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

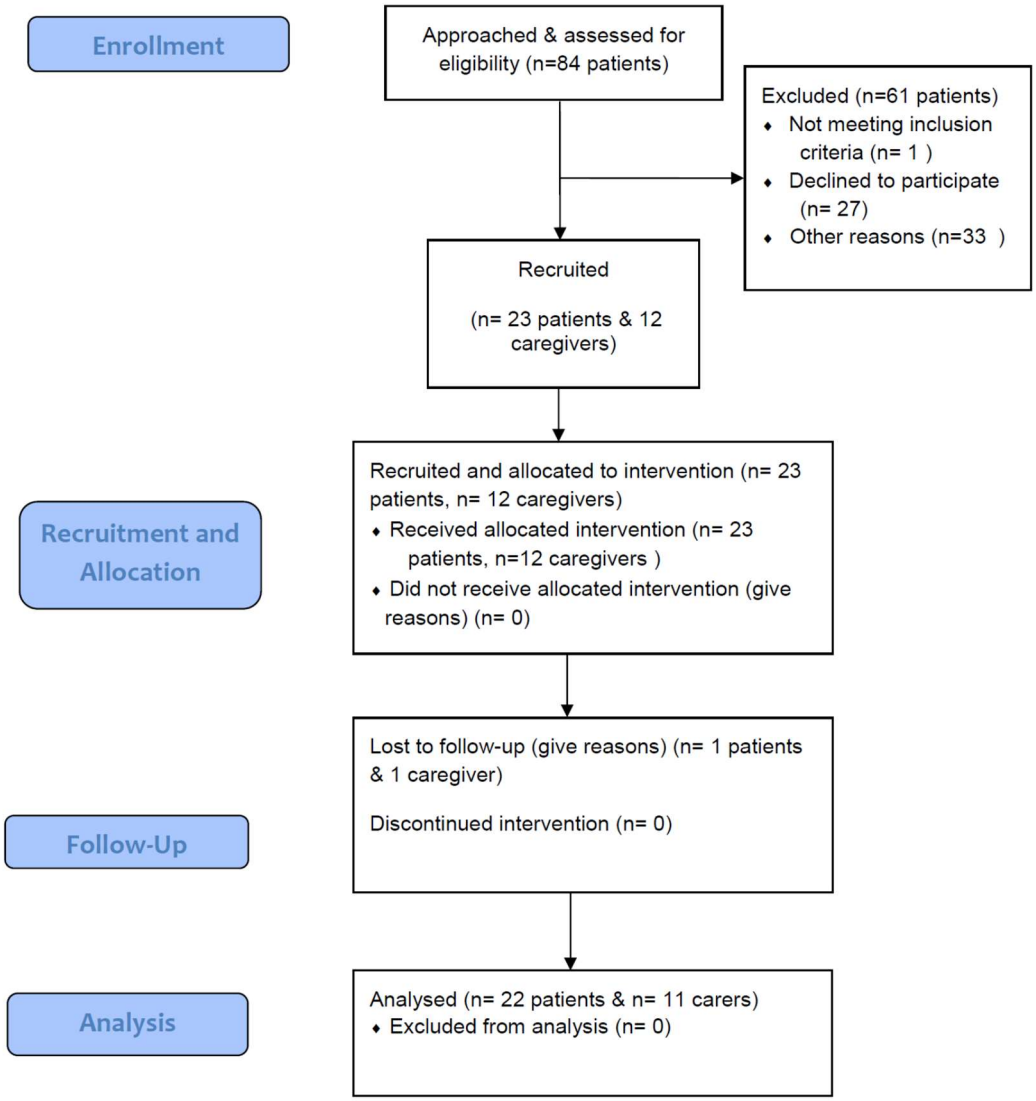
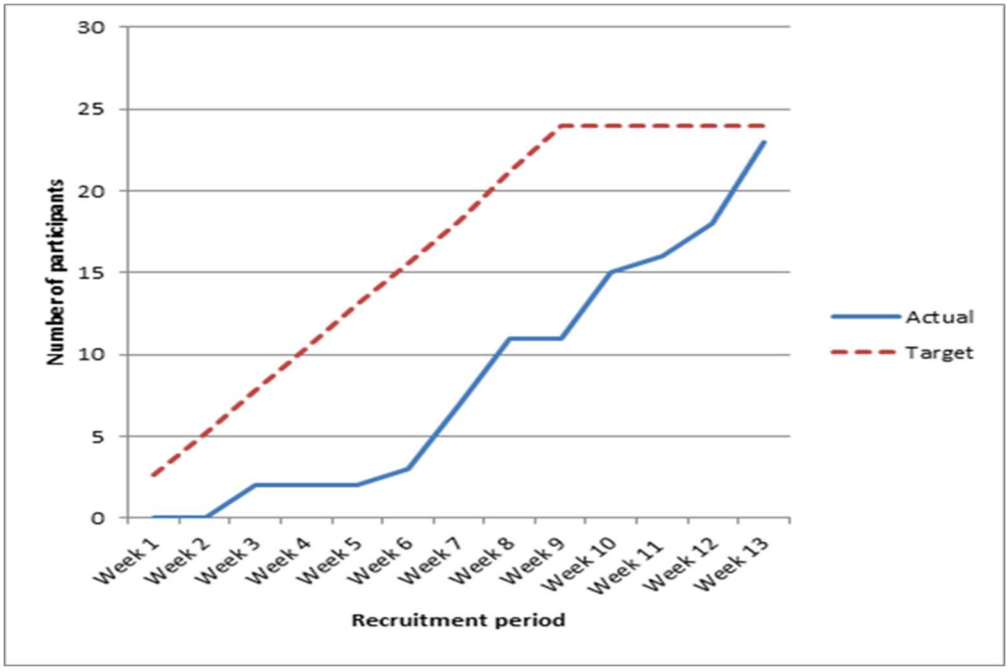


Figure 2. Study recruitment – target vs actual



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 Ex-smoker Never smoked	 0 (0) 13 (57) 10 (43)
NYHA status Class I Class II Class III Class IV	 2 (9) 15 (65) 6 (26) 0
Baseline use of medication (N=19) Beta-blocker Alpha 2 antagonist ACE inhibitor	 18 (95) 6 (32) 13 (68)
Diagnosis of HF (years) < 1 …1-2 …>2 …not available	 11 (48) 4 (17) 3 (13) 5 (22)
Main activity In employment or self-employment Retired Housework Other+	 5 (22) 16 (70) 1 (4) 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 are described in detail in Appendix 2b. The findings 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

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]	22, 32.0 (25.4) [2 to 94]
Physical score	22, 10.1 (8.2) [0 to 25]	22, 15.9 (11.2) [0 to 40]
Emotional score	22, 19.0 (10.8) [4 to 40]	22, 7.7 (6.7) [0 to 25]
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]	21, 270 (176) [60 to 810]
…*Effort scale*	*15, 5.3 (2.2) [1 to 10]*	*21, 4.4 (1.7) [2 to 8]*
EQ-5D[II]		
Tariff	23, 0.61 (0.27) [-0.06 to 1.00]	22, 0.67 (0.32) [-0.21 to 1.00]
Thermometer	21, 60.3 (17.8) [20 to 85]	22, 64.4 (21.6) [16 to 90]
Accelerometry[II]		
Ave mins/day light activity	17, 112 (64) [5 to 231]	21, 110 (46) [4 to 201]
....Ave mins/day at least light activity	17, 133 (77) [7 to 260]	21, 138 (56) [7 to 266]
…Ave mins/day at least moderate activity	17, 21 (23) [1 to 96]	18, 28 (23) [1 to 79]
….Ave mins/day vigorous activity	17, 0.1 (0.1) [0 to 0.4]	18, 0.5 (2) [0 to 8]
HADS[I]		
Depression score	23, 5.6 (3.3) [1.0 to 14.0]	22, 3.9 (3.4) [0 to 16.0]
Anxiety score	23, 7.3 (4.4) [1.0 to 18.0]	22, 5.9 (3.8) [0 to 16.0]
HeartQoL[II]		
Global score	23, 1.45 (0.78) [0 to 2.79]	22, 1.69 (0.66) [0.29 to 2.43]
Physical score	23, 1.28 (0.85) [0 to 2.70]	22, 1.49 (0.80) [0.75 to 3.00]
Emotional score	23, 1.86 (0.95) [0 to 1.93]	22, 2.18, (0.60) [0.07 to 3.00]
Self-care of Heart Failure Index (SCHFI)[II]		
Maintenance	23, 56.0 (13.5) [26.7 to 83.3]	22 65.7 (15.1) [43.3 to 100.0]
Management **	13, 46.5 (20.4) [15.0 to 95.0]	11, 54.5 (15.1) [30.0 to 75.0]
Confidence	23, 58.2 (22.8) [11.1 to 100.0]	22, 63.1 (17.5) [27.8 to 88.9]
Deaths	-	N=0
Total hospitalisations HF-related Not HF-related	-	N=2 N=1 N=1
BNP level (pg/mL)[I]	15, 670 (468) [72 to 1439]	15, 579 (375) [87 to 1555]

[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]	11, 3.9 (4.7) [0.0 to 15.0]
Anxiety score	12, 9.6 (6.7) [1.0 to 21.0]	11, 6.8 (5.7) [1.0 to 20.0]
Caregiver Contribution to Self-care of Heart Failure Index (CC-SCHFI)[II]		
Maintenance	12, 34.9 (22.4) [0.0 to 73.3]	11, 41.9 (25.5) [6.7 to 74.1]
Management **	8, 33.1 (11.3) [20.0 to 55.0]	3, 48.3 (20.2) [25.0 to 60.0]
Confidence	12, 48.1 (18.5) [16.7 to 77.8]	11, 59.1 (11.5) [38.9 to 72.2]
Caregiver Burden Questionnaire – Heart Failure (CBQ-HF)[I]		
Physical	12, 5.3 (5.7) [0.0 to 20.0]	11, 4.4 (5.5) [0.0 to 20.0]
Emotional	12, 22.6 (15.6) [4.0 to 52.0]	11, 18.0 (15.0) [2.0 to 59.0]
Social Life	12, 1.6 (2.3) [0.0 to 8.0]	11, 1.2 (1.8) [0.0 to 6.0]
Lifestyle	12, 5.2 (4.2) [0.0 to 15.0]	11, 4.4 (4.9) [0.0 to 16.0]
Family Caregiver-Specific Quality of Life Scale (FAMQOL)[I]		
Physical	12, 15.1 (3.2) [9.0 to 18.0]	11, 15.1 (3.2) [8.0 to 20.0]
Psychological	12, 12.2 (4.9) [5.0 to 20.0]	11, 12.9 (4.3) [5.0 to 20.0]
Social	12, 15.3 (3.3) [7.0 to 20.0]	11, 15.3 (4.4) [4.0 to 20.0]
Total	12, 56.3 (12.5) [29.0 to 74.0]	10, 55.9 (10.4) [27.0 to 64.0]

[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.