines of support and opportunities for collaboration within and across heart failure and cardiac rehabilitation teams were described alongside positive experiences of implementation. Familiarity with existing self-management programmes was noted by several interviewees as having supported their adaptation to REACH-HF; while, conversely, the facilitators who described the most negative experience of implementation also described negative experiences with other self-management programmes. Having at least some face-to-face interaction with patients was also commonly described as highly valuable to facilitators and beneficial to patients.

Perceptions of the programme's fit with service's ethos appeared to support implementation. The programme was seen as valuable because it was viewed as an opportunity both for individual professional and broader service development, which would in turn benefit patients. Perceptions of REACH-HF as offering value for money and adding value to existing practice were especially evident at two sites that had already committed to continuing with the programme at the time of the interviews.

'Background noise'

The COVID-19 pandemic had created "huge upheaval" across sites prior to and during implementation. Interviewees expressed frustration at its impact on CR services, and concerns around the pandemic's impact on their patients. Because no services were functioning as 'normal', some found it challenging to say exactly how REACH-HF might fit into routine practice. However, it was felt that REACH-HF had "filled a gap" for patients unable to participate in

centre-based CR, and the pandemic was seen by some as an opportunity to re-imagine both CR and HF care.

DISCUSSION

The SCOT:REACH-HF study assessed implementation of the REACH-HF home-based cardiac rehabilitation programme in routine clinical practice across NHS Scotland. Our findings demonstrate that participation in REACH-HF resulted in substantial gains in HRQoL as assessed by patient-reported disease-specific (MLHF), CR-specific (PROM-CR+), and generic (EQ-5D-5L) measures – and in HF self-care management. The pattern and magnitude of gains in patient-reported outcomes in SCOT:REACH-HF are consistent with those seen in the REACH-HF trial.[12] Our findings also echo the international body of literature showing that HRQoL improvements for people with HF engaging in home-based CR are similar to those participating in centre-based provision.[12,28] That the magnitude of improvement in total MLHF scores was not only statistically significant but also clinically meaningful, with a ≥5 point improvement in almost two-thirds of participants.

The COVID-19 pandemic necessitated modifications to the delivery of REACH-HF in the SCOT:REACH-HF study. These shifts included: to online facilitator training; to the majority of facilitator-patient contacts being by telephone or clinic (rather than home) visit; and to a slightly lower average contact time (4.8 vs 5.3 hours in the trial), and fewer overall sessions (5 hours vs 6.5 in the trial).[15] However, these do not appear to have reduced the effectiveness of the intervention. Analysis of our qualitative data does, however, suggest that 'hybrid' approaches to training and programme delivery may be preferable to health professionals, versus fully remote implementation. Our analysis also suggests that roll-out could be supported by fostering opportunities for collaboration and knowledge exchange, for example by supporting study days, 'bite size' training, and other local and national profile-raising opportunities.

It is interesting to compare our findings with those recently published on implementation of REACH-HF in four sites in NHS England. Conducted prior to and at the start of the COVID-19 pandemic (June 2019 to June 2020), similar adaptations to the REACH-HF model of delivery were needed. However, this study, which drew on routine data only, reported more modest improvements in HRQoL (pre-post MLHF total score mean change: -2.1). Reasons for this smaller improvement in HRQoL are unclear, but may reflect better HRQoL (lower MLHF scores) at baseline in the English cohort compared with SCOT:REACH-HF (mean MLHF total scores of 36.1 vs. 44.5).

There is a clear need for evidence to support clinicians and policy makers in assessing the implementability and applicability - both to their patients and local settings - of the findings from trials - and other means of developing and testing - complex health interventions.[18,30] SCOT:REACH-HF uniquely provides formal evaluation of the implementation of a home-based CR programme, following demonstration of its clinical and cost-effectiveness in a recent RCT.[15] The mixed-method design of the study allowed a rounded assessment of implementation, based on analysis of quantitative outcome, qualitative interview, and other essential implementation data. As such, it has addressed fundamental questions relating REACH-HF's implementability, cost, and scalability.[15]

Limitations

Our study has several potential limitations. Some patients (19%) and caregivers (43%) did not complete the study, which reduced statistical power and might have caused attrition bias . However, we found few differences in demographics, medical history, or baseline outcomes in withdrawals versus those who completed follow-up. Furthermore, the large effect on the primary outcome (MLHF) suggests the risk of type II errors because of loss of sample size was probably small. Due to COVID-19 restrictions, we were unable to assess exercise capacity. The demographic and medical characteristics of people with HF in this study were similar to recent large international randomised HF trials including PARADIGM-HF.[31] However, the mean age of SCOT:REACH-HF patient-participants was some 10 years younger than the general HF

population in United Kingdom.[32] While we were unsuccessful in enrolling participants of any ethnicity other than white participating health boards comprised areas of very low ethnic diversity (with typically less than 1% of the population of each coming from non-white ethnic groups). Our study findings can therefore not be directly extrapolated to a non-white population. Lastly, while we had a relatively small sample of sites and short follow-up period, our sites were geographically diverse and included urban and remote/rural populations.

CONCLUSIONS

Substantive improvements were seen in self-reported HRQoL and self-management by people with HF, following participation in the evidence-based REACH-HF CR and self-management programme, when implemented in CR services of six NHS Scotland regional Health Boards. Although undertaken during the COVID-19 pandemic – which required most sites to deliver REACH-HF primarily by telephone and clinic-based contacts rather than home-visits – the improvements seen in the recent REACH-HF RCT were nevertheless replicated. Findings from the SCOT:REACH-HF study support scaled roll-out of the home-based REACH-HF programme across NHS Scotland, as an alternative to traditional centre-based models, in order to improve CR access and uptake for people with HF and their families.

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DECLERATION OF INTERESTS

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The other authors declare no competing interests.

DATA AVAILABILITY

The data presented in this article are available on application to the study PI.

REFERENCES

1. Long L, Mordi IR, Bridges C, Sagar VA, Davies EJ, Coats AJ, Dalal H, Rees K, Singh SJ, Taylor RS. Exercise-based cardiac rehabilitation for adults with heart failure. *Cochrane DB Syst Rev* 2019(1).
2. Taylor RS, Walker S, Smart NA, Piepoli MF, Warren FC, Ciani O, Whellan D, O'Connor C, Keteyian SJ, Coats A, Davos CH. Impact of exercise rehabilitation on exercise capacity and quality-of-life in heart failure: individual participant meta-analysis. *J Am Coll of Cardiol* 2019 Apr 2;73(12):1430-43.
3. Daw P, Withers TM, van Zanten JJ, Harrison A, Greaves CJ. A systematic review of provider-and system-level factors influencing the delivery of cardiac rehabilitation for heart failure. *BMC Health Serv Res* 2021;21(1):1-4.
4. Ragupathi L, Stribling J, Yakunina Y, Fuster V, McLaughlin MA, Vedanthan R. Availability, use, and barriers to cardiac rehabilitation in LMIC. *Global Heart* 2017; 12(4):323-34.
5. Thygesen LC, Zinckernagel L, Dalal H, Egstrup K, Glümer C, Grønbæk M, Holmberg T, Køber L, la Cour K, Nakano A, Nielsen CV. Cardiac rehabilitation for patients with heart failure: association with readmission and mortality risk. *Eur Heart J Qual Care Clin Outcomes* 2021; (Online ahead of print).
6. Dalal HM, Doherty P, Taylor RS. Cardiac rehabilitation. *BMJ* 2015;351:h5000.
7. Redfern J, Gallagher R, O'Neil A, Grace SL, Bauman A, Jennings G, Brieger D, Briffa T. Historical Context of Cardiac Rehabilitation: Learning From the Past to Move to the Future. *Front Cardiovasc Med* 2022; 9:842567.
8. Drwal KR, Forman DE, Wakefield BJ, El Accaoui RN. Cardiac rehabilitation during COVID-19 pandemic: highlighting the value of home-based programs. *Telemed E-Health* 2020; 26(11):1322-4.
9. Anderson L, Sharp GA, Norton RJ, Dalal H, Dean SG, Jolly K, Cowie A, Zawada A, Taylor RS. Home-based versus centre-based cardiac rehabilitation. *Cochrane DB Syst Rev* 2017(6).
10. Thomas RJ, Beatty AL, Beckie TM, Brewer LC, Brown TM, Forman DE, Franklin BA, Keteyian SJ, Kitzman DW, Regensteiner JG, Sanderson BK, Whooley MA. Home-Based Cardiac Rehabilitation: A Scientific Statement from the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the American College of Cardiology. *J Am Coll Cardiol* 2019; 74(1):133-153.

11. Greaves CJ, Wingham J, Deighan C, Doherty P, Elliott J, Armitage W, Clark M, Austin J, Abraham C, Frost J, Singh S, Jolly K, Paul K, Taylor L, Buckingham S, Davis R, Dalal H, Taylor RS; REACH-HF investigators. 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.
12. Dalal HM, Taylor RS, Jolly K, Davis RC, Doherty P, Miles J, Van Lingen R, Warren FC, Green C, Wingham J, Greaves C. The effects and costs of home-based rehabilitation for heart failure with reduced ejection fraction: The REACH-HF multicentre randomized controlled trial. *Eur J Prev Cardiol* 2019; 26(3):262-72.
13. Taylor RS, Sadler S, Dalal HM, Warren FC, Jolly K, Davis RC, Doherty P, Miles J, Greaves C, Wingham J, Hillsdon M. The cost effectiveness of REACH-HF and home-based cardiac rehabilitation compared with the usual medical care for heart failure with reduced ejection fraction: a decision model-based analysis. *Eur J Prev Cardiol* 2019; 26(12):1252-61.
14. Purcell C, Daw P, Kerr C, Cleland J, Cowie A, Dalal HM, Ibbotson T, Murphy C, Taylor R. Protocol for an implementation study of an evidence-based home cardiac rehabilitation programme for people with heart failure and their caregivers in Scotland (SCOT: REACH-HF). *BMJ Open* 2020; 10(12):e040771.
15. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, Boyd KA, Craig N, French DP, McIntosh E, Petticrew M. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;374.
16. American Thoracic Society. Minnesota Living with Heart Failure Questionnaire. New York: American Thoracic Society; 2004. http://qol.thoracic.org/sections/instruments/ko/pages/MLHFq.html (last accessed 15/06/2022).
17. Cowie A, Hair M, Kerr E, McKay J, Allan L, Thomson P. Validity of a first draft PROM (PROM-CR1) at the start of the outpatient cardiac rehabilitation programme. *Br J Cardiac Nurs* 2019; 14(7):1-2.
18. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011; 20(10):1727-36.
19. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; 67(6):361-70.

20. Riegel B, Dickson VV, Faulkner KM. The situation-specific theory of heart failure self-care: revised and updated. *J Cardiovas Nurs* 2016; 31(3):226-35.
21. Osborne RH, Batterham RW, Elsworth GR, Hawkins M, Buchbinder R. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Pub Health* 2013; 13(1):1-7.
22. Nauser JA, Bakas T, Welch JL. A new instrument to measure quality of life of heart failure family caregivers. *J Cardiovasc Nurs* 2011; 26(1):53-64.
23. Vellone E, Riegel B, Cocchieri A, Barbaranelli C, D'Agostino F, Glaser D, Rocco G, Alvaro R. Validity and reliability of the caregiver contribution to self-care of heart failure index. *J Cardiovasc Nurs* 2013; 28(3):245-55.
24. Humphrey L, Kulich K, Deschaseaux C, Blackburn S, Maguire L, Strömberg A. The caregiver burden questionnaire for heart failure (CBQ-HF): Face and content validity. *Health Qual Life Outcomes* 2013; 11(1):1-2.
25. Curtis LA, Burns A. Unit Costs of Health and Social Care 2020. *Personal Social Services Research Unit*, Canterbury: University of Kent; 2020.
26. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology* 2009; 43(3):535-54.
27. Ritchie J, Spencer L. Qualitative data analysis for applied policy research, in Bryman A, Burgess RG (eds.) *Analysing Qualitative Data*. London: Routledge; 1994.
28. Candelaria D, Kirkness A, Farrell M, Roach K, Gooley L, Fletcher A, Ashcroft S, Glinatsis H, Bruntsch C, Roberts J, Randall S. Remote-delivered cardiac rehabilitation during COVID-19: a prospective cohort comparison of health-related quality of life outcomes and patient experiences. *Eur J Cardiovasc Nurs* 2022; (Online ahead of print).
29. Daw P, Harrison A, Doherty PJ, van Zanten JJ, Dalal HM, Taylor RS, van Beurden SB, McDonagh ST, Greaves CJ. A pragmatic effectiveness-implementation study comparing trial evidence with routinely collected outcome data for patients receiving the REACH-HF home-based cardiac rehabilitation programme. *BMC Cardiovasc Disord* 2022; 22(1):1-8.
30. Klaic M, Kapp S, Hudson P, Chapman W, Denehy L, Story D, Francis JJ. Implementability of healthcare interventions: an overview of reviews and development of a conceptual framework. *Implement Sci* 2022; 17(1):1-20.
31. Dewan P, Jhund PS, Shen L, Petrie MC, Abraham WT, Atif Ali M, Chen CH, Desai AS, Dickstein K, Huang J, Kiatchoosakun S. Heart failure with reduced ejection fraction: comparison of patient

characteristics and clinical outcomes within Asia and between Asia, Europe and the Americas. *Eur J Heart Fail* 2019; 21(5):577-87.

32. Healthcare Quality Improvement Partnership (HQIP). *National Heart Failure Audit 2020 Summary Report*. London: Healthcare Quality Improvement Partnership Ltd. https://www.nicor.org.uk/wp-content/uploads/2020/12/National-Heart-Failure-Audit-2020-FINAL.pdf (last accessed 15/06/2022).
33. Scottish Government. *Scotland's Census* 2011 - Census table data: Health Board 2006 https://www.scotlandscensus.gov.uk/documents/2011-census-table-data-health-board-2006/ (last accessed 15/06/2022).

Table 1. Baseline characteristics of recruited people with HF, n(%) unless otherwise stated

	N = 124
Demographics	
Age (years) - mean (SD)	68 (12.4)
Gender	
Female	34 (27%)
Male	90 (73%)
Other	0
BMI (kg/m^2) - mean (SD)	29.4 (7)
Ethnicity	
White (any)	124 (100%)
Any other	0
Partnership status*	
Married or civil partnership	76 (60%)
Divorced	19 (15%)
Widowed	18 (15%)
Single (never married)	7 (6%)
Live alone	44 (36%)
Smoking status	
Never	42 (34%)
In the past	68 (55%)
Current	14 (11%)
Employment status	
Employed/self-employed	23 (19%)
Unemployed	11 (4%)
Retired	85 (69%)
Full-time parent/carer	0
Student	0
Other	5 (4%)

Education**	
Post-minimum school leaving age	59 (48%)
Degree or equivalent	54 (44%)
Scottish Index of Multiple Deprivation Quintile	
1 (most deprived)	24 (19%)
2	28 (23%)
3	33 (27%)
4	24 (19%)
5 (least deprived)	15 (12%)
Medical history	
Ejection fraction (%) - mean (SD)	31% (8.1)
Cause of Heart Failure	
Ischaemic	54 (44%)
Non-ischaemic	49 (40%)
Unknown	21 (17%)
New York Heart Association (NYHA) class	
Class I	7 (6%)
Class II	66 (53%)
Class III	51 (41%)
Class IV	0
Comorbidities, past or present	
Angina pectoris	33 (27%)
Arthritis (osteo or rheumatoid)	23 (19%)
Asthma	15 (12%)
Atrial fibrillation or atrial flutter	60 (48%)
Cardiac arrest with resuscitation	7 (6%)
Cerebrovascular disease	6 (5%)
Chronic back pain	9 (7%)

Chronic renal impairment	18 (15%)
Depression	13 (11%)
Diabetes***	15 (15%)
Hypertension	60 (48%)
Myocardial infarction	42 (34%)
Osteoporosis	3 (3%)
Stroke	12 (10%)
Valvular heart disease	17 (14%)
Cardiac surgery/devices	
Coronary Artery bypass graft (CAGB)	11 (9%)
Coronary angioplasty (with or without stent)	35 (28%)
Implantable cardioverter defibrillator (ICD)	10 (8%)
Cardiac synchronisation therapy device (CRT)	9 (7%)
Combined CRT/ICD device	2 (2%)
Heart transplant	0
Pacemaker	5 (4%)
Pharmacological therapy	
Angiotensin-converting enzyme inhibitor (ACE)	44 (36%)
Aldosterone receptor antagonist (MRA)	85 (69%)
Angiotensin II receptor blockers (ARB)	13 (11%)
Angiotensin Receptor-Neprilysin Inhibitor (ARNI)	71 (57%)
Anti-coagulant	60 (48%)
Beta blocker	112 (90%)
Digoxin	20 (16%)
Ivabradine	5 (4%)
Loop diuretic	85 (69%)
Nitrate	23 (19%)
Sodium-glucose co-transporter 2 (SGLT-2) inhibitor	52 (42%)
Thiazide diuretic	

	0

*2 particpants with missing data; ** 1 participant with missing data; ***23 participants with missing data

Table 2. Patient baseline and 4-month outcome scores

	Baseline N, Mean (SD)	4-months N, Mean (SD)	Within-group baseline vs. 4-month difference Mean (95% CI), P-value
Primary outcome			
MLHF Total score Physical dimension score Emotional dimension score	124, 44.5 (23.9) 124, 21.6 (11.4 124, 11.6 (7.8)	98, 32.8 (23.1) 100, 15.9 (11.1) 98, 8.7 (7.0)	-9.8 (-13.2, -6.4), <0.001 -5.07 (-6.7, -3.4), <0.0001 -2.4 (-3.5, -1.3), <0.0001
Secondary outcomes			
EQ-5D-5L Visual analogue score (VAS) Utility score	124, 58.3 (21.4) 122, 0.59 (0.24)	99, 67.2 (18.2) 100, 0.67 (0.22)	8.3 (4.8, 11.8), <0.0001 0.06 (0.03, 0.1), <0.001
SCHFI Maintenance Symptom perception Management	124, 57.4 (14.1) 123, 48.2 (16.6) 122, 34.3 (17.2)	99, 65.6 (14.1) 99, 53.6 (15.3) 97, 37.2 (17.7)	7.4 (4.7, 10.2), <0.0001 5.1 (1.9, 8.3), <0.05 2.8 (-1.0, 6.6), 0.14
HLQ Feeling understood and supported	124, 3.4 (0.6)	101, 3.5 (0.6)	0.1 (-0.1, 0.2), 0.33

by healthcare providers			
Actively managing my health	124, 2.9 (0.6)	101, 3.2 (0.6)	0.3 (0.1, 0.4), <0.0001
Social support for health	124, 3.3 (0.6)	101, 3.4 (0.5)	0.1 (-0.1, 0.2), 0.40
Ability to actively engage with	124, 4 (0.8)	101, 4.1 (0.7)	0.1 (-0.1, 0.2), 0.25
healthcare providers	124, 4.2 (0.6)	101, 4.2 (0.6)	-0.002 (-0.1, 0.1), 0.96
Understand health information			
enough to know what do to			
HADS			
HADS-Anxiety			
HADS-Depression	124, 6.7 (4.3)	100, 5.8 (4.4)	-0.6 (-1.2, 0.1), 0.07
	124, 6.7 (4.2)	100, 5.8 (4.0)	-0.5 (-1.1, 0.2), 0.14
PROM- CR			
Total physical impact	123, 24.2 (9.2)	100, 19.2 (9.4)	-4.6 (-6.3, -2.9),
Total social impact	123, 13 (6.9)	101, 10.0 (6.1)	<0.0001
Overall health and wellbeing	123, 6 (2.0)	99, 6.7 (1.9)	-2.6 (-3.9, -1.4),
Overall physical wellbeing	123, 5.6 (2.0)	100, 6.5 (1.9)	<0.0001
Overall social wellbeing	121, 6.0 (2.4)	101, 6.6 (2.1)	0.65 (0.3, 1.0), <0.001
Overall emotional wellbeing	123, 5.8 (2.3	100, 6.8 (2.1)	0.79 (0.45, 1.12),
Total impact of care	124, 19.8 (4.7)	100, 21.1 (3.6)	<0.0001
			0.39 (-0.02, 0.8), 0.065
			0.68 (0.3, 1.1), <0.001
			0.85 (-0.1, 1.8), 0.070

1 N: number of patients

2

Table 3. Assessment of costs of [PROGRAMME]

Component	Total cost	Cost per patient in 2021 £s[1]
2-day online [PROGRAMME] facilitator training	£3,918.20[2]	£32.22
[PROGRAMME] manual & support materials		£40.00
[PROGRAMME] facilitator delivery time[3]		£325.00
Overall cost		£397.22

[1]Based on 122 people with heart failure receiving [PROGRAMME]

[2]Training costs: teaching faculty of 11.5 hrs of clinical psychologist (@band 9: £140/hr) + 13.0 hrs of nurse (@band 9: £137/hr) + 8 hrs of administrative support (@£65.90/hr)

[3]Based on median total contact time/patient of 180mins + non-contact time/patient of 80mins (@band 8 nurse: £75/hr) over 12-weeks of delivery

1 **Figure 1. Summary of REACH-HF programme components**

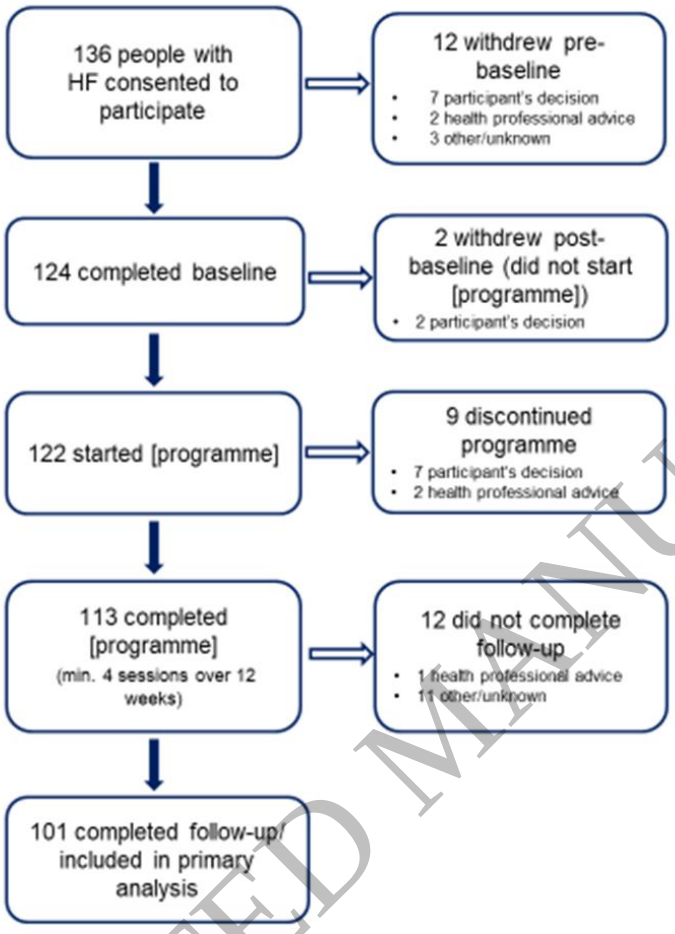
Figure 1. Summary of REACH-HF programme components

- Face-to-face and telephone facilitation over 12 weeks by a health professional trained in delivering the [PROGRAMME] programme.
- *The Heart Failure Manual*, which comprises information about HF for the person with heart failure, to increase understanding of their condition and address common misconceptions.
- Information on and strategies for managing HF, and additional related advice on managing lifestyle risk, wellbeing, and getting support from others.
- A choice of two exercise programmes: a walking programme and a chair-based programme (via DVD and online); with a recommendation that these should be engaged in three times weekly, alongside general physical activity.
- A stress-management programme provided in the manual and in audio format, including relaxation techniques, to help cope with anxiety and depression associated with HF.
- A progress tracker designed to facilitate an individual's learning from experience through self-monitoring of behaviour and symptoms. (This prompts help-seeking as appropriate).
- A *Family and Friends Resource* to increase caregiver understanding of HF, to enable them to support the person with HF's self-care and wellbeing.

2

3

Figure 2. People with HF flow through study



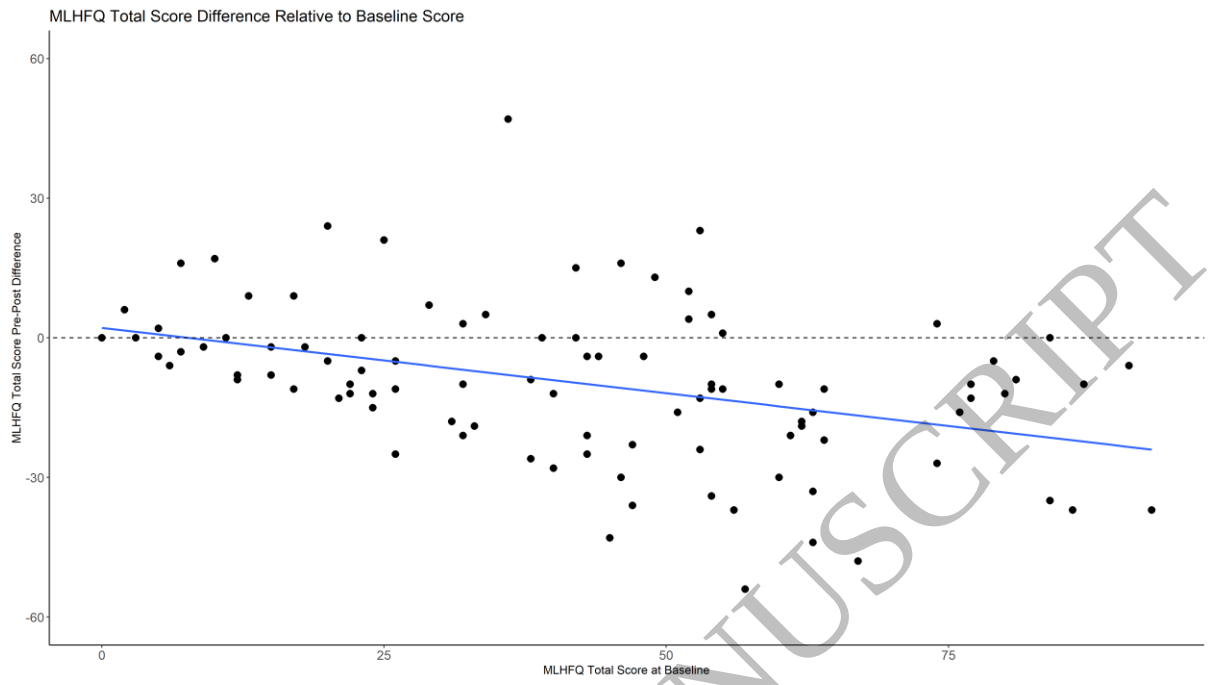
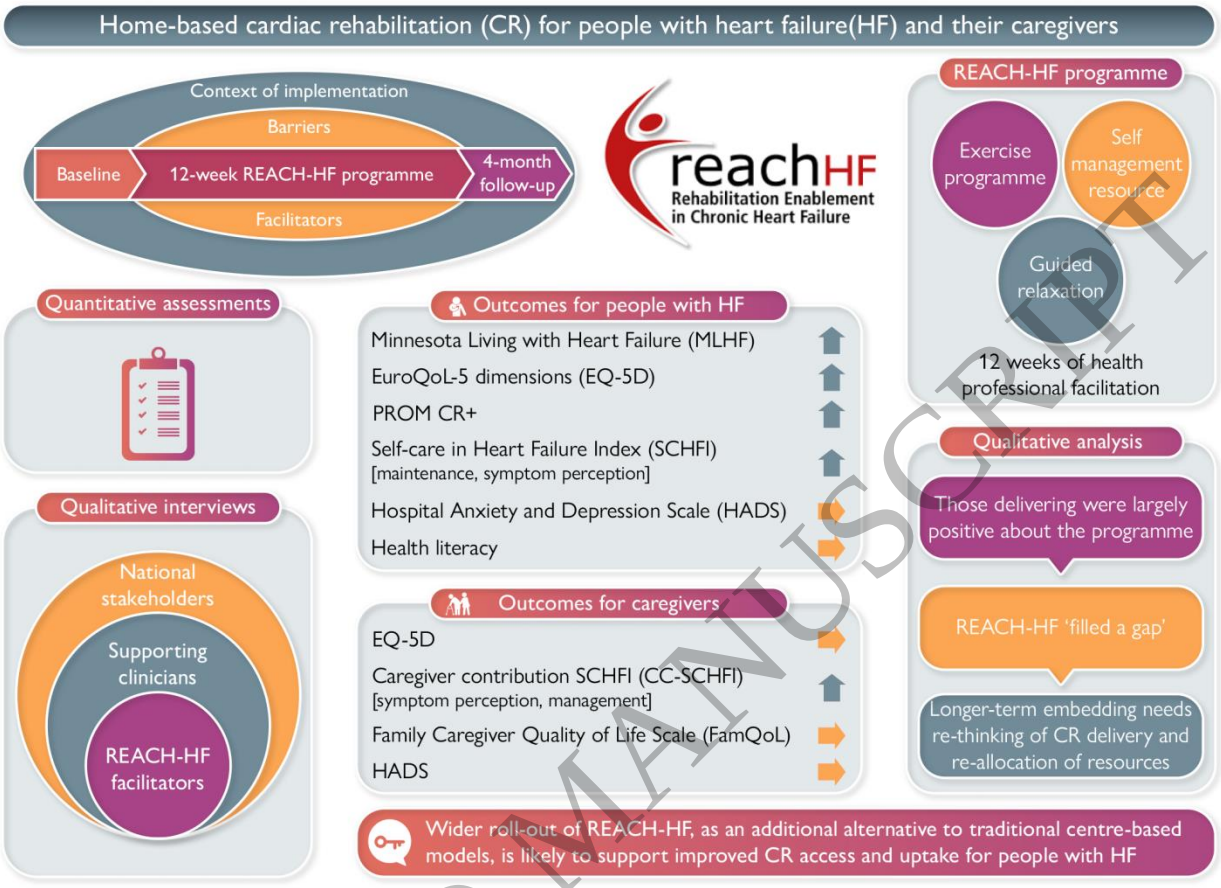


Figure 3
159x90 mm (1.9 x DPI)



Graphical Abstract