GREAVES, C.J., WINGHAM, J., DEIGHAN, C., et al. 2016. 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. [Dataset] *Pilot and feasibility studies* [online], 2(1), article number 37. Available from: https://doi.org/10.1186/s40814-016-0075-x

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. [Dataset]

GREAVES, C.J., WINGHAM, J., DEIGHAN, C., et al.

2016

Additional File 1: Needs assessment questionnaire to elicit initial ideas on the content, scope and delivery methods for the proposed REACH-HF Heart Failure Manual.

Please read the following and **add your own ideas** where indicated ….

1. The range of people that the Heart Failure Manual could be offered to

Current ideas:

- We will offer the Heart Failure Manual to people of any age with a confirmed diagnosis of heart failure, identified from GP or hospital records (Echo-cardiography showing a Left Ventricular Ejection Fraction less than 45% and natriuretic peptide levels (BNP) of 100pg/l or less, or NTProBNP of 400pg/ml or more).

- We also intend to design materials for people with HFPEF (Heart Failure with Preserved Ejection Fraction)

- The manual will be offered only after discharge from any recent hospital stay.

What people should **not** be offered a Heart Failure Manual?

Current ideas:

- People with terminal illness (e.g. terminal cancer), including people with severe heart failure who are entering palliative care services.

- People with communication difficulties or mental health problems that would prevent engagement with the service - although we can still provide the manual to carers in these circumstances.

Your ideas: *Please add any further ideas here …*

2. What kinds of information and support do people with Heart Failure need to help them to manage or 'self-care' for their condition effectively? Self-care of heart failure can be defined as actions aimed at maintaining physical stability, avoidance of behaviour that can worsen the condition, and detection of the early symptoms of deterioration (ESC guidelines, 2008).

Please add any ideas that you feel are missing in the empty space at the bottom of the table. Please tell us whether each item should be A) excluded B) included as part of the "Core Content" of the manual (i.e. if you think it is an essential issue for every patient) or C) included in an 'optional ' section of the manual (i.e. this issue will be covered only if needed or desired by the individual patient) .

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as "additional information" depending if it is important for a particular person?		
People with heart failure should be helped to develop a clear understanding of their situation. What causes heart failure, what does it mean for the individual (possible risks and consequences, what you can and can't do and how different actions might affect your symptoms) and what can be done to best manage the situation? Common mis-conceptions should be identified and addressed. (Expert opinion, REACH review of patient experiences)	A	B	C
People's reactions and responses to the development of heart failure vary considerably. Explaining and helping people to move through the 'five stage process' of disruption, conception, reaction, response and assimilation might be helpful here. (REACH review of patient experiences)	A	B	C
Encourage engagement in regular moderate daily activity (including both aerobic and muscle-strengthening activities). Patients should be re-assured and comfortable about engaging in physical activity (ESC[1] guidance) A recent ESC Position Statement (2011) advises at least 20 min, a minimum of three times a week aiming to achieve modest breathlessness during exertion.	A	B	C
Encourage engagement in physical activity training to improve mobility and the efficiency of movement and enhance the ability to perform functional activities associated with daily living (e.g. stair climbing, getting out of chairs). This may need to be individually tailored to build from the patient's initial level of ability. (Expert opinion) The principle here is that the heart may not be able to improve its output but the muscles can, with the correct form of exercise make more efficient use of the available oxygen. (Expert opinion)	A	B	C

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[1] European Society of Cardiology

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as “additional information” depending if it is important for a particular person?		
Taking the medications in the right way /as prescribed. This includes understanding what each medication is for and when to take them and also what effects or side effects to expect. (ESC[1])	A	B	C
Addressing concerns about medications, other treatments /interventions and their side effects. (Expert opinion)	A	B	C
The need for the dosage or type of medications to be changed over time should also be understood. (REACH review of patient experiences)	A	B	C
How to achieve clear and appropriate communication with healthcare professionals (ESC)	A	B	C
Engaging support from others (e.g. friends, family) to support self-care (ESC) This should include ideas about information support, emotional support and practical support. Consideration of how to manage if you are socially isolated may also be relevant here. (Expert opinion)	A	B	C
Patients should learn to recognize the symptoms of deterioration and take appropriate action such as increasing the dose of prescribed diuretic medications and /or contacting the healthcare team. (ESC) Agreeing a strategy for managing medications with the nurse-facilitator may be important here, including knowing when to adjust doses or when to consult with the nurse or GP. (Expert opinion)	A	B	C
Patients should weigh themselves on a regular basis to monitor weight change, preferably as part of a regular daily routine. In the case of a sudden unexpected weight gain of 2 kg or more in 3 days, patients may increase their diuretic dose and should alert the healthcare team. (ESC)	A	B	C

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as "additional information" depending if it is important for a particular person?		
Restricting salt in the diet for people with 'symptomatic heart failure' to prevent fluid retention (ESC. NB: there is no guidance on specific levels, but excessive intake should be avoided. The Mayo clinic recommends <2.0g per day or <1.5g /day for Afro-Caribbeans) NB: This recommendation needs further investigation, as it would seem that restricting salt intake may be harmful in some cases. It may be that we do not have enough evidence to make any specific recommendation about which patients should restrict salt intake and at what levels.	A	B	C
People with severe symptoms and where this has been identified by a health professional as being important should restrict fluid intake or take other measures to manage their fluid status. (ESC)	A	B	C
Alcohol intake should be limited to 10–20 g/day (1–2 glasses of wine/day, 2 units for women, 3 for men). (ESC) Patients with alcohol induced cardiomyopathy should stop drinking alcohol altogether. (Expert opinion)	A	B	C
Make changes to diet to reduce weight if Body Mass Index is more than 30Kg/m2. However, this is not recommended for people with evidence of cachexia (involuntary weight loss /body wasting). (ESC)	A	B	C
Basic advice about what constitutes a healthy diet for people with heart failure and maintaining a healthy body weight. We should refer to sources of relevant recipes online and elsewhere. (Expert opinion)	A	B	C

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as "additional information" depending if it is important for a particular person?		
Advice on smoking cessation (for those who smoke). (ESC). Avoidance of secondary smoking. (Expert opinion) It is suggested that brief information on the risks and consequences is provided, and if desired, referral by the facilitator to appropriate smoking cessation services. (Expert opinion)	A	B	C
Pneumoccocal vaccination and annual influenza vaccination (as long as no contra-indications). (ESC)	A	B	C
Be re-assured about of the safety of engaging in sexual activity, if desired. Explore concerns about sexual activity. Be aware of and able to use possible strategies for prevention of dyspnoea (breathing difficulties) and chest pain during sexual activity (e.g. nitroglycerine tablets). (ESC)	A	B	C
Women with heart failure should (if applicable) be aware of the potential risks associated with pregnancy and should discuss the use of contraceptives and /or planned pregnancy with a physician in order to take informed decisions. (ESC)	A	B	C
High altitudes (1500 m or more) and travel to very hot and humid destinations should be discouraged for symptomatic patients. Planned travel should be discussed with the healthcare team. (ESC, ESC Position Statement, 2011)	A	B	C
Sleep apnoea (breathing problems during sleep) should be recognised and steps taken to manage it. This may involve weight loss in severely overweight persons, smoking cessation, abstinence from alcohol, or use of CPAP treatment (breathing masks) if needed (ESC). Elevation of the head during sleep, and changing of eating and timing of diuretic medication may also be considered (Mayo Clinic)	A	B	C

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as “additional information” depending if it is important for a particular person?		
Manage the emotional impact of living with heart failure (ESC). The aim here should be to help the individual to adapt his or her lifestyle, life goals and expectations to the challenge presented by heart failure. The individual should be able to move from being a person disrupted by heart failure to being a person living with and coping with heart failure. The sense of attaining some form of ‘good-enough’ control, a sense of ‘safety’ and acceptance of the limitations and the inherent uncertainty of heart failure seem to be important here. This may include finding (or re-defining) the individual’s role within the home and in the wider world and in relation to friends /family. (REACH systematic review of patient experiences) An analysis of the individual’s past, present and possible future social roles might be relevant – acknowledging any current discrepancies /loss of roles and thinking about what is possible in the future. (Expert opinion)	A	B	C
Recognising and taking steps to manage depression, anxiety and other mental health aspects also seem important. (Expert opinion) This may include engaging in cognitive-behavioural therapies, engaging support from friends /family, use of medications or use of stress-relieving techniques. (Expert opinion)	A	B	C
Managing co-morbidities (other illnesses) that might affect the ability to manage heart failure. Especially mobility limitations, diabetes, COPD, other heart conditions. (ESC and expert opinion) This may include strategies for remembering to take medications regularly (e.g. pre-loaded pill boxes) and discussion of options with a pharmacist. (Expert opinion)	A	B	C

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as “additional information” depending if it is important for a particular person?		
Manage breathing difficulties /breathlessness and stress /anxiety using breathing control /relaxation techniques. (Expert opinion)	A	B	C
Managing the consequences of cognitive impairment /memory problems (e.g. remembering to take medications) (Expert opinion)	A	B	C
Self-monitoring of symptoms, energy levels and other important outcomes to identify possible problems and solutions. (Expert opinion)	A	B	C
Self-monitoring of blood pressure if blood pressure is high. (Expert opinion)	A	B	C
Engagement in problem solving and /or goal-setting to facilitate the above self-care behaviours (Expert opinion)	A	B	C
Use of home telemetry (remote monitoring of health indicators and access to advice via computer links to appropriate specialists) where available. (Expert opinion)	A	B	C
Correct use of devices (e.g. Implantable Cardiac Defibrillator, Cardiac Resynchronization Therapy). Understanding how to manage and respond to device alarms, where appropriate (Expert opinion)	A	B	C
Returning to work. (Expert opinion)	A	B	C
Planning and pacing yourself. Practical solutions, for managing activities of daily living, for example taking small loads of washing to the line. (Expert opinion)	A	B	C
Negotiation of the role of any caregivers /supporters. (Expert opinion)	A	B	C
Information about benefits that may be available and how to claim them. (Expert opinion)	A	B	C

Content that the Heart Failure Manual should include	**Should this content be ...** A: excluded B: included as essential content for **every** heart failure patient C: included as "additional information" depending if it is important for a particular person?		
Please insert your own ideas below			
		B	C
		B	C
		B	C
		B	C
		B	C
		B	C
		B	C

2b. How would the inclusion of people with Heart Failure with Preserved Ejection Fraction (HFPEF) affect the proposed content above? Which of the above elements will need to be different or not needed for those with HFPEF?

Your ideas: *Please add your ideas here....*

3. What are the key messages for people with Heart Failure? What messages do you believe would be useful in helping them to cope with /manage their Heart Failure?)

Current ideas:

- Importance of regular exercise /activity
- Ensure that medications are used in the best way to enable you to function positively
- Heart failure can usually be managed at home. Hope is important here.
- You are still an important and valued person.
- Support from health care professionals including after the initial support programme has finished.
- Ask from (your heart failure nurse, GP) for help if you are not coping.

Your ideas: *Please add your ideas here....*

4. What information do carers or relatives need and what behaviours should we try to encourage for these caregivers?

Ideas for carer behaviours that the Heart Failure Manual should encourage	**Should this content be** A: excluded B: included in the "Carers Manual"	
Caregivers should learn to recognize the symptoms of deterioration and help to take appropriate action such as increasing the prescribed diuretic dose and/or contacting the healthcare team. (ESC, Expert opinion)	A	B
Caregivers should help to manage the emotional impact of living with heart failure (ESC). This may include discussing problems, helping their loved one to feel valued, or help with the use of stress-relieving techniques. (Expert opinion)	A	B
Negotiation of the caregiver role / what support is required to self-manage the problem (e.g. managing medication, weighing, emotional support/encouragement, observing). (Expert opinion)	A	B
Caregivers should look after their own health, including ways to manage the emotional impact on themselves. (Expert opinion)	A	B

Caregivers should help to ensure good communication and a good working relationship with health professionals. (Expert opinion)	A	B
Caregivers should help the person they care for to understand and engage with all the other self-care behaviours listed above. (Expert opinion)	A	B
Care but don’t smother! Support patients to be as independent as possible and find their maximum potential. (Expert opinion)	A	B
Information about benefits and respite care. (Expert opinion)	A	B
Please insert your own ideas below		

5. Under what conditions should we advise patients to consult with their GP or Heart Failure Manual nurse?

Current ideas:

- Weight gain that does not respond to adjustment of diuretic dosage (JW)
- When they feel the symptoms or worries are hindering their confidence to effectively self-manage.
- Increase in breathlessness or fatigue, especially at rest
- If they feel the plan isn’t working and that the patients QoL is deteriorating
- A guidance booklet or card (optional) and a page in the manual formatted as a ‘traffic light’ system may be appropriate here
- If patient is consistently feeling ’’down or in a low -mood’’

- If they notice a step change in their ability to do basic daily activities
- If patient has been unable to take medication

Your ideas: *Please add your ideas here....*

6b. In what circumstances should we advise patients or their carers to seek emergency care?

Current ideas:

- Loss of consciousness (CG)
- Chest pains or sudden onset of palpitations (potential arrhythmia)
- If ICD (implanted defibrillator) shocks are applied for patients with these devices
- A guidance page or (optional) booklet formatted as a 'traffic light' system may be appropriate here

Your ideas: *Please add your ideas here....*

7. Are there any topics that we should NOT cover in the Heart Failure manual (e.g. too specialist or contentious, or potentially dangerous?)

Current ideas:

- Detailed coverage of palliative care (end of life) issues? (Expert opinion)

Your ideas: *Please add your ideas here....*

8. What is a 'good outcome' for a person with Heart Failure?

Current ideas:

- Reduced mortality /longer life
- Reduced morbidity (less symptoms, better Quality of Life, lower frequency of fluid retention problems, less breathlessness, increased exercise capacity)
- Reduced need for hospitalisation
- Reduced progression of cardiac health indicators (occurrence or progression of myocardial damage, myocardial remodelling
- Reduced costs of care
- Improved efficiency i.e. more or the same level of work for less effort
- Improved ability to live independently /to achieve activities of daily living

Your ideas: *Please add your ideas here....*

9. What range of delivery staff might deliver /facilitate the Heart Failure Manual intervention? (CRNs, PNs, other?)

Current ideas:

- Cardiac rehabilitation nurses, with additional training in heart failure treatment
- Practice nurses with appropriate training (this is contentious with some experts agreeing and others not)
- Heart failure specialist nurses
- Given the level of co-morbidity and the likely range of initial abilities, there should also be access to a specialist in adapting exercise e.g. physiotherapist or exercise specialist working in cardiac or pulmonary rehab services.
- Other specialists that it may be sensible to be able to refer on to might include dietitians and clinical psychologists

Your ideas: *Please add your ideas here....*

10. We don't want to re-invent the wheel, so what sources of information are relevant here that we can draw on ? For example, existing guidance, content of existing intervention programmes, existing patient information resources.

Current ideas:

- ESC Position Statement on Self-Care of Heart Failure. European Journal of Heart Failure 2011 Feb 1;13(2):115-26.
- BACR (2007)
- ESC
- NICE (CG5, 2010) and SIGN guidelines on heart failure
- The existing Heart Manual.
- Service Specification for Cardiac Rehabilitation (Dept of Health, 2010)
- NICE CG43 on obesity; CG48 on physical activity; PH1,5,10 on smoking
- Other Physical activity guidelines (ACPICR, 2009; ACSM (2010); AACVPR (2010)
- Guidance on patient education and supporting behaviour change : BACR, 2007; SIGN, 2002; NICE 2007
- Guidance on Cardiovascular Risk Factor management: NICE CG48; NICE CG34; NICE CG66; NICE - -CG87; NICE CG15; NICE CG67
- Davies et al 2010
- NICE CG 108
- www.heartfailurematters.org (ESC patient information website)
- BHF heart failure manual

Your ideas: *Please add your ideas here....*

11. Because people with heart failure have different needs for support, we are proposing to have two elements to our manual. One part of the manual will be the same for everyone and will deal with all the "Core Issues" – the things that everyone needs to know about and do to manage their condition. The second part will contain "Tailored Information" that only *some people* will need – for example there is no point giving you information about smoking if you don't smoke, or about managing your implanted defibrillator if you don't have one. So, the question that arises, is "How should we present the Tailored Information?" There are four choices here:-

A. Give all the information to everyone and tell you which chapters are relevant to you.

B. Give you a separate booklet for each piece of Tailored Information that is relevant to you.

C. Have the nurse pick out the right information chapters for you and put them into a ring binder, so that you only have only the information that is relevant to you and it is all gathered together in one place.

D. Provide website references so that you can look up the additional information yourself online.

Which option would you prefer? **A** **B** **C** **D** *(please circle one)*

12. For clinicians: What way should the nurse-facilitator training be conducted? Face to face; e-learning; mixture of both; other?

13. How might we need to adapt the manual for different demographic and ethnic /cultural groups?

Your ideas: *Please add your ideas here....*

14. A major component of rehabilitation for people with heart failure is to engage with as much physical activity as possible at a sensible / achievable level. The needs and abilities of individual patients will vary widely however and so we would like to explore the possibility of providing access to an appropriately qualified exercise specialist. So, would it be realistic to offer people with heart failure …

A. Group-based activity sessions in the community, led by a qualified (Stage 3 or above) exercise specialist?

B. 1-2 Individual sessions in the patient's home to design a home-based exercise programme to fit the individual's needs (based on information supplied by the nurse who is facilitating the Heart Failure Manual intervention)?

C. A choice of the above options?

D. None of the above

Which options are realistic? **A** **B** **C** **D** *(please circle one or more)*

Ideas for the content of a ‘manual’ for Heart Failure: Questions for service user advisors

Please read the following and **add your own ideas** where indicated ….

2. Who is the Heart Failure Manual for?

Current ideas: - We will offer the Heart Failure Manual to people of any age with a confirmed diagnosis of heart failure

What people should **not** be offered a Heart Failure Manual?

Current ideas:

- People who are entering palliative (end of life) care services.
- People with communication difficulties or mental health problems that would prevent engagement with the service - although we can still provide the manual to carers in these circumstances.

Your ideas: *Please add any further ideas here …*

2. What are the key messages for people with Heart Failure? Please feel free to highlight any that you think are particularly good or cross out any you think are wrong

Current ideas:

- Regular exercise /activity is important to keep you fit enough to get out and about and do the things you want to do in your life
- Getting too little physical activity gets you into a downward spiral (you lose fitness and can do less and then you lose more fitness ...etc).
- Building up your physical activity /exercise to a manageable level helps you to maximise your potential (as you gain fitness, you can do more and get on with your life more easily)
- However, don’t over-do it - doing too much can make you worn out the next day
- Ensure that medications are used in the best way to enable you to function positively
- Heart failure can usually be managed at home.
- Hope is important.
- You are still an important and valued person.
- You are not alone /help is available for coping with the condition even after the initial care programme has finished.
- Ask for help (from your heart failure nurse, or GP) if you are not coping.
- Don’t give up!
- It is important to keep up a positive mental attitude

- Do not ignore fluid build up or other changes in symptoms
- Heart failure disrupts your life but it is possible to learn to live with it
- Healthy eating helps
- No smoking – this is the worst possible thing you can do as far as your heart is concerned

- A number of patients don't understand what has happened. Often, they see it as a sudden event rather than the result of a decline. They therefore don't think it can be repaired or improved, when often it can. Understanding the condition helps them to understand what the treatment is trying to achieve and why.
- Self monitoring and early reporting of change in symptoms is key to managing the condition
- Patient empowerment is important – what they can do to be in control of their condition i.e monitoring weights, fluid restriction when appropriate, maintaining fitness etc.
- HF can't be cured, but there are ways to manage it to have as good a quality of life as you can
- We need to say clearly what are the early warning signs (when action is needed by the patient)
- We need to say clearly what are the urgent warning signs (when emergency care is needed)
- Heart failure is a serious condition (I know hope is important but it also should not be taken lightly!)

Your ideas: *Please add your ideas here....*

2. What is a 'good outcome' for a person with Heart Failure?

Current ideas:
- Longer life
- Less symptoms, better Quality of Life, lower frequency of fluid retention problems, less breathlessness, increased exercise capacity
- Reduced need for hospitalisation and NHS service use
- Improved efficiency i.e. more or the same amount of things achieved with less effort
- Improved ability to live independently /to achieve activities of daily living
- Return to work
- Feeling happy within themselves i.e. at ease /not stressed or emotional

Your ideas: *Please add your ideas here....*

3. What kinds of information and support do people with Heart Failure need to help them to manage or 'self-care' for their condition effectively? Self-care of heart failure can be defined as actions aimed at maintaining physical stability, avoidance of behaviour that can worsen the condition, and detection of the early symptoms of deterioration.

Content that the Heart Failure Manual should include	Your comments
People with heart failure should be helped to develop a clear understanding of their situation. What causes heart failure, what it means for the individual (possible risks and consequences, what you can and can't do and what can be done to best manage the situation? Common mis-conceptions should be identified and addressed.	
People's reactions and responses to the development of heart failure vary considerably. Explaining and helping people to move through the 'five stage process' might be helpful here. The five stages of adaptation to heart failure are: 1. Disruption – initial chaos and disruption to normal life patterns and emotions following diagnosis 2. Making sense of the situation 3. Reaction – this can range from denial (ignoring the problem) to positive engagement (doing things to address the problem) 4. Response - making plans about what to do to best manage the problem, trying out new ideas and strategies 5. Assimilation – learning how to live with the condition and to maximise quality of life, accepting and working around any remaining limitations.	
Encourage engagement in regular moderate daily activity (including both aerobic and muscle-strengthening activities). Patients should be re-assured and comfortable about engaging in physical activity A recent European guideline (2011) advises at least 20 min, a minimum of three times a week aiming to achieve modest breathlessness during exertion.	

Content that the Heart Failure Manual should include	Your comments
Encourage engagement in physical activity training to improve mobility and the efficiency of movement. This should aim to work on the ability to perform functional activities associated with daily living (e.g. stair climbing, getting out of chairs). This may need to be individually tailored to build from the patient's initial situation.	
Taking the medications in the right way /as prescribed. This includes understanding what each medication is for and when to take them and also what effects or side effects to expect.	
Addressing concerns about medications, other treatments /interventions and their side effects.	
The need for the dosage or type of medications to be changed over time should also be understood.	
How to achieve clear and appropriate communication with healthcare professionals	
Engaging support from others (e.g. friends, family) to support self-care This should include ideas about information support, emotional support and practical support.	
Patients should learn to recognize the symptoms of deterioration and take appropriate action such as increasing the dose of prescribed diuretic medications and /or contacting the healthcare team.	
Patients should weigh themselves on a regular basis to monitor weight change, preferably as part of a regular daily routine. In the case of a sudden unexpected weight gain of 2 kg or more in 3 days, patients may increase their dose of diuretic medication and should alert the healthcare team.	
Alcohol intake should be limited to 10–20 g/day (1–2 glasses of wine/day, 2 units for women, 3 for men). Patients with alcohol induced cardiomyopathy should stop drinking alcohol altogether.	
Basic advice about what constitutes a healthy diet for people with heart failure and maintaining a healthy body weight. We should refer to sources of relevant recipes online and elsewhere.	

Content that the Heart Failure Manual should include	Your comments
Advice on smoking cessation (for those who smoke). Avoidance of secondary smoking.	
Encouraging annual flu vaccinations.	
Be re-assured about of the safety of engaging in sexual activity, if desired. Explore concerns about sexual activity. Be aware of and able to use possible strategies for prevention of breathing difficulties and chest pain during sexual activity (e.g. nitroglycerine tablets).	
Women with heart failure should (if applicable) be aware of the potential risks associated with pregnancy and should discuss the use of contraceptives and /or planned pregnancy with a physician in order to take informed decisions.	
High altitudes (1500 m or more) and travel to very hot and humid destinations should be discussed with the healthcare team.	
Breathing problems during sleep should be recognised and steps taken to manage it. This may involve weight loss in severely overweight persons, smoking cessation, abstinence from alcohol, or use of CPAP treatment (breathing masks) if needed. Elevation of the head during sleep, and changing of eating and timing of diuretic medication may also be considered.	
Manage the emotional impact of living with heart failure: The aim here should be to help the individual to adapt his or her lifestyle, life goals and expectations to the challenge presented by heart failure. The individual should be able to move from being a person disrupted by heart failure to being a person living with and coping with heart failure. The sense of attaining some form of 'good-enough' control, a sense of 'safety' and acceptance of the limitations and the inherent uncertainty of heart failure may be important here. This may include finding (or re-defining) the individual's role within the home and in the wider world and in relation to friends /family.	
Recognising and taking steps to recognise and manage depression, anxiety and other mental health problems that may occur.	

Content that the Heart Failure Manual should include	Your comments
Managing other illnesses that might affect the ability to manage heart failure. Especially mobility limitations or joint problems, diabetes, COPD and other heart conditions. This may include strategies for remembering to take medications regularly (e.g. pre-loaded pill boxes) and discussion of options with a pharmacist.	
Manage breathing difficulties /breathlessness and stress /anxiety using breathing control /relaxation techniques.	
Managing memory problems (e.g. remembering to take medications)	
Self-monitoring of symptoms, energy levels and other important outcomes to help to identify possible problems and solutions.	
Self-monitoring of blood pressure if it is high.	
Returning to work.	
Planning and pacing yourself. Practical solutions, for managing activities of daily living, for example taking small loads of washing to the line.	
Negotiation of the role of any caregivers /supporters.	
Information about benefits that may be available and how to claim them.	
Please insert your own ideas below	

4. What information do carers or relatives need and what behaviours should we try to encourage for these caregivers?

Ideas for carer behaviours that the Heart Failure Manual should encourage	Your comments
Caregivers should help the person they care for to understand and engage with all the self-care behaviours listed above.	
Caregivers should learn to recognize the symptoms of deterioration and help to take appropriate action such as increasing medication dose or seeking medical help.	
Caregivers should help to manage the emotional impact of living with heart failure (ESC). This may include discussing problems, helping their loved one to feel valued, or help with the use of stress-relieving techniques	
Working with your loved one to decide what support is required (e.g. managing medication, encouragement, observing) and what responses might be unhelpful.	
Caregivers should look after their own health, including ways to manage the emotional impact on themselves.	
Caregivers should help to ensure good communication and a good working relationship with health professionals.	
Care but don’t smother! Support patients to be as independent as possible and find their maximum potential	
Information about benefits and respite care.	
Please insert your own ideas below	

Additional File 2: REACH-HF Needs Assessment Summary

1. Patient needs (and objectives for optimal self-care)

a qualitative literature review of the attitudes, beliefs and expectations of people with HF receiving CR [45]

a systematic review and metaanalysis of CR in people with HFPEF[21]

Scaffolding questionnaire responses

A summary of the Support group /focus group interviews

National and international guidelines on heart failure treatment

2. Commissioner /health professional needs

National postal survey

Scaffolding questionnaire responses

Comments and ideas from co-applicant stakeholders (expert opinion)

3. Service provider needs (nurse facilitators)

Scaffolding questionnaire responses

Comments and ideas from co-applicant stakeholders (expert opinion)

To map existing service provision (the context we are going into), WA conducted site visits and meetings with service providers at each study site, as well as asking for responses to a questionnaire on current service provision and summarised this in a report.

4. Caregiver needs

Scaffolding questionnaire responses

Qualitative interviews with caregivers (WP1B)

National and international guidelines on heart failure treatment (minimal data)

5. Expert group meetings and workshops

A one-day expert panel workshop was held in Birmingham. This was used to refine the suggested programme objectives and identify barriers and facilitators of change using small group (groups of 3-4) discussions among the panel members.

A specialist working group was established to develop the PA component and this had three formal meetings, several teleconferences and ongoing email exchanges to refine the objectives, determinants and intervention strategies further and to produce the final specifications for the exercise (walking training or CBE) component, initial exercise capacity and safety assessment procedures and the manual text for this component.

Synthesis

We thematically analysed the summary reports /findings from all the above data sources to draw out some preliminary programme objectives (below) and then we used intervention mapping matrices to develop detailed strategies and intervention content.

Table 1: Programme objectives identified by the Needs Assessment process

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
Engage with the programme	Patient empowerment is important – what they can do to be in control of their condition i.e monitoring weights, fluid restriction when appropriate etc. (1. HF Nurse 2. HF /CR Specialist Nurse) Patients who refuse rehab are offered it again at a later date. This is appropriate for	Post diagnosis, patients are often in shock and not ready to take on information. (Caregiver interviews)	It is self-evident that low engagement will lead to low effectiveness. So we need to maximise engagement with the programme. CG Some patients may have strong denial /minimisation-of-the-problem issues at this stage, we may need to sell it to them a bit to get these people initially engaged. Minimisation is usually based on fear so need to provide re-assurance and messages of hope and efficacy. (HPsych).	It is recommended that patients with heart failure are enrolled in a multidisciplinary-care management programme to reduce the risk of heart failure hospitalization. (ESC 2012)	All domains (based on logic /assuming the intervention as a whole is effective, then increased engagement across all domains will increase effectiveness across all domains)

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
	us too as people have to be ready to face up to life with heart failure.(CRN)				
Physical Activity	May need to be individualised and a generic statement [e.g. 20 min 3x per week] may not be appropriate (StQ-HF N) Think we need to increase the level building up (to at least 5 sessions per week 20-30 mins) as well as teaching people to self regulate in relation to their Borg RPE	Energy conservation /pacing (FG) Learn how to assess your level of breathlessness and to be able to exercise at the right level /and to slow down before it gets out of control (FG) The idea of teaching people to recognise their ventilatory threshold /other indicator of “exercising at the	Not just adherence to a set exercise regime, but being active as part of everyday life: climbing stairs, getting out and about, house work, walking the dog. (HPsychx2) Energy conservation /pacing (PAS, HPsych) At least 5 sessions per week 20-30 mins (Mayo clinic) A key principle here is that the heart may not be able to improve its output but the muscles can, with the correct form of exercise make more efficient use of the available oxygen. (SCM-PAS, StQ) One of the main advantages of the Heart Manual is that it is provides support for those that do not like	Supervised group exercise-based rehab programme designed for patients with HF. (CG108) Ensure patient is stable with no condition (e.g. uncontrolled hypertension) or device that would preclude PA. (CG108) Regular aerobic exercise should be encouraged to improve functional capacity and symptoms. (ESC 2012) At least 20 min, a minimum of three times	Should facilitate Activities of Daily Living (e.g. getting out and about, returning to work) ESC 2012 cites grade A evidence linking PA to HF morbidity, HRQoL and hospital admissions.

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
	scores. (StQ-HF Nurse) Important to bring the negative effects of over activity into the discussion (StQ-CRSN)	right level /when to slow down" was well received (HPsych /FG) Need to be able to recognise symptoms leading up to exhaustion (FG) Lists of ideas would be useful here (FG) Unmonitored exercise at home should not be encouraged. Need to cover questions like: How long should I exercise? Should I be breathless? How energetic should I be? Should my heart be racing? Should	group work and are unlikely to turn up for group based rehab. (HMO expert) Patients need to have confidence in exercising alone too, walking the dog, climbing stairs – things they are likely to be doing regularly as part of their normal routine and often alone.(HMO Expert) Pacing of exercises that are done safely can also provide confidence. This is all part of the cognitive behavioural model. (HMO Expert) Groups give support and reduce isolation. On the other hand, they can exert unintended peer pressure – "he's doing better than me" – and some people hate exercising in public, hence I think a choice is needed. A third possibility is an exercise video at various levels. This would also address variation in reading ability. (Pharmacist) The opportunity to share experiences	a week aiming to achieve modest breathlessness during exertion.(ESC Pos St 2011) Understand the benefits of exercise (HF Assoc, ESC 2012 Tab27) Perform exercise training regularly. (HF Assoc, ESC 2012 Tab27) Be reassured and comfortable about physical activity. (HF Assoc, ESC 2012 Tab27)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		I be sweating? (StQ Patient) Patient Focus Group expressed a strong preference for group based sessions due to the ability to share experiences with other people in the same situation and Supervision to ensure that exercise levels were safe (Patient FG). Group-based exercise in the community /near the patient's home has the following benefits: Professional staff on site;	could be achieved through a support group instead. (HPsych) Some kind of 'fitness to exercise' assessment may be needed to ensure that the patient is safe to exercise (SWGPA). The 6-minute walk test is sometimes used in hospital settings to provide an objective indicator of exercise capacity (ESC 2012). **Birmingham workshop (expert opinion) …** Overcome psychological barriers Manage expectations Education to include that some patients may need to drop a level or start at a much lower level after a period of illness. Those completing a high dose level must build in rest periods between each session – 3 sessions spread through the week.		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		encouragement by staff and other patients; Opportunity for Monitoring progress (e.g. BP); No opportunity to cheat! (Patient)			
Healthy eating	Healthy eating, no smoking (HF Nurse)	Avoid excessive fluid intake: fluid restriction of 1.5–2 L/day may be considered in patients with severe heart failure to relieve symptoms and congestion. Restriction of hypotonic fluids may improve hyponatraemia. Routine fluid restriction in all patients with mild	Basic advice about what constitutes a healthy diet for people with heart failure and maintaining a healthy body weight. (StQ-HPsych)	Make changes to diet to reduce weight if Body Mass Index is more than 30Kg/m2. However, this is not recommended for people with evidence of cachexia (body wasting). (ESC, 2008?)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		to moderate symptoms is probably not of benefit. Weight-based fluid restriction (30 mL/kg body weight, 35 mL/kg if body weight >85 kg) may cause less thirst. (HF Assoc, in ESC 2012, Tab27) Monitor and prevent malnutrition. HF Assoc, in ESC 2012, Tab27) Eat healthily and keep a healthy weight (HF Assoc, in ESC 2012, Tab27)			
		Need to be able to recognise	Managing fatigue /pacing is an important day-to-day challenge.		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
Manage fatigue		symptoms leading up to exhaustion and take early action to prevent it (FG) You have good days and bad days, so need alternative plans for the bad days. (Patient FG and PPI group)	Need to understand and adjust to the fact that people typically have 'good days and bad days' (REACH expert group workshop) Planning and pacing yourself. Practical solutions, for managing activities of daily living, for example taking small loads of washing to the line. (StQ: Mixed sources give 81% approval for this idea)		
Smoking	Healthy eating, no smoking (HF Nurse)	Stop smoking and/or taking illicit drugs (HF Assoc, in ESC 2012, Tab27)		Advice on smoking cessation (for those who smoke). Avoidance of secondary smoking. (ESC,2008?)	
Alcohol		Modest intake of alcohol: abstinence is recommended in patients with		Alcohol intake should be limited to 10–20 g/day (1–2 glasses of wine/day, 2 units for women, 3 for men).	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		alcohol-induced cardiomyopathy. Otherwise, normal alcohol guidelines apply (2 units per day in men or 1 unit per day in women). 1 unit is 10 mL of pure alcohol (e.g. 1 glass of wine, 1/2 pint of beer, 1 measure of spirit) (HF Assoc, in ESC 2012, Tab27)		Patients with alcohol induced cardiomyopathy should stop drinking alcohol altogether. (ESC, 2008?)	
Stress		Provide psychosocial support to patients and family and/or caregivers. HF Assoc	Manage the emotional impact of living with heart failure: (StQ-HPsych)		
Vaccination			Approval 80% (and 5% for as-needed section on this). (StQ mixed	Check status and offer if needed annual flu,	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			sources)	and pneumococcal vaccination, as long as no contra-indications. (CG108) Receive immunization against influenza and pneumococcal disease (HF Assoc /ESC 2012 Tab27)	
Depression		Provide psychosocial support to patients and family and/or caregivers. (HF Assoc) Learn about treatment options if appropriate (HF Assoc /ESC 2012 Tab27) Understand that depressive symptoms are	Recognising and taking steps to manage depression, anxiety and other mental health aspects. (StQ-HPsych)	Consider diagnosis. CG108 Reassess once heart failure has stabilised. CG108 Consider the risks and benefits of drug and other treatments. CG108 **The nurses' role here may be simply to identify and refer.**	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		common in patients with heart failure. (HF Assoc /ESC 2012 Tab27)			
Anxiety		Provide psychosocial support to patients and family and/or caregivers. HF Assoc A major problem, esp. close to diagnosis. “Heart failure” has very frightening connotations /not knowing makes you anxious. (FG) Breathlessness is frightening (things go round in your head) (FG)	Recognising and taking steps to manage depression, anxiety and other mental health aspects. (StQ-HPsych)		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
Cognitive function /memory problems		Learn about treatment options if appropriate (HF Assoc /ESC 2012 Tab27) Understand that cognitive dysfunction is common in patients with heart failure. (HF Assoc /ESC 2012 Tab27)			
Psychological adjustment /change in self concept		It's a bit of a shake up, so you need to put things back in order /get things back on track. (FG) You can't do the things you used to do (FG) May need to make	The aim here should be to help the individual to adapt his or her lifestyle, life goals and expectations to the challenge presented by heart failure. The individual should be able to move from being a person disrupted by heart failure to being a person living with and coping with heart failure. The sense of attaining some form of 'good-enough' control, a sense of 'safety' and acceptance of the limitations and the inherent	Include a "psychological and educational component". (CG108) People's reactions and responses to the development of heart failure vary considerably. Explaining and helping people to move	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		compromises (FG) Need to find other ways to get an enjoyable, healthy, active life (FG) "What we have to recognise is a new norm" (FG)	uncertainty of heart failure seem to be important here. This may include finding (or re-defining) the individual's role within the home and in the wider world and in relation to friends /family. (Qual MetaSyn, StQ-HPsych)	through the 'five stage process' of disruption, conception, reaction, response and assimilation might be helpful here. (Qual MetaSyn)	
Sleeping well		Engage in preventive behaviour such as reducing weight in obese patients, smoking cessation, and abstinence from alcohol. (HF Assoc, ESC 2012 Tab27) I stop breathing at night /fell more breathless at		Sleep apnoea (breathing problems during sleep) should be recognised and steps taken to manage it. This may involve weight loss in severely overweight persons, smoking cessation, abstinence from alcohol, or use of CPAP treatment (breathing masks) if needed. Elevation of the head during sleep,	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		might /when I lie down (FG) Learn about treatment options if appropriate. (HF Assoc, ESC 2012 Tab27)		and changing of eating and timing of diuretic medication may also be considered. (ESC,2008?)	
Monitor symptoms /progress	What they can do to be in control of their condition i.e monitoring weights, fluid restriction when appropriate etc. (StQ: HFN, HF/CR SN)	Monitor and recognise signs and symptoms and QoL. (HF Assoc, in ESC 2012) Record daily weight and recognize rapid weight gain. (HF Assoc, in ESC 2012) Patients would like to get feedback on some kind of clinical marker –	People with severe symptoms should (if recommended by HP) restrict fluid intake or take other measures to manage their fluid status. (StQ-HPsych) Need to specify what "severe symptoms" are. Also include symptoms of dizziness/ lightheadedness? (StQ HF/CR SN) Self-monitoring of symptoms, energy levels and other important outcomes to identify possible problems and solutions. (StQ HPsych) Self monitoring and how to recognise early signs of decompensation of HF ie orthopnoea/paroxysmal nocturnal dsypnoea/cough/oedema/ascites/inc	Self-care of heart failure can be defined as actions aimed at maintaining physical stability, avoidance of behaviour that can worsen the condition, and detection of the early symptoms of deterioration (ESC, 2008) In the case of increasing dyspnoea or oedema or a sudden unexpected weight gain of >2 kg in 3 days, patients may increase their diuretic dose	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		maybe BNP (but £25 a pop) – otherwise, can monitor progress in terms of QoL measure /how you are feeling (HF) - maybe monitor BP, energy levels, mood, PA? (HPsych) This is learnt as time goes on (StQ Patient) This needs to be part of regular reviews in primary care (StQ Patient) Recognize the common side effects of each drug prescribed (HF Assoc, ESC	SOB etc etc. And contact number so that patient can report this promptly to the Heart Failure team. (StQ: HF /CR Specialist Nurse) Chest pain management (StQ: HF/CR SN)	and/or alert their healthcare team (HF Assoc, ESC 2012, Tab 27)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		2012, Tab27)			
People with severe symptoms should (if recommended by HP) restrict fluid intake or take other measures to manage their fluid status			StQ approval 46% (and 38% think it should be included, but not for all patients.(Mixed sources) NB: This should be linked to monitoring of symptoms (HPsych)		
Manage Breathlessness		Learn about treatment options if appropriate. HF Assoc Learn how to assess your level of breathlessness and to be able to exercise at the right level /and to slow down before it gets out of control (FG) Breathlessness is frightening (FG)	Approval in StQ1 was 57/29% (StQ: Mixed sources)		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		Need to be able to recognise symptoms leading up to exhaustion (FG)			
Manage /organise the home and work environments		Suddenly the house you live in might not be suitable to live in – may need to live downstairs or even move house (FG)	Managing the Work environment might also be relevant for some people (access, workload, physical requirement). (REACH expert group workshop)		
Manage financial implications			Information about benefits that may be available and how to claim them. (StQ 67/19% approval: Mixed sources) Managing the financial burden (change in earnings, claiming benefits). (REACH expert group workshop)		
Smoking	Stop! (StQ: SNx5)	Avoid secondary smoking (StQ Patient)	StQ approval 53% (and 33% felt it should be an 'as needed' module). (StQ Mixed sources)	Stop. (CG108)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			Important to keep this in as smoking may be unnecessary as some patients may be non smokers only temporarily. (HMO Expert)		
Engage in sexual activity if desired		Be re-assured about of the safety of engaging in sexual activity, if desired. Explore concerns about sexual activity.(HF Assoc /ESC,2012 Tab 27)	Is erectile dysfunction a problem here? Can they use meds like Viagra? Who can they discuss such topics with? StQ1 for reassurance about engaging : approval 56 /34% (StQ: Mixed sources)	Discuss sexual activity if relevant to patient.(CG108) Be aware of and able to use possible strategies for prevention of dyspnoea (breathing difficulties) and chest pain during sexual activity (e.g. nitroglycerine tablets).(ESC 2008?) Women with HF should (if applicable) be aware of the potential risks associated with pregnancy and should discuss family planning	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
				issues with a physician. (ESC,2008?) Erectile dysfunction should be treated in the usual way; phosphodiesterase V inhibitors are not contraindicated other than in patients taking nitrates. Indeed these agents have favourable haemodynamic effects in patients with HF-REF. Phosphodiesterase V inhibitors may cause worsening LV outflow tract obstruction in patients with hypertrophic cardiomyopathy,which may be a concern in some patients with HF-PEF. (ESC 2012)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
Understanding the condition and its treatment /management	The earlier misconceptions are cleared up the better. (SCM-SN) Does high altitude include air travel? Need to be clear who to discuss travel with (StQ-GP, HFN, Patient FG).	Heart failure" suggests that there is no recovery. Need to address this early (asap!). (FG) Understand the cause of heart failure and why symptoms occur. (HF Assoc, in ESC 2012) Knowing symptoms /what it means. What are the symptoms that should ring alarm bells for a) stroke b) heart attack c) fluid retention /decompensation d) side effects . "is it heart problems or just old age?"	The earlier misconceptions are cleared up the better. (HPsych) What can be done to help and stress that HF doesn't mean they will drop dead tomorrow is what most patients want to know. (SCM) Understanding what each medication is for and when to take them and also what effects or side effects to expect (StQ-HPsych) Addressing concerns about medications, other treatments /interventions and their side effects. (StQ-HPsych) The need for the doctor or nurse to change the dosage or type of medications over time should also be understood.(StQ-HPsych) The details for air travel can quickly get out of date, so need to update facilitator training regularly. (StQ-HMO Expert) Over the counter medicines to avoid	"The goals of treatment in patients with established HF are to relieve symptoms and signs (e.g. oedema), prevent hospital admission and improve survival." (ESC 2012) Understand the cause of heart failure and why symptoms occur. (ESC 2012, Table 27) Understand prognosis /prognostic factors and make realistic decisions (ESC 2012, Table 27) Offer "education" tailored to patient needs. CG108 Air travel (CG108) Monitor for med side effects, fluid status, functional capacity,	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		(FG) Know how and when to notify healthcare provider. (HF Assoc, FGx2) Understand indications, dosing, and effects of drugs. (HF Assoc, ESC 2012) Know about side effects and what can be done to reduce them (FG) When travelling, carry a written medical history and current medication regimen and extra medication. (HFAssoc, ESC	because of possible worsening of heart failure (StQ: Pharmacist) Management of skin/oedema (StQ: HF/CR SN) Blood tests – why and when they are important (StQ: Pharmacist) Evidence base for medicines not as robust for HFPEF as for LVSD therefore medication advice may differ. Similarly for devices etc (StQ: HF/CR SN) Understanding of important medical terms such as ‘congestion’, ‘decompensation’. May not be essential, but could be helpful for some. (HPsych)	cognitive status, nutrition. CG108 *(patient, nurse, carer)* Know when /how to seek help (emergency and non-emergency). CG108 Discuss prognosis. CG108 High altitudes (1500 m or more) and travel to very hot and humid destinations should be discouraged for symptomatic patients. Planned travel should be discussed with the healthcare team. (ESC,2008?) NSAIDs should be avoided if possible as they may cause sodium and water retention, worsening	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		2012 Tab27) Prepare travel and leisure activities according to physical capacity. (HFAssoc, ESC 2012 Tab27) Monitor and adapt fluid intake particularly in hot climates. Beware adverse reactions to sun exposure with medications (e.g. amiodarone). HF Assoc Sometimes need specialist advice to help with medication dosing /adjustment (FG) What is heart		renal function and worsening HF (ESC 2012) "The aim of using diuretics is to achieve and maintain euvolaemia (the patient's 'dry weight') with the lowest achievable dose." (ESC 2012) "This means that the dose must be adjusted, particularly after restoration of dry body weight, to avoid the risk of dehydration leading to hypotension and renal dysfunction" (ESC 2012)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		failure (need this info at diagnosis). How does it occur? What are the symptoms? Why do some people get heart failure and others not? (FG) What is the problem and what can I do about it? (FG) Put things in layman's terms /non-technical language (FG) How much better can I expect to get from where I am now? (FG) Knowing how to explain the problem			

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		/symptoms to HPs (FG) Need to understand why the fluids build up and what to do about it. (FG) We're all different – some hearts beat too slow, some too fast – some need implants, some don't – So information needs to be tailored. (FG) What side effects might medications cause (e.g. panic attacks) – can they be reduced (e.g. by changing medication). When to contact			

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		HP about side effects. (FG)			
Diet and weight management		Sodium restriction may help control the symptoms and signs of congestion in patients with symptomatic heart failure classes III and IV. HF Assoc Eat healthily and keep a healthy weight. HF Assoc Monitor and prevent malnutrition. HF Assoc Avoid excessive fluid intake in severe HF. HF Assoc	Make changes to diet to reduce weight if Body Mass Index is more than 30Kg/m2. However, this is not recommended for people with evidence of cachexia (involuntary weight loss /body wasting).(StQ1) 76% (and 14%) approval for eating healthy and maintaining a healthy body weight (StQ mixed sources)	Some approaches may not be beneficial, e.g. advice to restrict sodium intake. ESC 2012 Obesity should be managed as recommended in other guidelines (ESC 2012) Iron deficiency may contribute to muscle dysfunction in HF and causes anaemia. May be treated with iron therapy (supplements) (ESC 2012)	
Alcohol		Modest intake of		Patients with alcohol-	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		alcohol (2 units per day in men or 1 unit per day in women): abstinence for patients with alcohol-induced cardiomyopathy. HF Assoc		related heart failure to abstain. CG108 Discuss consumption with other patients and tailor advice to circumstances. CG108	
Taking meds		Increase diuretic dose and/or alert healthcare team if increasing dyspnoea or oedema or sudden unexpected weight gain (>2 kg in 3 days). (HF Assoc, in ESC 2012, Tab 27) Use flexible diuretic therapy if appropriate and recommended		Titration of diuretics, **as needed**, for congestion and fluid retention. CG108 Regular taking of other meds, as outlined in CG108 Many patients can be trained to self-adjust their diuretic dose, based on monitoring of symptoms/signs of congestion and daily weight measurements. (ESC 2012)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		after appropriate education and provision of detailed instructions. (HF Assoc, ESC 2012, Tab 27) The aim is to use medications in the best way to help you function positively (StQ) Useful to talk with the pharmacist. Discuss changes, ask for bubble packs (pre-packed daily medication combinations) (HF) Understanding of dose changes and titration is too much but a ‘how		Patient involvement in symptom monitoring and flexible diuretic use (HFA and Table 26 in ESC 2012) In the case of increasing dyspnoea or oedema or a sudden unexpected weight gain of >2 kg in 3 days, patients may increase their diuretic dose and/or alert their healthcare team (HF Assoc, ESC 2012, Tab 27)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		to' approach to identify when things need to change could work.(StQ: SN) Self-titration should be optional for those patients who feel they would like to take this on. (StQ: SCM) Some patients may not be comfortable adjusting dose themselves, so need to agree a strategy with the HFN (FG)			
Correct use of devices (e.g. Implantable Cardiac Defibrillator,			Understanding how to manage and respond to device alarms, where appropriate. StQ Approval 14 /71%,so recommended where such devices are in use. (Stq: Mixed		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
Cardiac Resynchronization Therapy).			sources) The nurse's role here may be to simply identify the problems and then refer for more specialist advice. (HPsych)		
Communication with Health Professionals			How to achieve clear and appropriate communication with healthcare professionals (StQ HPsych)		
Helpseeking	We need a big push on early warning signs (StQ: HF/CR SN)	When to contact HP about side effects. (FG) This is learnt as time goes on (StQ-Patient) – This needs to be part of regular reviews in primary care. (StQ-Patient)	Ask for help from (your heart failure nurse, GP) if you are not coping (StQ) **You should seek help from a GP or HF nurse when you:-** - Have sudden Weight gain that does not respond to adjustment of diuretic dosage (CRN) - Feel the symptoms or worries are hindering your confidence to effectively self-manage. - Have an increase in breathlessness	Deterioration in symptoms indicates heightened risk of hospitalization and death, and is an indication to seek prompt medical attention and treatment. (ESC 2012) Know how and when to notify healthcare provider (HF Assoc, ESC 2012, Tab 27)	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			or fatigue, especially when at rest - Feel that the plan isn’t working and QoL is deteriorating - Consistently feel ’’down or in a low - mood’’ - Notice a step change in your ability to do basic daily activities - Are unable to take medication – need to say for what reasons (Patient FG) - Are on Warfarin and have bruising or bleeding (Patient) - or your partner /caregiver have further questions and concerns about the condition or about planned investigations /procedures. (HFN) - Have serious problems sleeping or breathing during sleep (CG) - Your partner/carer is struggling to cope or has medical needs of their own that are worsening.(Pharmacist) - Experience episodes of vomiting		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			and diarrhoea (they may need adjustment of diuretic dosages). (HF Nurse) - Have worsening shortness of breath /PND or oedema (HF/CR SN) - Have increasing frequency of chest pain (HF/CR SN) - Have an increase in sputum expectoration/ dirty sputum (HF/CR SN) - Have unusual palpitations (HF/CR SN) - Experience symptoms which might indicate side effects of drug therapy (Pharmacist) (StQ, Mixed sources) - A guidance booklet or card (optional) and a page in the manual formatted as a 'traffic light' system may be appropriate here (HPsych) - Traffic light system is a definite		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			must as most of us are now using this approach and resource now available via CHSS. (HF/CR SN) **You should seek emergency care (go to hospital or call an ambulance) if you have:-** - Loss of consciousness - Chest pains or sudden onset of palpitations (potential arrhythmia) - If ICD (implanted defibrillator) shocks are applied (for patients with these devices) - Unrelieved shortness of breath while sitting still (HFN x 2) - Acute increase in shortness of breath (HFN) - Coughing up frothy, pink sputum (HFN) - Distressing sudden breathlessness especially at night (HF/CR SN) - Patient not responding to treatment (HF/CR SN)		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			A guidance page or (optional) booklet formatted as a ‘traffic light’ system may be appropriate here (H Psych) Ensure DNR discussed or covered somewhere in booklet (HF/CR SN) I’d divide emergency care into a) blue light and b) GP or out of hours GP callout. For example, anuria may not be a blue light problem, but the GP would certainly want to know within a few hours. (Pharmacist)		
Engaging support from others (e.g. friends, family) to support self-care	Need to be sure not to undermine confidence for people who don’t have support.	Need to be careful not to push this as being essential. Need re-assuring messages /alternatives for people with no social support” (1. Patient FG 2. SCM) Access to support from others in the	This should include ideas about information support, emotional support and practical support.(StQ-HPsych) Engaging support: This can be done in the manual. A separate resource has been popular (patient audit feedback). (StQ-HMO Expert) Negotiation of the role of any caregivers /supporters. (StQ 61/19%: Mixed sources)		

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
		same situation should be facilitated. E.g. through access to a local support group. (Patient FG)			
Maintain social roles /social relationships		Maintain social roles /relationships. (Interviews with caregivers)	Maintain social roles /relationships. (REACH expert group workshop)		
Managing co-morbidities (other illnesses) that might affect the ability to manage heart failure			Approval in StQ1 was 38/47%. (StQ Mixed sources) Over one third of CVD patients have one or more significant co-morbidities including COPD and arthritis. Co-morbidity is linked with poor prognosis and poor recruitment to lifestyle initiatives (SCM). This may include strategies for remembering to take medications regularly (e.g. pre-loaded pill boxes) and discussion of options with a	Important co-morbidities include anaemia, angina, arthritis, diabetes, COPD and asthma, cachexia, cancer, depression, erectile dysfunction, gout, hypertension, hyperlipidemia, iron deficiency, kidney dysfunction, renal dysfunction, sleep	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
			pharmacist. (HPsych) Mobility limitations (from arthritis or otherwise) are also important because they can interfere with /act as barriers to exercise-based rehabilitation. (HPsych)	disturbance, prostatic obstruction and obesity. (ESC?) Management of co-morbidities is a key component of the holistic care of patients with HF (ESC 2012) Co-morbidities may affect the use of HF treatments; drugs used to treat co-morbidities may cause worsening of HF or interact with HF drugs (e.g. NSAIDS); and they may worsen HF outcomes (ESC 2012) Obesity should be managed as recommended in other guidelines (ESC 2012)	
Manage end of life issues	It is worth discussing	Prognosis – how long have I got?	Even if we decide to exclude end stage HF patients there may be	Ensure opportunity at all stages of care to	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
	mortality and the possibility of sudden death. Carers in particular are disappointed /shocked that they were not prepared for this when it happens and they haven't had time to engage in any end of life planning. (CRN)	(FG)	concerns about the palliative stage that people may have even if they are at an earlier stage in their illness which should be addressed either in the manual or via the facilitator e.g. decisions about deactivating ICD, do not resuscitate (DNR) orders and living wills. (H Psych)	discuss issues of sudden death and living with uncertainty. CG108 Identify and manage palliative care needs as soon as possible. CG108 Ensure access to HPs with skills in palliative care. CG108 Frequent assessment of patient's physical, psychological, and spiritual needs. ESC2012 Focus on complete symptom relief from both HF and other co-morbidities. ESC2012 Advanced care planning, taking account of preferences for place of death and	

Programme objectives (behl, psychl, envl outcomes to be targeted)	**Nurses**	**Patients /patient groups**	**Other**	**Guidance / evidence**	**QoL domain addressed (MLHFQ)**
				resuscitation (which may include deactivating ICD). ESC2012 The nurses' role here may be simply to identify and refer.	

Other cross-cutting ideas (and source):

NB: The following may need to be incorporated into Table 1 as Programme Outcomes /Objectives, or they may pertain to the content or delivery of the training manual /training course rather than the HF Manual itself

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care. (NICE CG108)

Treatment and care should be patient-centred, taking into account patients' individual needs and preferences. (NICE CG108)

Treatment should be delivered as part of an integrated approach to care delivered by a multidisciplinary team. (NICE CG108)

A meta-analysis of RCTs suggests that structured telephone support in addition to conventional care may reduce the risk of hospitalization in patients with HF. (ESC guidance, 2012)

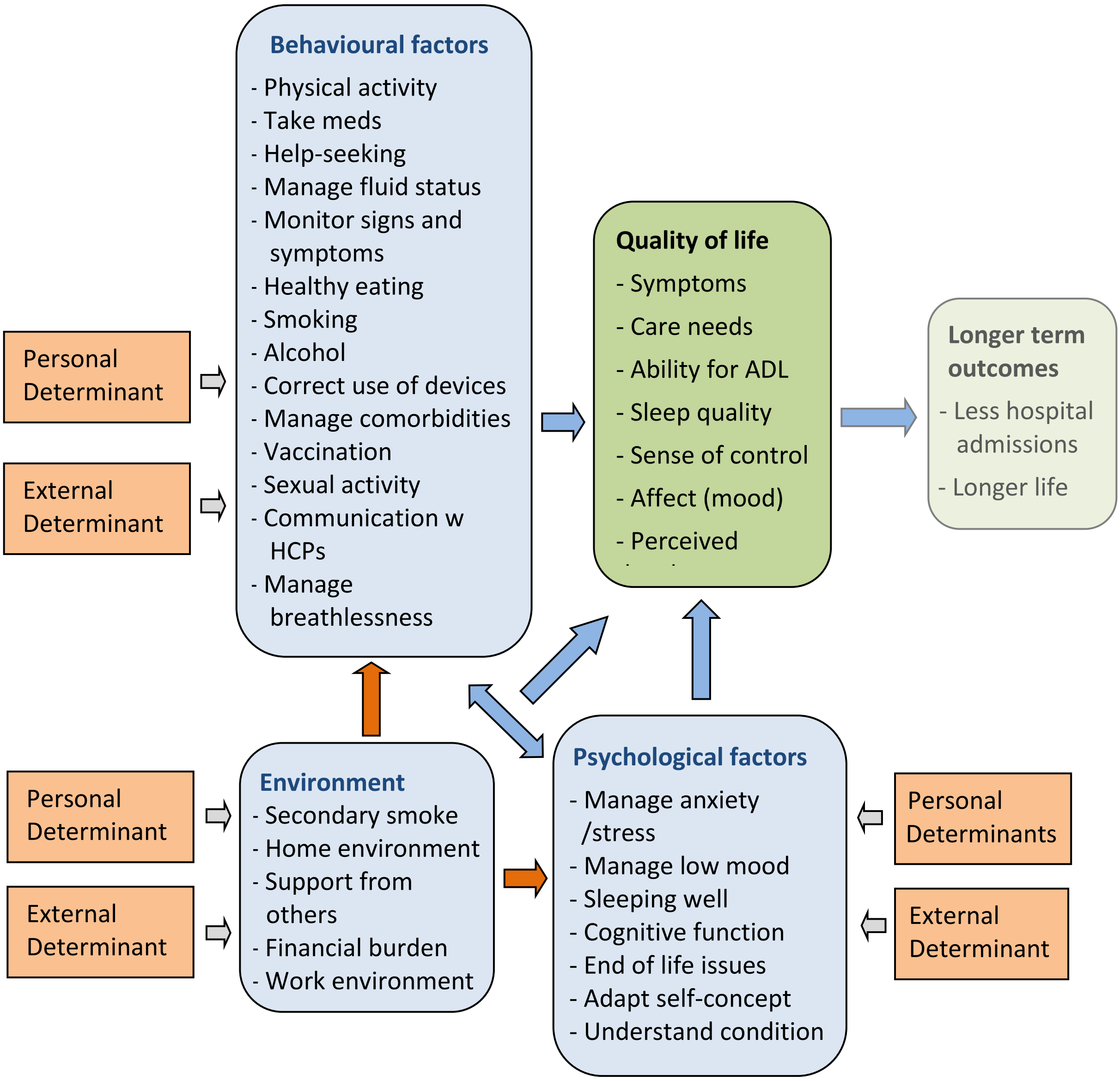

Fig. 2: Applying the PRECEDE planning model to the self-management of heart failure: *The following diagram shows how the programme outcomes /objectives identified above relate to the overall intervention model*

Over-arching themes:

1. Engaging with the intervention

2 .Ongoing (lifelong) adherence to self-care behaviours

Additional File 3: Extracts from intervention maps for stress management, medication management and managing symptoms (NB: These are only selections from the full intervention maps for each topic).

Table 3.1 Extract from the REACH-HF intervention map for the change target "Support patients and /or caregivers to manage stress, anxiety and breathlessness". NB: this is only a selection from the full intervention map for this change target. Other performance objectives (not shown) were "3. Ongoing use (maintenance) of stress recognition and stress management actions; 4. Prevention of stress; 5. Recognise when breathlessness (due to acute stress or anxiety) becomes problematic; 6. Manage breathlessness".

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
1. Recognise problematic levels of stress	*Knowledge /motivation:*- Belief that it is worth bothering about (perceived	[b] Provide information on identity, timeline, causes, consequences and control to build a functional	Nurse to check for and address misconceptions. What do you know about how stress affects your heart condition? (F)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
(including acute and chronic stress and anxiety) *For action by:* Patient Facilitator Caregiver	importance and treatment efficacy) Knowledge of signs and symptoms and different types of stress (chronic, acute) Understanding what is normal and what might be problematic	understanding /illness model (how stress works and how to manage it) [a] Provide information on consequences [b] Simultaneous self-monitoring of behaviour and symptoms (linking use of stress-management techniques to stress levels, sleep quality and HF symptoms; linking physical activity and stress	Explain how stress affects heart failure symptoms (and vice-versa). Explain how stress works and how it can be managed (give hope!) (F,M) Provide normative information about others' experiences of stress. Can include a good news case study or Patient Voices (quotes) "having a heart problem made me realise what was important in life – I don't fret about the small stuff so much these days" (M)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
		levels)	Provide information on behavioural patterns indicative of stress (e.g. via case study) (M)
	Skills: Self-awareness (skills for symptom recognition /categorisation) Prior experience of recognising and managing stress	[a] Model/ demonstrate the behaviour (through case study) [a] Set graded tasks (gradual capacity building for stress-recognition /categorisation skills) [a] Prompt practice [b] Self-monitoring of symptoms	Self-assessment using HADS or stress assessment scale (M) Facilitated assessment if needed using HADS or stress assessment scale (F) Self-assessment of stressors (what causes stress for the individual /what the most common causes are – e.g. sleep disturbance, palpitations; mood swings; concentration

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			issues; lack of coping strategies) (M) Nurse to Identify existing strengths /skills and positive attitudes (F)
	Social /contextual: Social support /encouragement	[a] Plan social support [a] Prompt barrier identification and problem solving [b] Engage health care support	Problem-solving in relation to engaging social support /seeking help if needed (F) Encourage P to open up a conversation with significant other and vice versa (discuss how patient may be coping/how carer may be coping) (F, M, CGM)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
	Other: Avoidance of the issue (e.g. due to fear of consequences)	[b] Cognitive behaviour therapy (to address reasons for denial /minimisation) [b] Referral for medical intervention	Briefly reflect on /explore reasons for avoidance of the issue (need to be careful not to exceed professional competencies here). Link to manual sections on living with uncertainty /end of life issues) (F)
	Side effects of medication (affecting cognitive function, or as a direct cause of anxiety /stress symptoms)		Consider medications as a possible factor and prompt to seek advice on changing meds if appropriate (F) Signpost to contact with other health professionals /other services if needed (F)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
2. Manage stress (including acute and chronic stress and anxiety). i.e. Taking action once abnormal stress has been identified *For action by:*	*Knowledge /motivation:* - Perceived importance (why should stress be managed?) - Treatment efficacy (belief that something can be done about it) - Knowledge about how to access appropriate help - Self-efficacy (can I do it? (e.g. relaxation techniques))	[b] Provide information on identity, timeline, causes, consequences and control to build a functional understanding /illness model (how stress works and how to manage it) [a] Provide information on behaviour /health link [a] Provide information about consequences of behaviour	See section above (*PO1 Knowledge*): Nurse to check for and address misconceptions (F); Explain how stress affects heart failure symptoms, how stress works and how it can be managed (F,M); Provide normative information about others' experiences of stress (M); Provide information on behavioural patterns indicative of stress (M); Outline evolutionary purpose of stress and illustrate how that can be maladaptive today. (e.g. fight or flight reaction) (M)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
Patient Caregiver		[a] Prompt intention formation (for stress management)	Reinforcement from facilitator (and in relaxation CD) promoting the importance of stress management (F, M) Prompt self-monitoring of outcomes and relate progress /changes to actions (to help understand what works /what doesn't work for the individual) (M, F) F to discuss /summarise reasons for engaging in stress-management and prompt intentions for stress management /following text in the

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			manual on potential benefits (M, F)
	Skills Existing stress management skills and prior experience	[a] Stress management (multiple techniques) [a] Provide instruction (how to do relaxation techniques) [a] Prompt practice (of stress management skills /relaxation techniques)	Text in manuals and CD with selected, easy to learn /use, mindfulness and techniques and other alternatives (e.g. progressive relaxation, diaphragmatic breathing, visualisation) for managing acute stress (M) Prioritisation of what is really important to achieve in a day/week (M) Encourage communication with others to resolve sources of conflict (e.g. using

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
		[a] Prompt practice (of pleasurable activities) [a] Set graded tasks [a] Prompt specific goal setting [b] Prompt self-monitoring of outcomes [a] Prompt barrier identification and	assertiveness methods to outline personal needs and negotiate support). Esp. discussion between cared for and caregiver (M, F, CGM)) Provide information about when to seek help from GP and counselling or mental health services (M, F) Provide checklist of ‘red flag’ signs to prompt appropriate help-seeking (M, F)

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
		problem solving [a] Model/Demonstrate behaviour [a] Teach to use prompts/cues [a] Relapse prevention	Plan for 'Me' time – within the home and outside the home (M, CGM) Tips on avoiding stressors – e.g. Where available /relevant, sleeping in a separate room may allow better sleep; listening to music, reading, spending time with family/ pets, hobbies: gardening etc (M, F) Nurse support during the intervention and referral to an alternative support system (if needed) at the end of the intervention (F)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			Demonstrate selected relaxation /stress management techniques including breathing & progressive relaxation if useful (F) Encourage social Interaction /having fun as a way to ameliorate stress (M) Prompt identification of opportunities for practising stress management by giving examples via case studies or tips (M, F)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			Address & support solutions to barriers /resistance to practising stress management via discussion (F) and providing examples via case studies or tips (M) Prompt use of environmental cues to remind individuals to carry out stress management activities. Provide tools to practice stress reduction e.g. relaxation CD with exercises to follow (M, F)
	Social /contextual:	[a] Plan social support	Promote use of social support structures –

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
	- Social support /encouragement - Lack of time (for practice) - Access to referral (if needed) to appropriate health service	[b] Engage healthcare support	texting, support groups, extended family, friendships (M, F, CGM) ‘Patient Voices’ in quotes /illustrations on the importance of managing stress and benefits of using relaxation techniques. Signpost to sources of respite care to help with caregiver stress if needed (F, CGM) If needed, Nurse to facilitate referral to appropriate health service provider (e.g. for

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			clinical levels of depression or anxiety) (F)

*M = Manual content; F = Facilitator task; CGM = Caregiver Manual

[a] Techniques listed in the Abraham & Michie (2008) taxonomy.[1]

[b] Techniques not listed in the Abraham & Michie (2008) taxonomy.

Table 3.2 Extract from the REACH-HF intervention map for the change target "The patient (and caregiver if appropriate) should manage their heart failure (and other) medications using them in such a way as to optimise their physical condition and mental well-being /quality of life". NB: this is only a selection from the full intervention map for this change target. Other performance objectives (not shown) were "1. The patient (and any caregivers /supporters) should have a clear understanding of how to use their medication as a key part of the management of their HF; 3. Recognising and monitoring side-effects; 4. Taking appropriate action if medication missed; 5. Taking appropriate action during other illness (e.g. gastric upset, cold); 7. Self-management /self-titration of diuretics where the patient is willing and the GP /heart failure team is in agreement.

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
1. The patient should take all their medications as prescribed (and	*Knowledge /motivation:* - Knowledge about what to take, how and when - Beliefs about medication	[a] Provide information on consequences [a] Provide instruction	Nurse (and text in manual) to explain about medication, how /why medication may change, type of medication and dose of medication (F, M)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
consult a health professional if there are any problems in doing this) *For action by:* Patient Caregiver	effectiveness (treatment efficacy /expectations of benefit or harm) - Beliefs about seeking health care support if any problems - Patient concerns /past experience (esp. about side effects) - Carer's concerns/past experience - Trust in prescriber - Confusion over branding	[b] Simultaneous self-monitoring of behaviour and symptoms (linking use of medication to well-being and HF symptoms). [a] Motivational interviewing [b] Engage healthcare support	Provide normative information about how other people benefit /what to expect from your medication (M) Possible case study or use of 'Patient Voices' in quotes /illustrations on attitudes to medication-taking (M) Nurse to identify any patient concerns, problems or reasons for non-adherence, address any misconceptions and work with patient (and wider health care team if needed) to seek solutions (F)

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
	/packaging /how and how many to take - Consistency of messages from different care staff (mixed messages)		Advise patient to use regular pharmacy for repeat prescriptions to minimise confusion (pharmacists don’t always use the same brand) (F, M) See sections elsewhere on making an ‘emergency plan’ in case of serious side effects decompensation or fluid build-up (M, F) Travel advice: When travelling, carry a written medical history and current medication regimen and extra medication. High altitudes

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
			(1500 m or more) and travel to very hot and humid destinations should be discouraged for symptomatic patients. Planned travel should be discussed with the healthcare team. Beware adverse reactions to sun exposure with some medications. Details for air travel advice can change, so facilitator needs to stay updated (M, F) Follow up performance (symptom changes in relation to adherence, any side effects) (F) Encourage patient /caregiver to discuss with

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
			facilitator or GP if they have any concerns or queries about their medications, or any problems in taking them (M, F) The nurse facilitator should check if any of the information covered conflicts with anything else the patient has been told and seek to resolve any conflicts (contacting other HPs involved if necessary) (F) Text in manual on common barriers to taking medication and possible solutions. (M)

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
			Facilitation to elicit any other individual barriers and possible solutions(F)
	Skills - Memory/ cognitive function	[a] teach to use prompts/cues [a] Use of follow up prompts [a] Prompt barrier identification (and problem-solving) [a] Prompt self-monitoring of behaviour	Discuss use of dosette box or pharmacy system to help organise meds (F, M) Include a simple check on medication adherence (and a medication plan) in the planning /monitoring resource (M) Record changes to medication – when, who, why (M) Facilitator to assess whether patient has

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			cognitive abilities to take medication as prescribed (F) Encourage use of aide-memoires for taking medication – organisation system – Diary? Alarm on phone (M, F) Text in manual on common barriers to taking medication and possible solutions. (M) Facilitation to elicit any other individual barriers and possible solutions(F)
	Social /contextual:	[a] Plan social support	Involve carer in monitoring medication use –

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
	- Changes in circumstances - Eyesight - Environment (e.g. holidays /travel) - Social support (esp. caregiver and other family - Presence of side-effects - Support from GP /care team around managing any problems	[b] Engage health care support [a] Prompt barrier identification	may need to facilitate some negotiation between caregiver and patient about what the caregiver's role is here (F, CGM, M) See above re text on travel advice (M) Nurse to work closely with specialist nurse, clarification of roles, clear communication strategy and pathway, facilitator to contact specialist nurse or GP re changes needed to medications /managing of side effects etc (F) Nurse to identify any other patient concerns,

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			problems or reasons for non-adherence, address any misconceptions and work with patient (and wider health care team if needed) to seek solutions (F) Assess whether eyesight good enough to read labels (F)
6. Avoiding over-the-counter (OTC) medications and supplements if	• Knowledge • Social support • Health care support (pharmacist)	[a] Provide information on consequences (and general information) [a] Plan social support	Prompt P and CG to ask pharmacist about *any* OTC medication or supplement purchases (M, F) Recommend using a regular pharmacist who knows you have HF (M)

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
harmful *For action by:* Patient Caregiver		[b] Engage healthcare support	Carry prescription or medication record with you to show pharmacist if unable to use the regular system (M) Highlight that OTCs can contain a variety of medications that can affect the way your HF medications work e.g. cold remedies –Aspirin (M) Positive messages around safe options (e.g. Paracetamol and drinking honey/lemon/water as a lay remedy for colds that soothes sore

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			throats and is not harmful) (M) Engage caregiver in checking /monitoring here (and also to know that they should not buy these products for the patient) (CGM)

*M = Manual content; F = Facilitator task; CGM = Caregiver Manual

[a] Techniques listed in the Abraham & Michie (2008) taxonomy.[1]

[b] Techniques not listed in the Abraham & Michie (2008) taxonomy.

Table 3.3 Extract from the REACH-HF intervention map for the change target “The patient should monitor and respond to Signs and Symptoms of Heart Failure – this is important to inform appropriate help-seeking and also for managing fluid status”. NB: this is only a selection from the full intervention map for this change target. Other performance objectives (not shown) were “1. Monitor symptoms of heart failure (general); 4. Detecting other signs and symptoms (e.g. heart attacks, change in mood)”.

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
2. Self-Monitor specific symptoms related to decompensation *For action by:* Patient	*Knowledge /Motivation* Knowledge of signs and symptoms of decompensation Knowledge of potential causes of decompensation Knowledge of normal	[b] Provide information on identity, timeline, causes, consequences and control to build a functional understanding /illness model (how fluid build-up can happen in HF, the consequences and how to manage it) [a] Provide information on	Provide a clear rationale for monitoring fluids /symptoms relating to decompensation (M, F) Provide information on decompensation symptoms: Oedema, sudden weight gain, breathlessness, coughing, nocturnal dyspnea, fatigue etc. (M) Provide Information on when /how to contact

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
Caregiver	/acceptable levels of symptom severity /what levels should trigger action Belief that symptom monitoring will improve QoL (treatment efficacy) Knowledge of potential cause of sleep disturbance in relation to symptoms Knowledge of how and when	consequences [a] Motivational interviewing	healthcare provider (M, F). Quiz /checklist to help actively process information (M)

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
	to notify healthcare provider		
	Skills Skills in measurement /assessment Belief that patient can take the actions needed (self-efficacy)	[b] Prompt self-monitoring of outcomes (decompensation-specific symptoms) [a] Barrier identification (and problem-solving) [a] Modelling [a] Motivational interviewing	Identify any possible barriers to self-monitoring (e.g. ask 'what might stop you'; present several typical barriers) and discuss possible solutions (NB: it is ideal if patient generates the ideas, but can also put some examples in the manual) (M, F) Use of monitoring tools in a symptom diary or checklist. Include traffic light tool mentioned elsewhere (appropriate help-seeking section) (M). Including ..

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
			- Ankle circumference - Weight - Other symptoms Case-study including daily self-monitoring (M)
	Social /contextual: Social support (esp. people who live with patient and can help with monitoring) Cognitive functioning	[a] Plan social support [a] Barrier identification (and problem-solving) [a] Motivational interviewing	Identify social and contextual /other barriers to self-monitoring and discuss possible solutions (NB: it is ideal if patient generates the ideas, but can also put some examples in the manual) (M, F)
	Other	CBT to address avoidance issue	Nurse to assess and address any reluctance

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
	Avoidance of the problem. This may stem from not wanting to think about HF due to anxiety /fear, or it may stem from not wanting to appear weak or vulnerable (self concept issues).		to engage /avoidance issues (F) Engage caregiver /other co-habitees in helping to monitor (F, CGM)
3. .Prevention of decompensation through management of	Knowledge about decompensation and its causes (as above)	[b] Provide information on identity, timeline, causes, consequences and control to build a functional understanding /illness model	Information on what decompensation is /its causes (M, F), including • Fluid overload • Poor medication concordance

Performance Objective	**Modifiable determinants of change**	**Change Techniques**	**Strategies**
fluid status and taking medications	Self-efficacy(confidence about being able to take the actions needed) Social support Quality of health care support	(how fluid build-up can happen in HF, the consequences and how to manage it) [a] Prompt specific goal setting [a] Barrier identification /problem-solving [a] Plan social support Engage health care support	- Illness; infection, event e.g. MI Information on signs and symptoms of decompensation and appropriate action to take if it occurs (or starts to build up) (M, F) - Case-study - Quiz - Danger signs /red flag symptoms Include a ‘traffic light’ action-planning guide as part of the self-monitoring tool to guide appropriate action – green = no problem, keep going; amber = check self-care

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
			behaviours and monitor more closely, adjust diuretic dose as instructed (or call GP or HF nurse for guidance) (maybe take it easy /manage fatigue); red = seek help urgently) Strategies to support taking medication are specified in the "Taking medications" section. Engage caregivers /co-habitees in fluid monitoring /management (CGM, F) Encourage wider advice-seeking and /or help-seeking, as appropriate from health care

Performance Objective	Modifiable determinants of change	Change Techniques	Strategies
			system (F, M) Nurse to provide emergency (and non-emergency) help numbers for using the local system and record in manual (F, M)

*M = Manual content; F = Facilitator task; CGM = Caregiver Manual

[a] Techniques listed in the Abraham & Michie (2008) taxonomy.[1]

[b] Techniques not listed in the Abraham & Michie (2008) taxonomy.

References:

1. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol 2008;**27**(3):379-87.

Additional File 4: REACH-HF Facilitation Stages

Stage 1 – Introducing the intervention

This stage is characterised by a meshing of the facilitator's (health) agenda with that of the patient (and caregiver)'s individual agenda to produce a joint approach regarding the nature and pace of the intervention.

- Needs assessment/appraisal of patient (and caregiver)'s current situation including some history taking.
- Eliciting patient's key priorities – using the manual topics to facilitate these if the patient does not identify issues.
- Manual is introduced – emphasis on reading the manual in bite-size / 'cup-of-tea size' chunks.
- Progress tracker is introduced – main emphasis on traffic lights, completing daily weight section, and exercise section. (NB. Other sections may also be highlighted and discussed in the first session.)
- Physical activity programme discussed and agreed. CBE DVD introduced as applicable. Initial exercise goal set.

(Other topics may be discussed and goals set depending on the individual needs and capacity of the patient.)

- (Where applicable) caregiver resource introduced and caregiver involvement emphasised.

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Stage 2 – During the intervention period

This stage is characterised by the patient (and caregiver) learning how to engage with the facilitation role, how to use the materials, and individual application of new learning and behaviours.

- An initial treatment plan is identified and agreed. This is responsive to the individual.
- The facilitator continues to signpost to the manual as well as having in-depth discussions about topics.
- The facilitator encourages use of the materials – including Progress Tracker, DVD and CD (as applicable).

- The progress tracker is used for monitoring and review.
- New patient priorities may be identified and incorporated into the intervention plan (either addressed directly or via onward referral).
- Problem solving and revisiting key topics as required.
- Caregiver involvement and caregiver needs explored and responded to.

Stage 3 – Bringing the intervention to a close

This stage is characterised by review and reflection, and future and forward planning.

- Prior to the final session the facilitator reminds the patient (and caregiver) that the intervention is coming to an end.
- The facilitator encourages the patient (and caregiver) to identify any unaddressed issues prior to the final session.
- Reflection and review are used to highlight and celebrate progress made, and to identify skills and approaches that will help deal with any setbacks and with long-term maintenance.
- Future planning includes:
    - goal setting (to continue with current behaviours e.g. daily weighing, and/or inclusion of new ones e.g. increase exercise level – if applicable)
    - withdrawal of facilitator support and signposting to who to contact if further support is required (e.g. HFSN, GP, carer support group)
    - strategies for managing setbacks
    - self-monitoring strategies e.g. where to record information previously recorded in tracker
    - ongoing use of the manual as a reference guide

Additional File 5: Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) – Feasibility study

A multicentre single-arm intervention study with parallel process evaluation to assess the feasibility and acceptability of the REACH HF manual for patients, facilitators and caregivers.

END OF STUDY REPORT [with outcome data at follow up redacted]

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1. EXECUTIVE SUMMARY

Background

The REACH-HF feasibility study was a multicentre single-arm feasibility study with parallel process evaluation to assess the feasibility and acceptability of the REACH HF manual for systolic HF patients, their caregivers and facilitators delivering the intervention. The feasibility study was conducted in preparation for a fully powered randomised controlled trial assessing the clinical effectiveness and cost effectiveness of the HF Manual vs. usual care in patients with systolic HF and a separate single centre pilot trial in patients with HFpEF.

Study aims

Research aims:

- To assess the feasibility and acceptability of the addition of the HF Manual to usual care for systolic HF patients, caregivers and intervention facilitators.
- To assess the fidelity of HF Manual delivery by intervention facilitators.
- To evaluate components of the study process to inform the main randomised controlled trial design: feasibility of outcome data collection processes, and outcome burden and completion/attrition rates for patients and caregivers.

Intervention development aims:

- To identify any further training needs for the intervention facilitators.
- To identify any changes needed in the HF Manual.
- To finalise the content and format of the HF Manual and training materials

This report provides a summary of the outcome of the REACH feasibility study against the research aims.

Methods

The study used a four centre (Birmingham, Cornwall, South Glamorgan and York) single-arm design with a parallel process evaluation. Following identification and recruitment, patients with systolic HF received the HF manual intervention which was delivered over a period of 12 weeks by trained intervention facilitators, in addition to their usual care. The parallel process evaluation utilised qualitative methods and an observed structured clinical assessment using an intervention fidelity checklist in the context of delivering the REACH HF Manual to people with systolic HF. Multiple rounds of data collection and interaction with the intervention facilitators delivering the intervention generated feedback that informed both changes to the HF Manual, and changes to the training materials (i.e. the way the HF Manual is delivered by the intervention facilitators). The patient and caregiver outcome measures planned for the main trial of clinical effectiveness and cost-effectiveness were collected pre- and post- intervention in this study, in order to test procedures for collection, burden for patients, completeness of data collection and the rate of patient attrition/loss to follow up.

Results

Recruitment of patients and their caregivers took place over the 12 week period from 1st March 2014 to 31st May 2014, a one month extension on the planned 2-month period due to delayed excess treatment costs (ETC) agreement and delayed recruitment start at one centre (York). A total of 23 patients and 12 caregivers were recruited – meeting the recruitment target for the study. A total of 7 intervention facilitators were recruited.

- REACH-HF manuals appear to have been well accepted by patients, caregivers and facilitators.
- Patients and caregivers were highly satisfied with REACH-HF intervention.

- There was a need for some modifications to the manual content and format & facilitator training.
- Fidelity scoring indicated adequate delivery for most aspects of the intervention by all the facilitators
- Two items (addressing emotional consequences of being a caregiver and caregiver health and well-being) need reinforcement in future intervention delivery.
- There were generally excellent levels of outcome completion and patients/caregivers perceive relatively low outcome burden.
- A number of patient and caregiver outcomes following REACH-HF intervention showed evidence of improvement (with all caveats of a small population of selected participants and the study design of pre-post comparison with no control group).
- No safety issues were identified.
- The incremental shuttle walk test (ISWT) was not universally popular with patients and failed to show change over time

Conclusions
Following the feasibility study and discussion with the Programme Steering Committee (PSC), a small number of revisions to the main trial processes were implemented and are detailed in this report.

2. INTRODUCTION

Heart failure (HF) is becoming more prevalent worldwide and in the UK around 900,000 people have HF. Two editorials in the *Lancet* (2011) highlighted the current challenges of HF management, including the need for patients to be admitted to hospital or receive specialist care for extended periods, and the resulting financial costs of up to £1 billion per year.

There is no ‘cure’ for HF. Treatment includes medication and a range of self-management activities including exercise, planning and pacing activities of daily living, adjusting medication dosage, managing the emotional consequences of having heart failure, monitoring for signs and symptoms of deterioration, and communicating with health professionals.

Cardiac rehabilitation (CR) can be defined as ‘the process by which patients with cardiac disease, in partnership with health professionals, are encouraged and supported to achieve and maintain optimal physical health’. A Cochrane systematic review of exercise-based CR for HF identified important quality of life benefits in participants, as well as reductions in HF admissions compared with usual care. Based on this evidence, in 2010 the National Institute of Health and Care Excellence (NICE) recommended offering CR based on supervised group exercise CR for people with both systolic and diastolic HF. Despite this recommendation, our recent survey indicates that few UK centres (16% of those surveyed) currently have a specific CR programme for those with HF. The UK uptake of CR for people with HF therefore remains poor. We believe an important potential solution to this poor provision and uptake is the development of a home-based self-help CR manual designed to meet the needs of people with heart failure and their caregivers.

REACH-HF is funded by a Programme Grant for Applied Research (reference number RP-PG-1210-12004) awarded by the National Institute for Health Research. Details of the various REACH HF work packages are available elsewhere (http://www.rcht.nhs.uk/RoyalCornwallHospitalsTrust/WorkingWithUs/TeachingAndResearch/ReachHF/ResearchProjects.aspx). The overarching aim of REACH-HF is to develop and evaluate a facilitated, home-based HF manual to enhance quality of life and self-management of people with HF and their caregivers.

Since the beginning of the REACH HF project in January 2013, the focus of the project has been the development of a facilitated HF manual according to MRC guidelines for complex interventions. The REACH-HF Manual has been developed using a systematic intervention development process called intervention mapping, theories of social support and behaviour change, and existing research evidence. The HF Manual development has been overseen by a Truro-based patient and public involvement (PPI) group that includes HF patients and caregivers. The core interventional components of the HF manual are exercise training/physical activity promotion, stress management, and education.

The REACH-HF feasibility study was a multicentre single-arm study with parallel process evaluation to assess the feasibility and acceptability of the REACH HF manual for systolic HF patients, their caregivers and facilitators delivering the intervention. The feasibility study was conducted in preparation for a fully powered randomised controlled trial assessing the clinical effectiveness and cost effectiveness of the HF Manual vs. usual care in patients with systolic HF and a separate single centre pilot trial in patients with HFpEF.

The feasibility study has both research aims and intervention aims, as detailed below;

Research aims:

- To assess the feasibility and acceptability of the addition of the HF Manual to usual care for systolic HF patients, caregivers and intervention facilitators.
- To assess the fidelity of HF Manual delivery by intervention facilitators.
- To evaluate components of the study process to inform the main randomised controlled trial design: feasibility of outcome data collection processes, and outcome burden and completion/attrition rates for patients and caregivers.

Intervention development aims:

- To identify any further training needs for the intervention facilitators.
- To identify any changes needed in the HF Manual.
- To finalise the content and format of the HF Manual and training materials

The purpose of this report is to provide a summary of the outcome of the REACH feasibility study against the research aims.

The impact of the feasibility study on intervention development aims is presented elsewhere: *'REACH-HF Feasibility Study Process Evaluation Interim Report – July 2014' and 'REACH-HF Feasibility Study Process Evaluation Final Report – September 2014'.* Reports compiled by Anna Sansom, Jenny Wingham and Colin Greaves.

3. METHODS

3.1 Study Design

The study used a four centre (Birmingham, Cornwall, South Glamorgan and York) single-arm design with a parallel process evaluation.

Following identification and recruitment, patients with systolic HF received the HF manual intervention which was delivered over a period of 12 weeks by trained intervention facilitators, in addition to their usual care. The parallel process evaluation utilised qualitative methods and an observed structured clinical assessment using an intervention fidelity checklist in the context of delivering the REACH HF Manual. Multiple rounds of data collection and interaction with the intervention facilitators delivering the intervention generated feedback that informed both changes to the HF Manual, and changes to the training materials (i.e. the way the HF Manual is delivered by the intervention facilitators). These changes are outlined in the separate feasibility study intervention development report[1]. The patient and caregiver outcome measures planned for the main trial of clinical effectiveness and cost effectiveness were collected pre- and post- intervention in this study, in order to test procedures for collection, burden for patients, completeness of data collection and the rate of patient attrition/loss to follow up.

3.2 Study populations

In this study, patients, caregivers and the intervention facilitators were considered participants. A sample size calculation was not performed as this study was examining feasibility objectives and was not powered to undertake inferential within-group analyses. The range of 16-24 patients and 4-8 intervention facilitators for this study was derived empirically based on the objectives of the study and to reflect what was practical across the four sites. Where possible, sites were requested to provide 2 intervention facilitators (8 in total) each with a case load of 3 patients (i.e. a total of 24 patients). It was considered that experience of providing several sessions for 3-4 patients each would give the facilitators sufficient exposure to the intervention to be able to comment on its feasibility and acceptability. Based on a previous trial of CR in HF patients and their caregivers we expected to include 11-17 caregivers in this study.

3.2.1 Patients: eligible patients were adults (aged ≥18 years), with a confirmed diagnosis of systolic HF on echocardiography (i.e. left ventricular ejection fraction < 45%) within the last 5 years, had been clinically stable for at least 2 weeks and in receipt of medical treatment for HF, were deemed suitable for exercise, and who did not have a contraindication to exercise (as adjudged by the PI in collaboration with the local clinical team with reference to the American Heart Association 2013 guidelines) and provided informed consent to take part.

Exclusion criteria were:

- Patients who had undertaken cardiac rehabilitation (CR) within the previous 12 months
- Patients who had received an intra-cardiac defibrillator (ICD), cardiac resynchronisation therapy (CRT), or combined CRT/ICD device implanted in the previous 6 months.
- Patients who were in a long term care establishment or who were unwilling or unable to travel to research assessments or accommodate home visits.
- Patients who were unable to understand the study information or unable to complete the outcome questionnaires.

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[1] 'REACH-HF Feasibility Study Process Evaluation Interim Report – July 2014' and 'REACH-HF Feasibility Study Process Evaluation Final Report – September 2014'. Reports compiled by Anna Sansom, Jenny Wingham and Colin Greaves.

- Patients who were judged to be unable to participate in the study for any other reason (e.g. psychiatric disorder, diagnosis of dementia, life threatening co-morbidity).
- Patients who were participating in concurrent interventional research which may have over-burdened the patient or confounded data collection.

3.2.2 Caregivers: patient's caregivers who were aged 18 years or older were invited to participate if they met the following definition: *'Someone who provides unpaid support to family or friends who could not manage without this help. This could be caring for a relative, partner or friend'* and provided informed consent to take part. Patients were still able to participate in the study if they didn't have an identified caregiver, or if the patient's caregiver was not willing to participate; the separate caregiver component of the HF manual was not applicable for such patients.

3.2.3 Intervention facilitators: the CR service in each of the four sites was asked to identify 1 or 2 members of the team to act in the capacity of the facilitator to deliver the HF Manual ('the intervention facilitator'). The intervention facilitator recruitment process specified that the intervention facilitator would be required to take part in the process evaluation. This included having consultations audio-recorded, taking part in a qualitative interview and completing questionnaires and providing other information as requested by the research team. Informed consent was obtained from the intervention facilitators.

3.3 Patient identification and recruitment processes

Patients were identified for this study using a three-pronged approach i.e. via primary care, secondary care and the local specialist HF nurse services.

Patients who expressed an interest in the study when returning the study reply form, were provided with an information pack which included a Study Invitation letter, a copy of the patient Participant Information Sheet (PIS) and a separate information pack for their caregiver (comprising a study invitation letter and a copy of the caregiver PIS). If the patient had an identified caregiver, they were prompted by their study invitation letter to pass the caregiver information pack to their caregiver for consideration. A member of the research team at the local site contacted the patient using the contact details provided by the patient on the reply form, once they had had at least 24 hours to read the study information. If the patient and their caregiver were still interested in participating, a screening assessment form was completed with them over the phone, enabling a provisional assessment of patient and caregiver eligibility. Provisionally eligible patients and their caregivers were then invited to the local investigator site for a baseline visit. Ineligible patients were provided with an explanation as to why they were not eligible to take part in the study at that time.

Patients were asked to attend two research clinics; one before (baseline) and one after the twelve week intervention period. A tabulated schedule of events for the study is provided in Appendix 1.

Following successful recruitment, consent was obtained from patients and caregivers at the baseline visit. After written informed consent was obtained by the PI (or authorised delegate), demographic and medical history information was collected from participating patients. Each participant was allocated a unique study number by which they were identified in all study-related documentation. Participating patients were then asked to complete a questionnaire booklet, perform an incremental shuttle walking test (administered by the PI or research nurse to assess exercise capacity), answer some questions relating to healthcare service utilisation over the prior three months, provide a blood sample for measurement of natriuretic peptide levels and wear an accelerometer for seven days. Patients were asked to return the device (via stamp addressed package) after seven days. Participating caregivers were also asked to complete a questionnaire booklet at the initial visit.

3.4 Intervention

The intervention was the REACH-HF facilitated heart failure manual in addition to usual care that includes treatments and management as defined by current NICE guidelines (2010) and local practice. The REACH-HF intervention is a bespoke novel evidence-based intervention developed by the REACH-HF team.

The HF manual comprises a self-help manual which patients worked through with facilitation by the REACH-HF intervention facilitator. The manual includes information and interactive elements relating to a wide range of topics relating to living with/adapting to living with heart failure, and covers four core elements:

(1) An exercise training programme based on a walking programme or a chair-based exercise DVD, or a combination of the two (the patient's choice);
(2) Stress management
(3) Medication management.
(4) Monitoring and managing symptoms (especially fluid build up)

Building a functional understanding of heart failure and the effects of self-care on symptoms and well-being is a further key target which applies to all the above goals.

In addition, patients were given a 'Progress Tracker' booklet and encouraged to record weekly activities to monitor and manage their symptoms to track The REACH-HF intervention facilitator worked to build the patient's and the caregiver's understanding of their situation and how to manage heart failure. The manual provides a wealth of information to facilitate increased knowledge and coping skills. The caregiver resource includes three chapters; providing support, becoming a caregiver and getting help.

The intervention facilitators were trained by the REACH-HF team in a three-day training course including both written and interactive (face-to-face) training materials. They also received monthly supervision by teleconference from members of the intervention development team. This provided opportunity to share feedback about intervention delivery and to provide updates and advice to refine intervention delivery procedures during the course of the study.

The REACH-HF facilitators were not responsible for adjusting the patient's medication. However, if during a consultation, the patient or caregiver reported side-effects that might be associated with the patient's current medical therapy; these were reported to the patient's GP or appropriate service such as an HF nursing service. Similarly, if during a visit the intervention facilitator considered a patient to be unwell, and that immediate medical care was required, the facilitator immediately made a referral to the appropriate health professional, or in the case of an emergency to the emergency services. These practices were specified in the training materials for the intervention facilitators.

Participating patients and their caregivers were contacted by a local intervention facilitator following completion of the screening/baseline visit in order to arrange the initial home visit. At the initial visit, patients and caregivers were provided with their copies of the HF Manual and were given a detailed introduction by the intervention facilitator. During the 12 weeks that followed, the intervention facilitator conducted a minimum of two further visits to the patient's home (which the caregiver was also asked to attend) and typically made 4 telephone contacts. The number of contacts, timing and contact time varied depending on the patient's needs.

3.5 Process evaluation

Audio recordings of all home-visit and telephone interactions between the intervention facilitator and patients/caregivers were made by the intervention facilitator. Patients and caregivers consented for these audio recordings to be made as part of their informed consent. As part of the process evaluation, patients and caregivers were also asked to complete questionnaires asking them to rate their satisfaction with the HF Manual. These questionnaires assessed feasibility, satisfaction and ideas for improvement and were given a) after each face-to-face session and b) at 3 months (end of intervention/the last facilitator visit). These also included some questions about any telephone contacts that they received between visits. A similar questionnaire was given to the intervention facilitators as part of the ‘facilitator contact sheet’. The questionnaires contained mainly open-ended questions and a single satisfaction/overall feasibility question with a Likert response scale. The facilitator contact sheet was completed for each patient contact to record basic attendance and contact time. The contact sheet asked the intervention facilitator to make notes immediately after the patient contact about what was covered, what went well in the session; what worked less well; what s/he could have done differently and what could be improved about the intervention materials or the delivery process.

Process evaluation data collected during the 12 week intervention period was the primary data used to assess intervention fidelity. The procedure involved: a) identifying the change techniques and delivery processes that were associated with the intervention (as defined by prior intervention mapping) and b) using the Dreyfus skill acquisition scale to rate the competence of providers in delivering the targeted techniques and delivery processes. This produced a score of 0 to 6 for each targeted element of the intervention process. The scale was anchored such that a score of 3 was considered acceptable, 0 was non-existent and 6 was perfect performance. Two experts in behaviour change intervention listened to the set of recordings for each patient and applied the fidelity measure to rate competence in each element of intervention in each session and across the whole set of recordings. They marked sections of the recording that were useful for informing feedback to the facilitators (examples of good or poor practice, or which illustrated the intended intervention processes). This allowed the construction of formative feedback and prompts for discussion for each intervention provider. These sections were occasionally transcribed so that they could be used to inform future training. Where processes were consistently difficult to deliver and performance did not improve with feedback, or if the facilitators felt strongly that part of the intervention was not working/not workable, this suggested changes to the HF Manual or to the delivery procedures.

A semi-structured supervision session for the intervention facilitators was provided once every 4 weeks during the delivery period (3 in total). This was an opportunity to share ideas/good practice, problem-solve, and provide and discuss formative feedback based on the review of recorded sessions. The importance of completing the facilitator contact sheets was also reinforced during these sessions. The supervision sessions were conducted by teleconference to pool learning across the 4 sites and these sessions were also recorded. The last supervision session was run as a focus group targeted specifically at identifying ways to improve the intervention and the training. A topic guide was developed during the study, based on the feedback received in the earlier stages of data collection.

Brief semi-structured interviews, either by telephone or face-to-face, were conducted with 12-16 patients and their caregivers about their experiences of receiving the HF manual after 6 weeks (half way through intervention period) and between week 13 and 17 (the end of the intervention period). Topic guides were developed in consultation with the intervention development team, the REACH HF co-applicants, and the PPI group.

On completion of the 12-week intervention delivery period, participating patients and caregivers attended a second and final research clinic, overseen by the PI. As part of their assessment, participating patients and caregivers completed the assessments they completed at the initial baseline visit. In addition, patients were asked to identify contacts with healthcare and personal social services contacts during the intervention delivery period. For all hospitalisations and incidence of death, the hospital discharge letter and/or death certificate was obtained by the PI (or delegate), anonymised and sent to the Peninsula Clinical Trials Unit (‘CTU’). These records were subsequently made available to an independent event adjudication committee and were used for safety reporting procedures.

Each patient and caregiver recruited was involved in the study for approximately 4 months between initial approach and clinic visit 2. A sample of patients participated for longer as they were selected for interview.

3.6 Outcome measures

The outcome measures planned for the definitive REACH HF trial in systolic HF {Work Package 3) and pilot REACH-HFpEF (Work Package 2) trials were collected from patients and caregivers in this feasibility study to allow researchers to test processes for collection and to assess the outcome completion rate. We also assessed outcome burden using the Trial Process Questionnaire which was completed by patients and caregivers (if appropriate) during the second research clinic visit.

The proposed primary outcome for the definitive and pilot trials is disease specific health related quality of life (HRQoL) measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) in patients. Secondary outcome measures include: composite outcome of death or hospital admission related to HF or not related to HF (patients), blood natriuretic peptide levels (patients), Incremental Shuttle Walk Test (ISWT) (patients), Hospital Anxiety and Depression Scale (HADS) (patients & caregivers), physical activity level (obtained from accelerometer worn over two 7-day periods) (patients), EQ-5D (patients), HeartQoL (patients), SCHFI (caregivers), CBQ-HF (caregivers), CC-SCHFI (caregivers), FAMQOL (caregivers), healthcare utilisation (patients), safety outcomes (patients). All outcomes were assessed by clinic visit at baseline (visit 1) and at 3-months (visit 2). Outcome questionnaires were self-completed with the exception of healthcare utilisation and safety that were administered by the PI/research nurse.

This study assessed the feasibility and acceptability of collecting data on participant NHS and related resource use (self-report and/or routine/electronic records) to inform the health economic evaluation to be undertaken in the definitive and pilot trials. During the feasibility study we have developed and tested methods for estimating the resource use and costs associated with delivery of the intervention (e.g. via case report forms, and/or interviews with intervention providers). Levels of data completion on these outcomes were assessed.

All serious adverse events were recorded regardless of relatedness; non-serious, unrelated adverse events were not recorded. HF-related hospital admissions and HF-related death was a clinical outcome measure collected during this study. In order to collect this outcome measure data, the PI (or authorised delegate) obtained a death certificate or hospital discharge summary for every hospitalisation or death reported as a serious adverse event. Documents pertaining to a hospitalisation or death were anonymised prior to being sent to the CTU for subsequent adjudication by an independent event adjudication committee.

Safety information pertaining to caregivers was not be collected or reported since risks to caregivers were expected to be negligible. However, the protocol stipulated that any safety concerns identified through caregivers' completion of questionnaires or interviews were duly managed and reported.

A table summary of the outcome collection timings is detailed in Appendix 1.

3.7 Data management

Data was recorded on study specific data case report forms (CRFs), usually by the research team at each site. All persons authorised to collect and record trial data at each site were listed on the study site delegation logs, signed by the relevant PI. Source data included all data recorded straight into the CRF, blood test result forms, accelerometer data, death certificates (if applicable), discharge summaries (if applicable), and any patient completed questionnaire booklets. Completed CRFs were transferred to the CTU for double-data entry onto a password-protected database. All forms and data were tracked using a web-based trial management system. Double-entered data was compared for discrepancies using a stored procedure. Discrepant data was verified using the original paper data sheets.

3.8 Data analysis

3.8.1 Qualitative analysis

Audio files and transcriptions of the data were collected by the Process Evaluation Team, comprising REACH-HF team co-applicants and collaborators.

The analysis of audio recordings (of sessions and interviews, supervision sessions and patient interviews) did not rely on the recordings being transcribed. The audio files were listened to and notes taken by the researcher and also by one of the intervention development team. The purpose of analysing this data was not to produce a robust, in-depth qualitative analysis, but to provide sufficient feedback on the intervention to inform refinements to the intervention and training materials. Analysis of raw audio recordings, rather than transcribed data was considered sufficient for this purpose. The audio files were stored on secure servers at the University of Exeter and the Royal Cornwall Hospitals Trust. Access was password protected and limited to the REACH-HF study team.

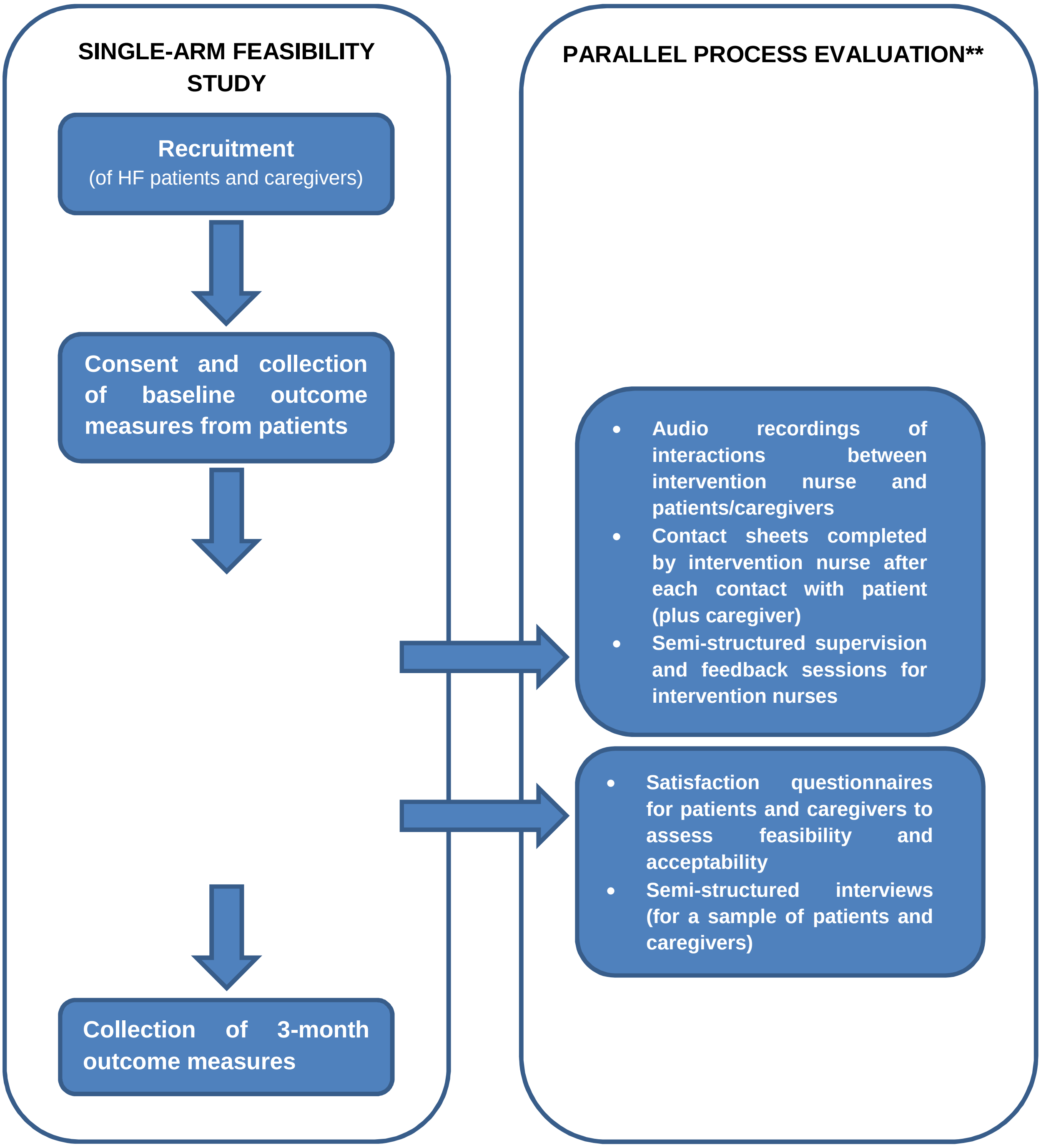
Intervention fidelity checklist scores were summarised using simple descriptive statistics (means and standard deviations) and collated both in total and by facilitator. Examples of good practice were flagged, transcribed and extracted as audio clips (with the facilitator’s permission) to inform future training. Checklist items were scored for each recording and as a summary score (in relation to the full set of available recordings for each patient). Low-scoring items for some or all facilitators identified areas where change was needed (either via formative feedback and a training update or via changes to the intervention materials). The checklist scores and notes taken about good practice and learning needs during the review of the recordings provided ideas for individualised formative feedback to each facilitator (in written form). The methodology had been used successfully before in previous complex intervention trials undertaken by the applicants.

Feasibility and acceptability was assessed via: a) data from patient and caregiver interviews and from recordings of the supervisory meetings and b) patient and facilitator feedback questionnaires, which included satisfaction scores as well as open-ended feedback on what worked well and what improvements could be made. The qualitative data was analysed using descriptive, thematic analysis to identify salient themes from the interview transcripts and open-ended sections of the questionnaires. The data was analysed with the aim of addressing the research aims above, in particular to see if patients, caregivers and facilitators have different views, and to extract recommendations for changes needed to the intervention manual and/or the intervention delivery processes.

3.8.2. Quantitative analysis

Given the feasibility nature of this trial we did not propose to formally inferentially test differences in outcomes and costs within groups. Mean and standard deviation for primary and secondary outcomes were reported at baseline and 3 months’ follow up. Participant flow through the study was summarised using the CONSORT diagram (adapted for complex interventions) and reflects the number of recruitment letters sent, numbers consenting, numbers participating , number undertaking intervention, and number of completed outcomes. Attrition rates were calculated with 95% confidence intervals

Figure 1 Overview of study design



4. RESULTS

4.1 Patient flow and baseline demographic data

Study enrolment, allocation to intervention and follow-up of study patients and caregivers is summarised in Figure 1.

4.1.1 Patients and caregivers approached

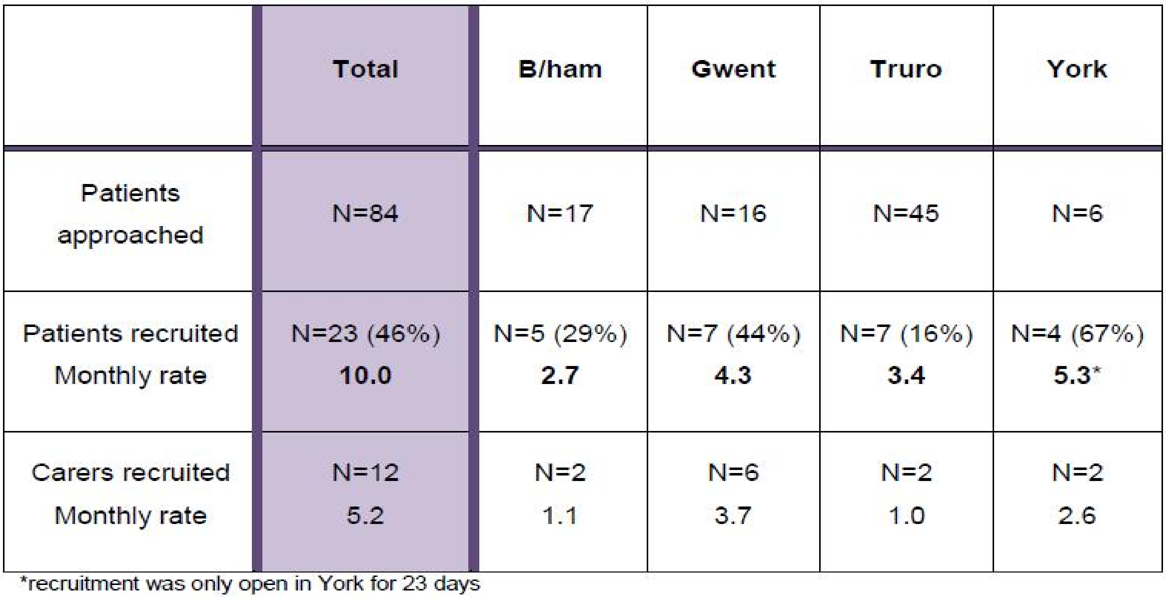
Recruitment of patients and their caregivers took place over the 12 week period from 1st March 2014 to 31st May 2014, a one month extension on the planned 2-month period due to delayed ETC agreement and delayed recruitment start in York. The numbers approached and recruited are summarised in Table 1 and were fairly consistent across sites. Of the 84 patients approached, 23 were recruited i.e. an approach to recruit ratio of ~4:1.

4

4.1.2 Rates of recruitment

Following approaches to 84 patients, a total 23 patients and 12 caregivers were recruited – meeting the recruitment target for the study. For the period of time that sites were open, the overall study recruitment rate across the 4 sites was 10 patients/month and 5 caregivers/month. Rates of patient recruitment across the four sites are summarised in Table 1. The target recruitment rate for the study was 4-6 patients per month per site.

Table 1. Patient recruitment overall and across sites



	Total	**B/ham**	**Gwent**	**Truro**	**York**
Patients approached	N=84	N=17	N=16	N=45	N=6
Patients recruited Monthly rate	N=23 (46%) **10.0**	N=5 (29%) **2.7**	N=7 (44%) **4.3**	N=7 (16%) **3.4**	N=4 (67%) **5.3***
Carers recruited Monthly rate	N=12 5.2	N=2 1.1	N=6 3.7	N=2 1.0	N=2 2.6

*recruitment was only open in York for 23 days

Figure 2 shows the target versus actual recruitment for patients. A total of 7 intervention facilitators were recruited slightly higher that the planned 2 per site.

Figure 1. Study flow

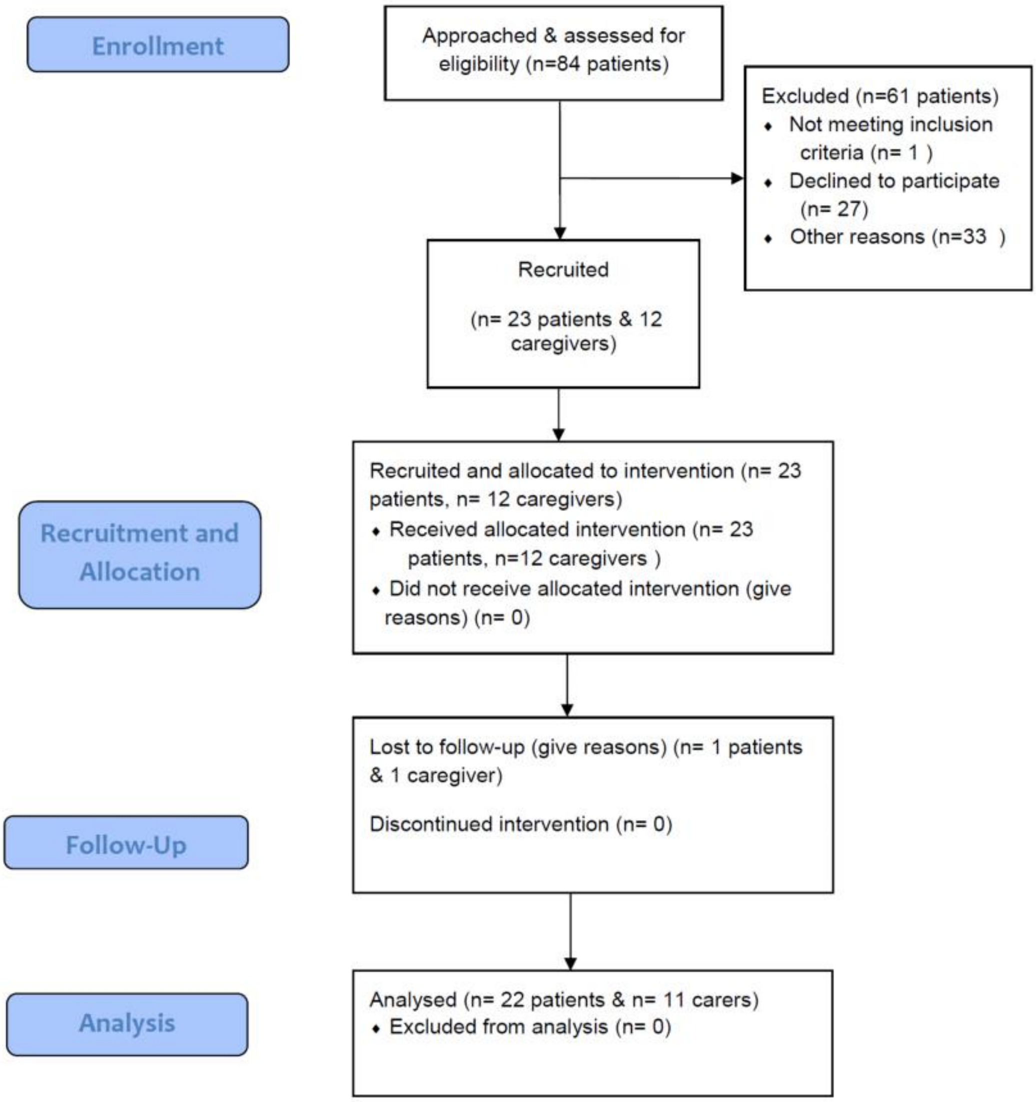
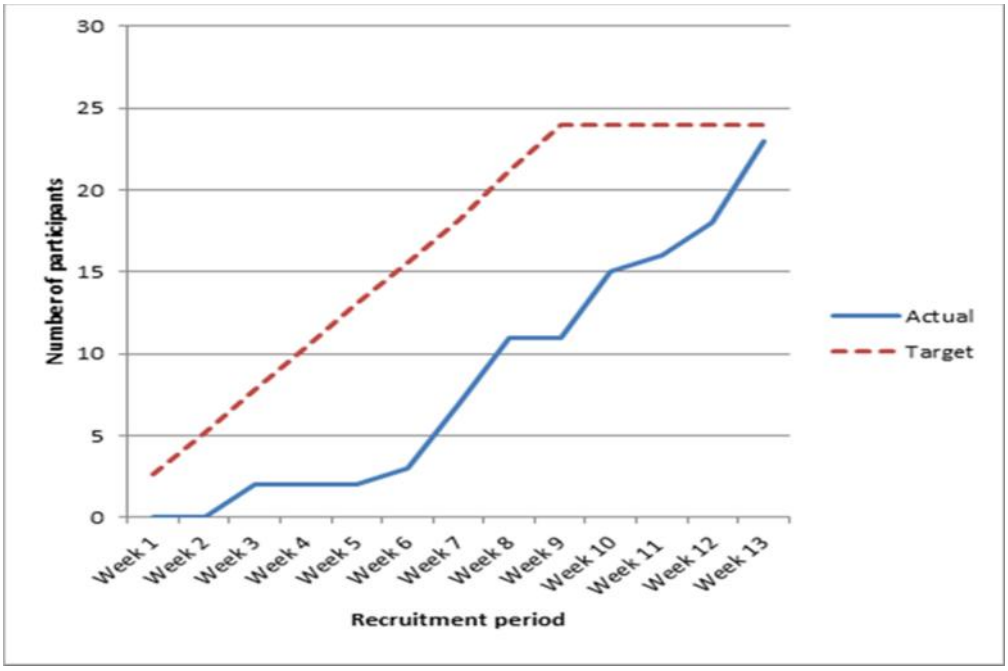


Figure 2. Study recruitment – target vs actual



4.1.3 Baseline demographics of recruited patients

The baseline characteristics of the included 23 patients and 12 caregivers are summarised in the tables below.

Table 2. Baseline demographics of patients (N=23)

Characteristic	**N (percent) or mean (SD) [range]**
Male	16 (70)
Age (years)	66 (14) [38 to 83]
BMI	32.2 (6.9) [23.1 to 53.0]
Smoking status	
Current smoker	0 (0)
Ex-smoker	13 (57)
Never smoked	10 (43)
NYHA status	
Class I	2 (9)
Class II	15 (65)
Class III	6 (26)
Class IV	0
Baseline use of medication (N=19)	
Beta-blocker	18 (95)
Alpha 2 antagonist	6 (32)
ACE inhibitor	13 (68)
Diagnosis of HF (years)	
< 1	11 (48)
…1-2	4 (17)
…>2	3 (13)
…not available	5 (22)
Main activity	
In employment or self-employment	5 (22)
Retired	16 (70)
Housework	1 (4)
Other+	1 (4)
Undertaken post school education	15 (65)

Table 3. Baseline demographics – caregivers (N=12)

Characteristic	**N (percent) or mean (SD)**
Male	4 (33)
Age	63 (14) [36 to 84]
Relationship to patient	
Partner	12 (100)

4.2 Intervention Feasibility & Acceptability

The quantitative and qualitative data collected to assess intervention feasibility and acceptability can be summarised as follows:

- Satisfaction questionnaire
  - N = 50 patient/caregiver questionnaire replies: mean score = 1.9 (see Table 3 below)
  - First questionnaire (first 1 to 2 weeks): mean 2.3 (median 2) & last questionnaire (last 10-12 weeks): mean 1.7 (median 2)

Table 3. Summary of patient/caregiver satisfaction scores (first 50 questionnaires)

1 Excellent	16
2 Very good	26
3 Good	4
4 Satisfactory	3
5 Poor	1
6 Very poor	0

- Facilitator contact sheets: N = 18 patients completed interventions
- Mean number of sessions = 8 (median 8, range 6 to 11)
- Mean duration = 346 minutes (median 338, range 110 to 583)
- Patient tracker: all patients (15/15) used exercise record section (but degree of completion very variable and lesser proportion completion for other sections)
- Intervention drop out: Nil
- Interviews: facilitators, patients & caregivers overwhelmingly positive (albeit specific recommendations for adaption of manual content, presentation & training). The following is a sample of patient quotes:

“Thank you for inviting me to take part. I feel so much more confident about managing my condition and I intend to keep active and keep improving my level of fitness. Thank you again.”
“(The facilitator) has gone over things in a way my partner and I find brilliant. A really brilliant explanation of anything I have asked.”
“(The facilitator) has been a great help and I am beginning to feel much better as time goes on.”
“I have found everything brill and the support from (the facilitator) excellent. This has already made a difference.”
“Having (the facilitator) visit gives me confidence… I feel more at ease about myself now”.
“The facilitator has provided us with the knowledge that we can be positive about the future”.
“We both feel more positive now about what we are dealing with and how to enjoy certain experiences”

4.3 Fidelity of manual delivery

Intervention fidelity was checked by applying our 13-item intervention fidelity checklist to all recorded intervention sessions (i.e. all the phone and face-to-face sessions for the 18 participants for whom data was returned). Table 4 shows the mean intervention fidelity scores and range of scores for each item and Table 5 shows the scores for each facilitator. The scores indicated adequate delivery (defined as a score of 3 or more) for most aspects by all facilitators. However, the mean score for items 10 (*addressing emotional consequences of being a caregiver*) and 11 (*caregiver health and well-being*) was less than 3. Analysis of the scores for each facilitator show that only one of the six facilitators delivered these elements of the intervention as intended.

Table 4: Mean intervention fidelity scores

	Item 1	**Item 2**	**Item 3**	**Item 4**	**Item 5a**	**Item 5b**	**Item 6**	**Item 7**	**Item 8**	**Item 9**	**Item 10**	**Item 11**	**Item 12**
N	18	18	18	18	18	18	18	18	18	15	15	15	18
Minimum	3.0	3.5	3.0	2.0	3.0	3.0	3.0	2.5	2.0	2.0	.0	.0	.0
Maximum	6.0	5.5	5.0	6.0	6.0	6.0	6.0	5.5	6.0	5.0	4.5	5.0	6.0
Mean	5.056	4.611	4.361	4.250	4.639	4.667	4.611	4.472	4.194	3.800	2.700	2.567	3.583
SD	.6157	.6543	.7237	.8952	.7031	.6642	.7962	.8309	1.1775	1.0657	1.4736	1.635	1.458

Table 4: Mean intervention fidelity scores by facilitator

		IF Score Item 1	IF Score Item 2	IF Score Item 3	IF Score Item 4	IF Score Item 5a	IF Score Item 5b	IF Score Item 6	IF Score Item 7	IF Score Item 8	IF Score Item 9	IF Score Item 10	IF Score Item 11	IF Score Item 12
		Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean
Facilitator ID	1	5.1	3.9	3.5	3.1	3.9	4.0	3.9	3.4	2.5	3.5	2.2	1.3	2.4
	2	5.3	4.2	4.0	4.2	4.5	5.0	4.7	4.5	3.8	3.8	2.5	2.3	3.3
	3	5.5	5.2	5.0	5.3	5.5	5.3	5.3	5.0	5.3	3.5	1.5	2.0	5.0
	4	5.0	5.1	4.8	4.5	4.8	4.5	4.4	5.0	4.5	5.0	4.1	4.4	4.0
	5	5.0	5.0	5.0	4.0	5.0	5.0	6.0	5.0	6.0	.	.	.	6.0
	6	4.3	4.7	4.5	4.5	4.7	4.7	4.7	4.5	4.7	2.7	2.3	2.0	2.7
	7	.	.	.	.	.	.	.	.	.	.	.	.	.

4.4 Patient and caregiver outcome results

[follow up data and text redacted]

4.4.1 Patient outcomes

The baseline (pre-intervention) and 3-month follow up results for the included patients are summarised in Table 5. With all caveats of this feasibility study (i.e. small population of selected participants and the study design of pre-post comparison with no control group) a number of patient outcomes following the REACH-HF intervention showed some evidence of improvement following intervention. The one exception was the lack of change in ISWT distance over time. The reasons for non-completion of the ISWT are provided in Appendix 2.

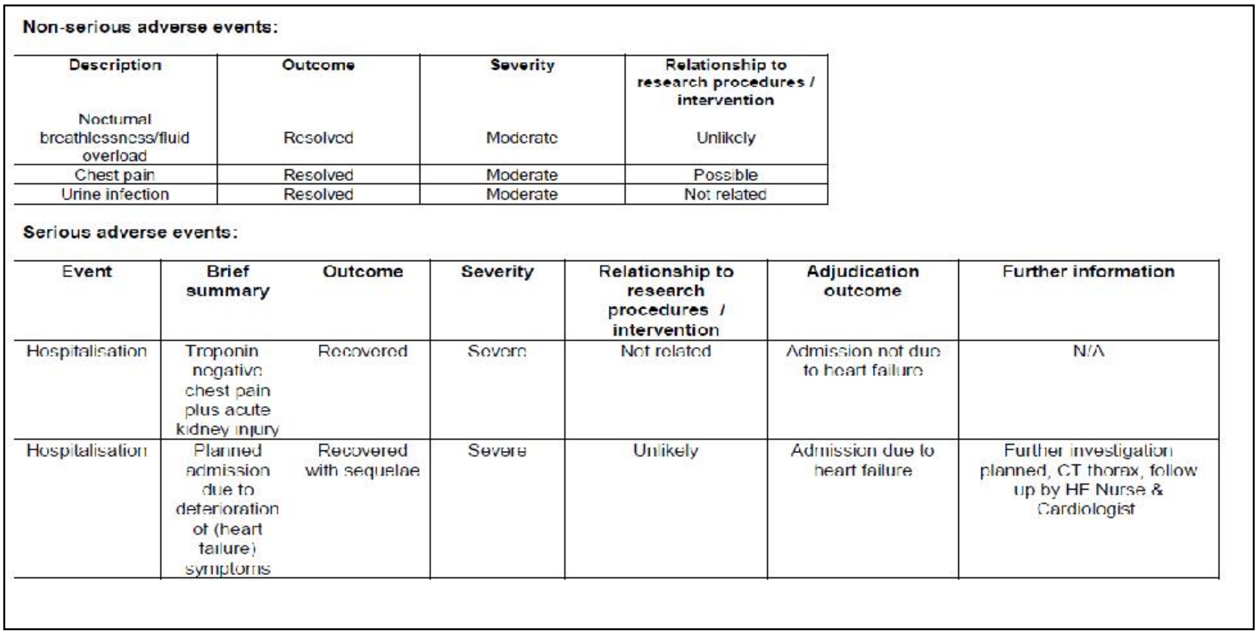
Adverse events are summarised in Table 6. Two serious adverse events requiring hospitalisation were seen during the 3 months of follow-up. One of these events was judged by the independent adjudication panel as HF-related and the other as non HF-related.

Table 5. Patient outcomes and baseline and 3-months

Outcome	**Baseline** **Frequency* (percent) or N, mean (SD) [range]**	**3-months follow up** **Frequency* (percent) or N, mean (SD) [range]**
Primary outcome		
MLwHF[I]		
Total score	22, 39.5 (24.6) [64 to 91]	[redacted]
Physical score	22, 10.1 (8.2) [0 to 25]	[redacted]
Emotional score	22, 19.0 (10.8) [4 to 40]	[redacted]
Secondary outcomes		
ISWT distance (m)[II]		
Practice	22, 265 (201) [40 to 780]	
Effort scale	*22, 4.9 (2.5) [0 to 10]*	
Main	16, 325 (226) [40 to 900]	[redacted]
…*Effort scale*	*15, 5.3 (2.2) [1 to 10]*	[redacted]
EQ-5D[II]		
Tariff	23, 0.61 (0.27) [-0.06 to 1.00]	[redacted]
Thermometer	21, 60.3 (17.8) [20 to 85]	[redacted]
Accelerometry[II]		
Ave mins/day light activity	17, 112 (64) [5 to 231]	[redacted]
....Ave mins/day at least light activity	17, 133 (77) [7 to 260]	[redacted]
…Ave mins/day at least moderate activity	17, 21 (23) [1 to 96]	[redacted]
….Ave mins/day vigorous activity	17, 0.1 (0.1) [0 to 0.4]	[redacted]
HADS[I]		
Depression score	23, 5.6 (3.3) [1.0 to 14.0]	[redacted]
Anxiety score	23, 7.3 (4.4) [1.0 to 18.0]	[redacted]
HeartQoL[II]		
Global score	23, 1.45 (0.78) [0 to 2.79]	[redacted]
Physical score	23, 1.28 (0.85) [0 to 2.70]	[redacted]
Emotional score	23, 1.86 (0.95) [0 to 1.93]	[redacted]
Self-care of Heart Failure Index (SCHFI)[II]		
Maintenance	23, 56.0 (13.5) [26.7 to 83.3]	[redacted]
Management **	13, 46.5 (20.4) [15.0 to 95.0]	[redacted]
Confidence	23, 58.2 (22.8) [11.1 to 100.0]	[redacted]
Deaths	-	[redacted]
Total hospitalisations	-	[redacted]
HF-related		[redacted]
Not HF-related		[redacted]
BNP level (pg/mL)[I]	15, 670 (468) [72 to 1439]	[redacted]

[I] Outcome where a lower score, indicates better outcome; [II] Outcome where a lower score, indicates better outcome ** There is no management total if there are any missing individual scores.

Table 6. Adverse outcomes in patients over 3-months follow up



Non-serious adverse events:

Description	Outcome	Severity	Relationship to research procedures / intervention
Nocturnal breathlessness/fluid overload	Resolved	Moderate	Unlikely
Chest pain	Resolved	Moderate	Possible
Urine infection	Resolved	Moderate	Not related

Serious adverse events:

Event	Brief summary	Outcome	Severity	Relationship to research procedures / intervention	Adjudication outcome	Further information
Hospitalisation	Troponin negative chest pain plus acute kidney injury	Recovered	Severe	Not related	Admission not due to heart failure	N/A
Hospitalisation	Planned admission due to deterioration of (heart failure) symptoms	Recovered with sequelae	Severe	Unlikely	Admission due to heart failure	Further investigation planned, CT thorax, follow up by HF Nurse & Cardiologist

Table 7. Caregiver outcome results at baseline and 3-month follow up

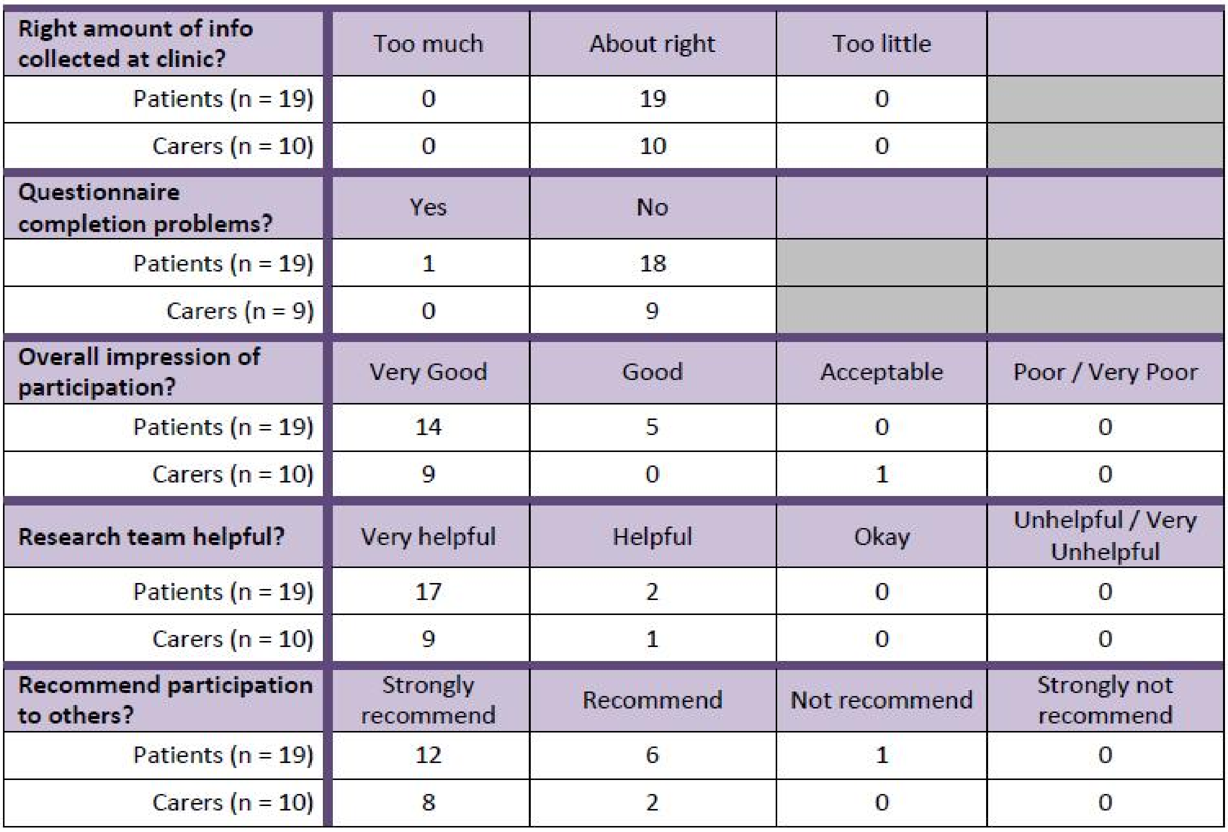
Outcome	Baseline Frequency* (percent) or N mean (SD) [range]	3-months follow up Frequency* (percent) or N mean (SD) [range]
HADS[I]		
Depression score	12, 5.2 (4.5) [1.0 to 17.0]	[redacted]
Anxiety score	12, 9.6 (6.7) [1.0 to 21.0]	[redacted]
Caregiver Contribution to Self-care of Heart Failure Index (CC-SCHFI)[II]		
Maintenance	12, 34.9 (22.4) [0.0 to 73.3]	[redacted]
Management **	8, 33.1 (11.3) [20.0 to 55.0]	[redacted]
Confidence	12, 48.1 (18.5) [16.7 to 77.8]	[redacted]
Caregiver Burden Questionnaire – Heart Failure (CBQ-HF)[I]		
Physical	12, 5.3 (5.7) [0.0 to 20.0]	[redacted]
Emotional	12, 22.6 (15.6) [4.0 to 52.0]	[redacted]
Social Life	12, 1.6 (2.3) [0.0 to 8.0]	[redacted]
Lifestyle	12, 5.2 (4.2) [0.0 to 15.0]	[redacted]
Family Caregiver-Specific Quality of Life Scale (FAMQOL)[I]		
Physical	12, 15.1 (3.2) [9.0 to 18.0]	[redacted]
Psychological	12, 12.2 (4.9) [5.0 to 20.0]	[redacted]
Social	12, 15.3 (3.3) [7.0 to 20.0]	[redacted]
Total	12, 56.3 (12.5) [29.0 to 74.0]	[redacted]

[I] Outcome were a lower score, indicates better outcome; [II] Outcome were a lower score, indicates better outcome ** There is no management total if there are any missing individual scores.

4.5 Patient/caregiver perception of trial processes

The table below present the questionnaire results from a questionnaire regarding trial processed completed patients and caregiver participants at end of the study. These data show that overall, participants found their involvement in the feasibility study to be a very positive one and there was no evidence of outcome completion burden.

Table 8. Summary of perception of trial process questionnaire



Right amount of info collected at clinic?	Too much	About right	Too little	
Patients (n = 19)	0	19	0	
Carers (n = 10)	0	10	0	
Questionnaire completion problems?	Yes	No		
Patients (n = 19)	1	18		
Carers (n = 9)	0	9		
Overall impression of participation?	Very Good	Good	Acceptable	Poor / Very Poor
Patients (n = 19)	14	5	0	0
Carers (n = 10)	9	0	1	0
Research team helpful?	Very helpful	Helpful	Okay	Unhelpful / Very Unhelpful
Patients (n = 19)	17	2	0	0
Carers (n = 10)	9	1	0	0
Recommend participation to others?	Strongly recommend	Recommend	Not recommend	Strongly not recommend
Patients (n = 19)	12	6	1	0
Carers (n = 10)	8	2	0	0

5. CONCLUSIONS

The conclusions of this feasibility study in terms of its research aims are summarised as follows:

Feasibility & acceptability of intervention

- REACH-HF manuals appear to have been well accepted to patients, caregivers and facilitators.
- Patients and caregivers were highly satisfied with REACH-HF intervention.
- There was a need for some modifications to manual content and format & facilitator training (see Appendix 3).

Fidelity of intervention delivery

- Fidelity scoring indicated adequate delivery for most aspects by all facilitators.
- Two items (addressing emotional consequences of being a caregiver and caregiver health and well-being) need reinforcement in future intervention delivery.

Trial processes

- Generally excellent levels of outcome completion and patients/caregivers perceive relatively low outcome burden.
- a number of patient and caregiver outcomes following REACH-HF intervention showed evidence of improvement (with the all caveats of a small population of selected participants and the study design of pre-post comparison with no control group).
- No safety issues identified.
- ISWT was not universally popular with patients and failed to show change over time

Following the feasibility study and discussion with the Programme Steering Committee, it was agreed that the following revisions to the trial processes be implemented:

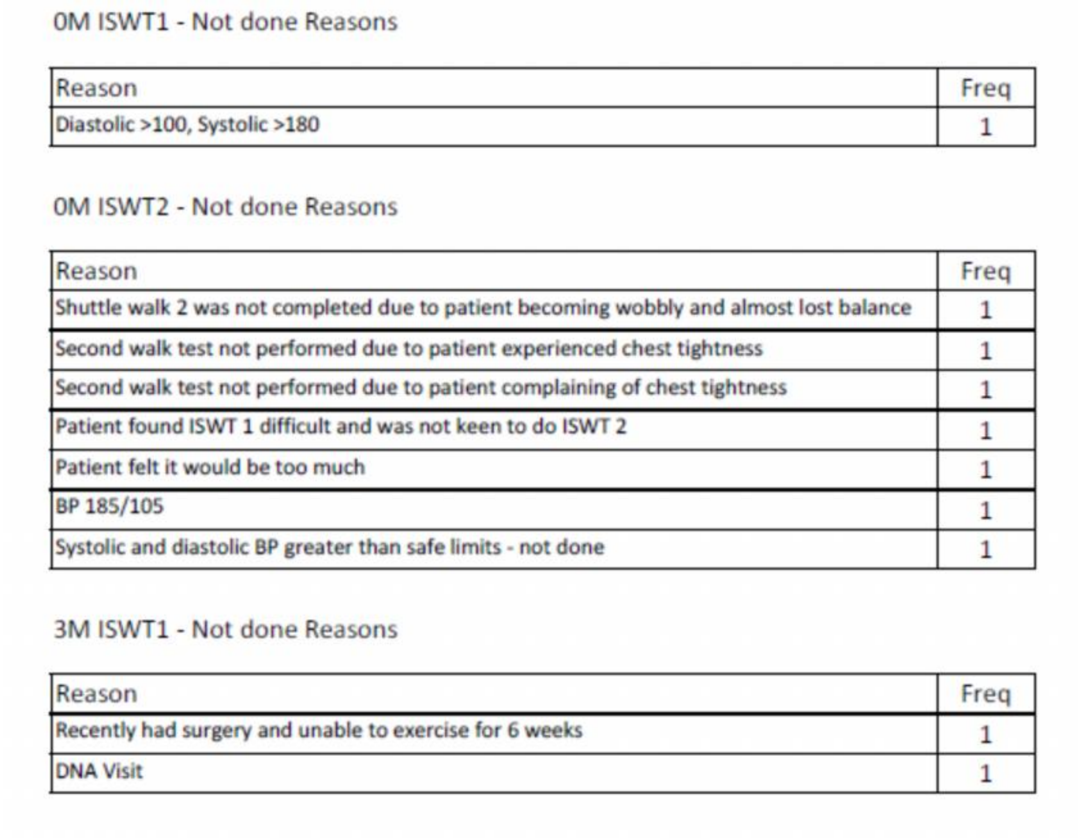
- Reinforce/supplement outcome assessor training on the conduct of ISWT
- Review recruitment processes and plans with sites (i.e. patient information, recruitment monitoring) and identify ‘backup’ recruitment strategy(ies) in the event that recruitment is slower than expected
- Ensure that recruitment reflects the population of HF patients (in terms of age, disease severity)
- Extend baseline assessment to capture the full range of clinical descriptors
- Addition of EQ-5D for caregivers
- Modification to patient tracker (compliance measure of intervention compliance & analysis algorithm)
- Check accelerometry procedures (charging & transport) to minimise loss of data

6. APPENDICES:

Appendix 1: Outcome collection schedule

Study Schedule			
	Clinic visit 1 (Baseline*)	12 week treatment period	Clinic visit 2 (3 months)
Demographics (e.g. age, sex, NYHA class)	X		
Concomitant medication	X		X
Medical history	X		
Informed Consent	X		
Intervention delivery** (HF Manual)		X	
Process evaluation **		X	
MLHFQW	X		X
Hospital Anxiety and Depression Scale (HADS)	X		X
Self-care of Heart Failure Index (SCHFI)	X		X
Caregiver Burden Questionnaire – Heart Failure (CBQ-HF)	X		X
Caregiver Contribution to Self-care of Heart Failure Index (CC-SCHFI)	X		X
Heart-QOL	X		X
FAMQOL	X		X
Blood sample for natriuretic peptide levels	X		X
Shuttle walk test	X		X
Physical activity level (wear accelerometers for 7 days)	X		X
EQ_5D	X		X
Trial Process Questionnaire			X
Assessment of healthcare utilisation	X		X
Adverse events	X		X

Appendix 2. Reasons for non-completion of ISWT



0M ISWT1 - Not done Reasons

Reason	Freq
Diastolic >100, Systolic >180	1

0M ISWT2 - Not done Reasons

Reason	Freq
Shuttle walk 2 was not completed due to patient becoming wobbly and almost lost balance	1
Second walk test not performed due to patient experienced chest tightness	1
Second walk test not performed due to patient complaining of chest tightness	1
Patient found ISWT 1 difficult and was not keen to do ISWT 2	1
Patient felt it would be too much	1
BP 185/105	1
Systolic and diastolic BP greater than safe limits - not done	1

3M ISWT1 - Not done Reasons

Reason	Freq
Recently had surgery and unable to exercise for 6 weeks	1
DNA Visit	1

Appendix 3. Modifications to REACH HF manuals and training materials following feasibility study

Manual and materials

The Heart Failure Manual

- Include more testimonials particularly around relaxation/managing stress and managing changes in symptoms/ups and downs.
- Additional advice for people who are returning to work after a period of long term sick leave.

Progress Tracker

NOTE: We do not have a complete data set of end of intervention PTs (n=15/23), in addition, different facilitators may have placed differing emphasis on completing the PTs (some requesting that the patient did it 'to help the research' and others focusing on the benefit and appropriateness for the individual). Therefore it is suggested that the following recommendations be interpreted within this context.

- Ensure all sections have space for a full 12 week record.
- Review whether to include cause and specific advice in the 'My health care' section.
- Consider renaming 'Is it time to have some fun?' to e.g. 'leisure and fun'.

Other issues

- Give an indication of the timeframe for taking part in the research at the outset (including when to expect the first facilitator visit).
- Some sections had a negative tone: end of life and living with uncertainty sections – it was suggested that it could be a separate section for people it is more relevant for. Difficulty in feeling hopeful and positive from majority of HFM and then being 'brought down' by that section.

Training

Facilitator role

- Check time availability, preference, expectations and other commitments with participants before beginning the intervention. E.g. Is it realistic to have sessions that last for more than hour?

Progress Tracker

- If cause and specific advice in the 'My health care' section is to remain, reinforce in facilitator training re encouraging patients to complete this section (i.e. facilitators help patients to understand the benefit of using it).
- Emphasise in facilitator training the need to complete contact section on the Traffic Lights page.
- Emphasise that not all sections need to be completed: it is up to each individual patient to identify the most relevant and helpful sections for them. However, we may want to emphasise use of the weight, weekly progress, and exercise records (as a minimum) to focus on – in keeping with the aims of the intervention.

Other issues

- Where a facilitator had another role as HFSN there was potential for some ambiguity at the end of the intervention regarding whether the patient could still contact them or not. This led to some differences in how the facilitator ended the intervention and whether the patient +/or caregiver still felt supported by the same person. This distinction may be worth exploring more/being made more explicit.
- One participant's lifestyle did not allow them to complete the requests in the manual as s/he was also a caregiver for partner and friends.