vCare Final Event:
UMFCD Heart failure pilot results

29-08-2022

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Recommendations for exercise rehabilitation in patients with chronic heart failure

Recommendations	Class[a]	Level[b]
Exercise is recommended for all patients who are able in order to improve exercise capacity, QOL, and reduce HF hospitalization.[c 324−328,335−337]	I	A
A supervised, exercise-based, cardiac rehabilitation programme should be considered in patients with more severe disease, frailty, or with comorbidities.[95,324−327,338]	IIa	C

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HF = heart failure; QOL = quality of life.
[a]Class of recommendation.
[b]Level of evidence.
[c]In those who are able to adhere to the exercise programme.

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Aim:

- ensuring continuity of medical care and access to personalized cardiac rehabilitation program at home for patients with cardiovascular disease using vCare system.
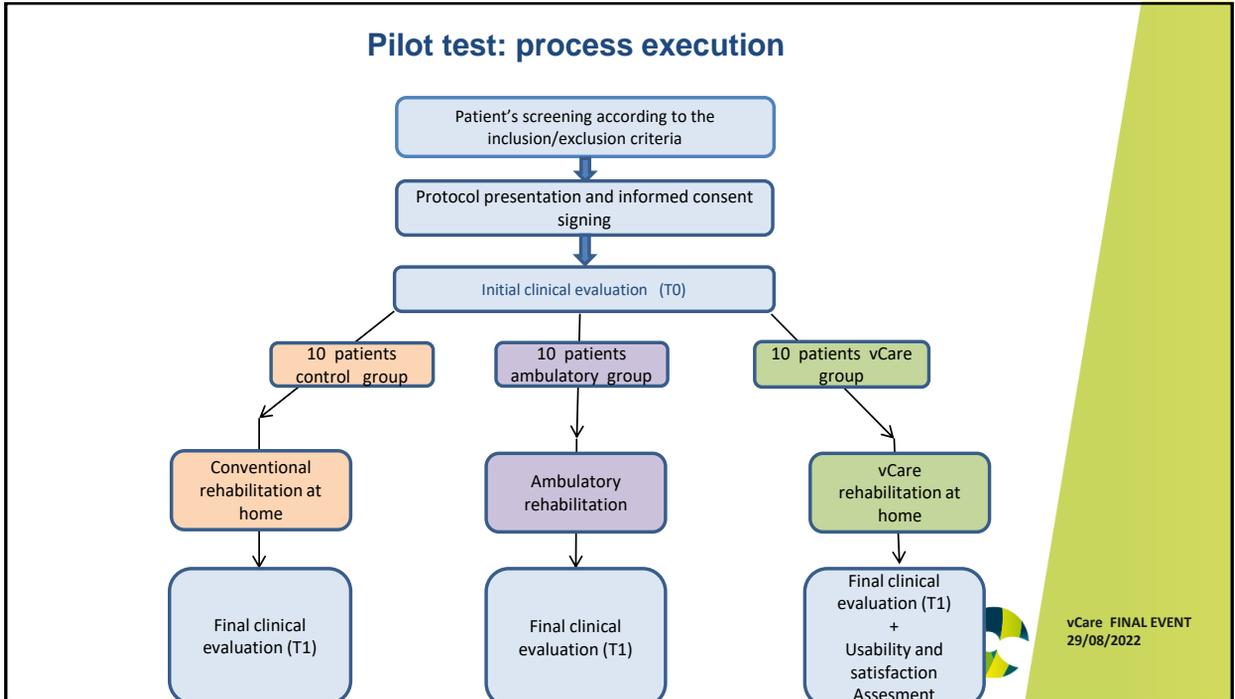
Cardiologist

inpatient

HOSPITAL

outpatient

Home
Environment

Continuity
of Care

Cardiologist,
Physiotherapist,
Psychologist,
Nutritionist

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Covid-19 impact

Ethical approval
December 2021

Covid-19 restriction

January- March 8 2022

14.02.2002
First patient recruited

delays in receiving the devices

29.06.2022
Completed the enrolment
process

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Pilot test: process execution

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┌─────────────────────────────────────────┐
│ Patient's screening according to the     │
│ inclusion/exclusion criteria             │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│ Protocol presentation and informed       │
│ consent signing                          │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│ Initial clinical evaluation  (T0)        │
└─────────────────────────────────────────┘
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10 patients control group	10 patients ambulatory group	10 patients vCare group
Conventional rehabilitation at home	Ambulatory rehabilitation	vCare rehabilitation at home
Final clinical evaluation (T1)	Final clinical evaluation (T1)	Final clinical evaluation (T1) + Usability and satisfaction Assesment

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Pilot test: inclusion and exclusion criteria

Exclusion criteria:
- Unstable angina;
- Systolic resting blood pressure >200mmHg, Diastolic >110mmHg;
- Blood pressure decrease with more than 20mmHg at standing position;
- Severe Aortic Stenosis;
- Sepsis;
- Uncontrolled arrhythmias;
- Uncontrolled Atrial Tachycardia HR >120bpm;
- Decompensated Heart Failure;
- Atrial-ventricular Grade 3 Transmission Block;
- Recent Pulmonary Thromboembolism;
- Phlebitis;
- Persistent ST segment elevation of more than 2 mm;
- Uncontrolled Diabetes;
- Locomotor disabilities;
- Thyroiditis, Hypokalaemia, Hyperkalemia, Hypervolemia;
- Incapacity to understand the study and provide informed consent;
- Refusal to sign the informed consent

Inclusion criteria:
- Diagnosis of heart failure class NYHA II-III;
- Age ≥50 years old;
- Availability to interact with digital devices;
- High-speed internet connection at home;
- Presence of a TV screen at home with HDMI port.

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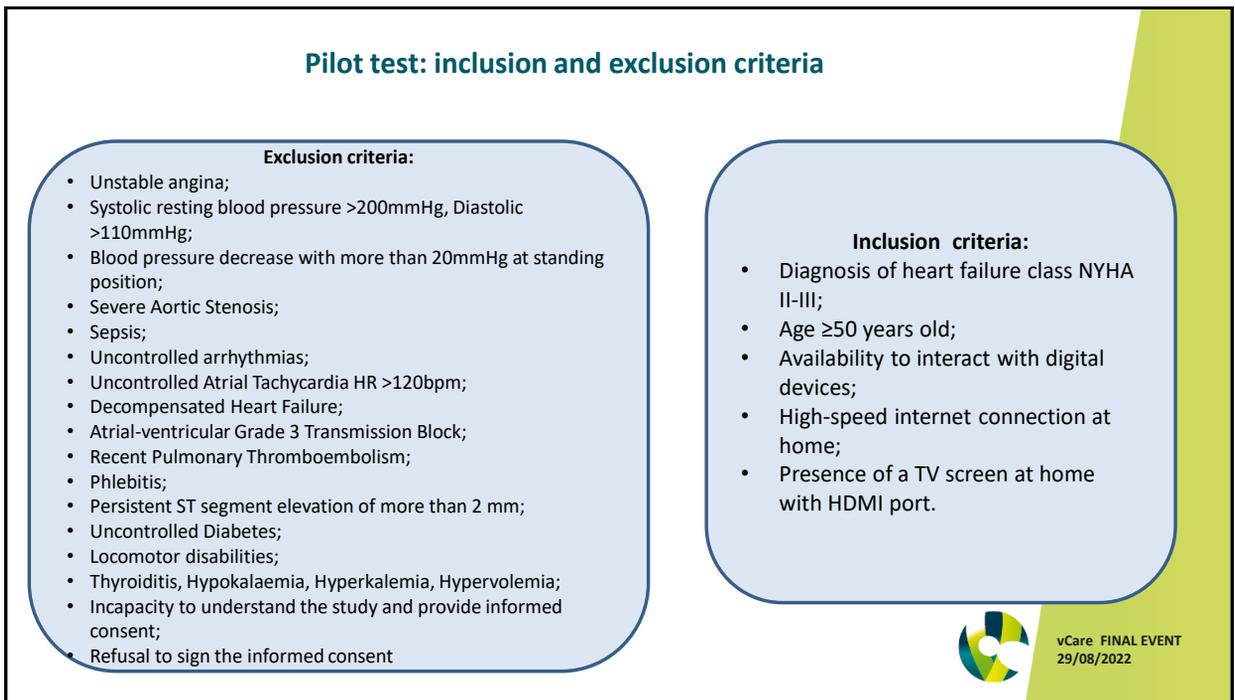## Pilot test: clinical evaluation

- The baseline assessment:

➢ quality of life measurement perceived by the subjects and portrayed by EuroQol-5D (Euro Quality of Life 5 Dimensions).

- Secondarily: the patients have been clinically characterized using the following evaluation scales for the identification of risk factors:

➢ Fagerstrom test for nicotine dependence
➢ HADS scale (Anxiety and in-hospital depression)
➢ Minnesota Living with Heart Failure
➢ ECG stress test (VO_2 max*)

*VO2 max=maximal Oxygen consumption by the body (measured in mL/kg/min)

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Pilot test: expected outcomes

Outcomes	Improvement indicator
Primary outcome	
Improvement of the quality of life (evaluated by EuroQoL5D)	10% increase of the QoL score at the end of in-house pilot study
Secondary outcome	
Reduction of risk factors	
Daily number of steps	improve at least by 10%
Weekly time spent exercising	improve at least by 10%
Weekly number of corrective e-learning lessons	at least once a week
Changes in weight loss	expected to reach normal body-mass index during Pilot Test
Medication adherence	blood pressure values should be under 140 mmHg for systolic blood pressure and 90 mmHg to express medication adherence and dietary risk factors control
Number of cigarettes smoked	expected to decrease during Pilot Test
Cholesterol levels reduction	more than 15% reduction in LDL cholesterol

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Pilot test: usability and satisfaction

List of scales used for usability and satisfaction in Heart Failure use case

Use Case	Scales
Heart Failure - UMFCD	UEQ (User Experience Questionnaire)
	SUS (System Usability Scale)
	TAM (Technology Acceptance Model)

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Pilot test: vCare activities in the pilot test

Activity	App	Device
E-learning (A3)	vCare avatar app	Tablet
Daily motor activity (A 12)	UMFCD Rehability Motor App	Set top box Camera TV
Aerobic physical activity (A13)	vCare avatar app MiFit app	Tablet Wristband
Resistance training (A14)	vCare avatar app MiFit app UMFCD Rehability Motor App	Tablet Wristband Set top box Camera TV
Vital stats control (A16)	vCare avatar app	Tablet Beurer M85
Weight control (A17)	vCare avatar app	Tablet XIAOMI Weight scale
Smoking cessation activity (A18)	vCare avatar app	Tablet
Anxiety and depression reduction (A19)	vCare avatar app	Tablet
Healthy daily n° of steps	vCare avatar app	Tablet Wristband

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Pilot test: results

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Limitations

- delay in receiving the necessary equipment
    - → late enrolment of patients
    - → shorter time in patient's use of the system.

- technical issues

- home environmental issues (small space)
    - → camera calibration could not be done properly
    - → the patients could not use the serious games.

- technical difficulties in using the system for elderly patients
- Internet access

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Pilot test: patient's characterization

We had 1 dropout patient for the experimental group

Gender Distribution

■ Male ■ Female

43%

57%
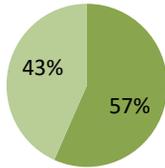
Smokers patients

■ vCare group ■ ambulatory group ■ control group

40% 30%

30%
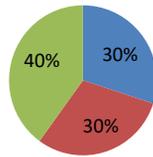
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Pilot test: clinical results

Exercise ECG test: assessment of the effort capacity measured by VO2 max

VO$_2$max Pre and Post-Intervention

19.21 | 21.32

19.18 | 21.98

18.46 | 17.04

EG AG CG

■ T0 ■ T1
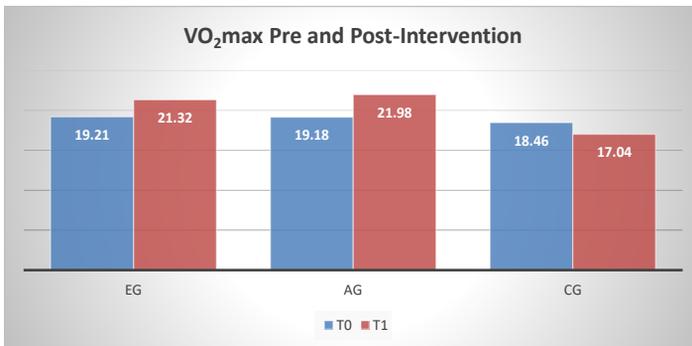
Increase with 11 % in EG
Increase with 14 % in AG
Decrease with 8 % in CG

EG= experimental group
AG= ambulatory group
CG=control group

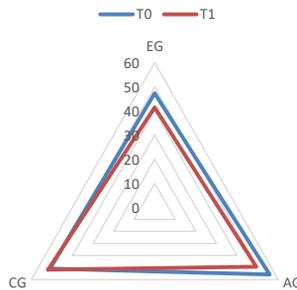T0= pre-intervention evaluation
T1= post-intervention evaluation
VO2 max = maximal Oxygen consumption by the body
measured in mL/kg/min

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Pilot test: clinical results
risk factors-

LDL- cholesterol values Pre and Post Intervention
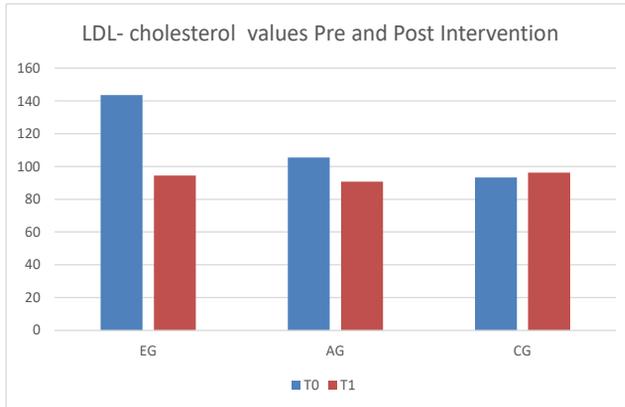
Decrease with 34 % in EG
Decrease with 14 % in AG
Increase with   3 % in CG

EG= experimental group
AG= ambulatory group
CG=control group

T0= pre-intervention evaluation
T1= post-intervention evaluation

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Pilot test: clinical results

MLHFQ Pre and Post-intervention

EG= experimental group
AG= ambulatory group
CG=control group

T0= pre-intervention evaluation
T1= post-intervention evaluation
MLHFQ= Minnesota Living with Heart
Failure questionnaire

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Pilot test: clinical results
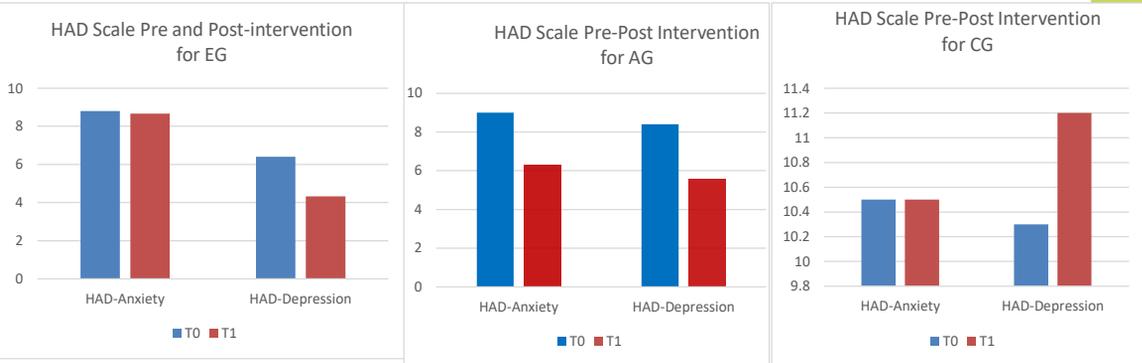
HAD Scale Pre and Post-intervention for EG

HAD Scale Pre-Post Intervention for AG

HAD Scale Pre-Post Intervention for CG

EG= experimental group
AG= ambulatory group
CG=control group

T0= pre-intervention evaluation
T1= post-intervention evaluation
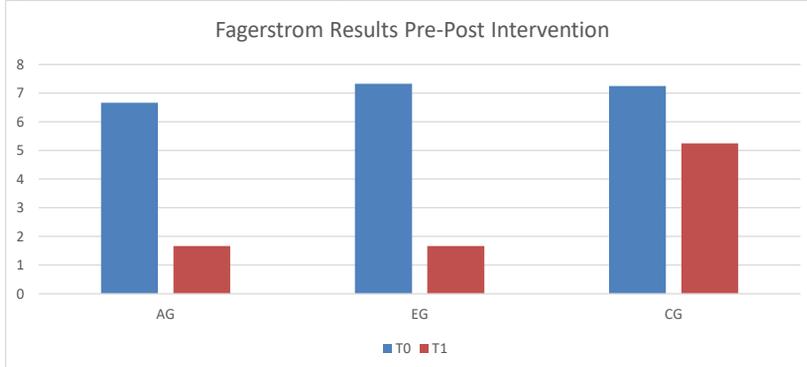HAD= Anxiety and in-hospital depression scale

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Pilot test: clinical results

Fagerstrom test for nicotine dependence

Fagerstrom Results Pre-Post Intervention

EG= experimental group
AG= ambulatory group
CG=control group

T0= pre-intervention evaluation
T1= post-intervention evaluation

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Pilot test: clinical results

- Average blood pressure values for each patient and the standard deviation

	Systolic blood_presssure mean	Systolic blood_presssure std	Diastolic blood_presssure_mean	Diastolic blood_presssure_std
Patient1	118	14	85	4.645787
Patient2	128	11	77	5.125102
Patient4	130	6	83	6.150643
Patient5	122	5	74	12.28821
Patient6	123	11	74	9.465484
Patient8	124		73	
Patient9	126	9	83	8.599136
Patient10	DO			
mean	124.7673	9.644208	78.80059	7.712393
std	3.980314	3.428677	5.219423	2.943974

DO = drop-out

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Pilot test: quality of life assessment

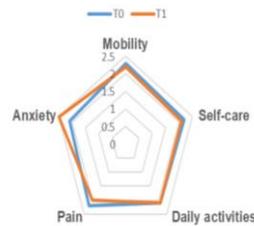- Quality of life assessment using EuroQol-5D questionnaire
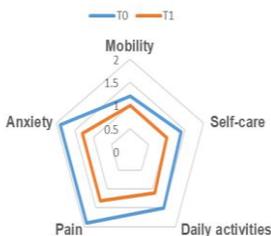
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Pilot test: vCare parameters

- Steps parameter and relative metrics depicted for each subject

	Active_days	Adherence	Average steps per active days
Patient1	3	8%	211
Patient2	7	30%	1467
Patient4	22	25%	8632
Patient5	1	2%	704
Patient6	7	6%	5251
Patient7	3	4%	524
Patient8	3	10%	474
Patient9	35	38%	2545
Patient10	DO		
mean	10.1	16%	2476.
std	12	0.1	2993

DO = drop-out

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Pilot test: vCare parameters

- Avatar App (expressed as Accesses and Interactions between patient and VC) depicted for each subject and as mean across group.

	Active_weeks	Adherence	Average accesses per active weeks
Patient1	4	72%	3
Patient2	3	91%	2
Patient4	10	79%	6
Patient5	2	32%	5
Patient6	13	80%	5
Patient7	3	31%	2
Patient8	4	93%	3
Patient9	14	93%	10
Patient10	DO		
mean	6.6	71%	4
std	4.9	0.2	3

DO = drop-out

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Pilot test: vCare parameters

- vCare Motor Games App parameter and relative metrics depicted for each subject

	Completed session	Played games	Scheduled games	Played time mean [sec]	Played time sum [sec]	Played time max [sec]	Adherence in using vCare games App
Patient 1	2	37	50	1180	8260	1758	74%
Patient 2	1	4	9	350	700	700	44%
Patient 3	0	1	8	254	254	254	13%
Patient 6	12	56	94	260	9602	1465	60%
Patient 7	2	6	26	202	1010	391	23%
Patient 9	27	110	130	680	20409	1709	85%
mean	6.3	30.6	46	475	7705	1037	43%
Std	10	41.1	49	464	7486	843	0.3

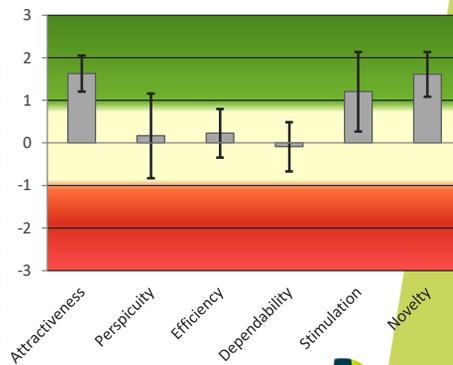VCARE FINAL EVENT
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Pilot test: usability and satisfaction

UEQ (User Experience Questionnaire)

- UEQ's domains results

|	Attractiveness	Perspicuity	Efficiency	Dependability	Stimulation	Novelty
PAT 01	2	0.25	1.25	0.5	1.75	2
PAT 02	1.6	2.33	0	-0.25	2	1.5
PAT 03	1.83	2	-2	-1.25	1.75	1.75
PAT 04	2.3	-1.25	-0.5	0	2.75	2.5
PAT 05	2.83	1.5	0.75	1.25	3	2.5
PAT 06	1.33	-1.25	1.25	1	-1	1.25
PAT 07	1.83	1.25	0.75	-1	2	1.5
PAT 08	2	-1.5	1	0.25	1.75	2.25
PAT 09	0.5	-2.5	0.25	1	-2.25	-0.75
PAT 10	1.16	1.75	-0.5	-1	0.5	1.75
mean ± std.	1.73 ± 0.58	0.25 ± 1.57	0.22 ± 0.91	0.05 ± 0.82	1.22 ± 1.50	1.62 ± 0.84

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Pilot test: usability and satisfaction

SUS (System Usability Scale)

- SUS scores obtained by patients enrolled in EG
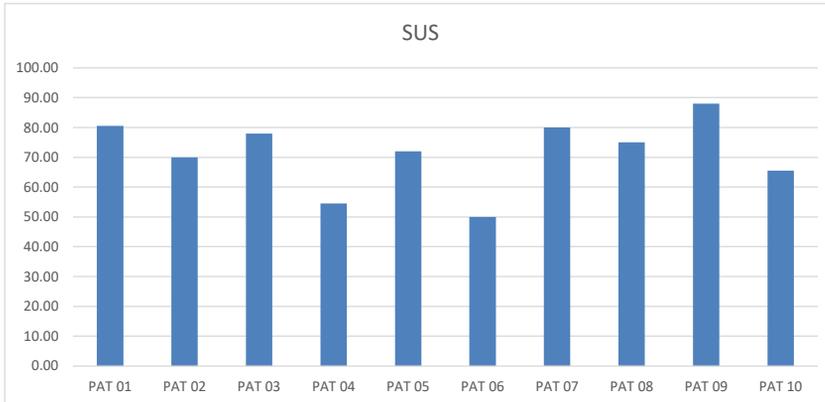
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Pilot test: usability and satisfaction

TAM (Technology Acceptance Model)

- The TAM questionnaire: mean and standard deviation score for each item

CONSTRUCT	MEASUREMENT INSTRUMENT	MEAN (SD)
Perceived usefulness	Using the vCare system as a rehabilitation tool would speed up my progress	4.5 ± 0.8
	Using the vCare system would improve my rehabilition performance	5.6 ± 0.8
	Using the vCare system as a rehabilitation tool would make it easier to conduct rehabilitation sessions at home	5.4 ± 0.66
	Using the vCare system would reduce my level of disability	4.1 ± 0.7
	Using the vCare system would positively affect my quality of life	5.6 ± 0.48
	I think that using the vCare system is helpful for my rehabilitation	5.3 ± 0.64
	TOTAL	**30.5 ± 4.08** (max=42)
Perceived ease of use	Learning to use the vCare system was easy for me	4.5 ± 0.67
	Dealing with the vCare system was intuitive for me	4.8 ± 0.4
	The interaction between me and the vCare system was well defined	5.3 ± 0.64
	I think that the vCare system is clear and understandable	5.3 ± 0.45
	I think that it is easy for me to control the vCare system's different features	4.6 ± 0.66
	I think that the vCare system is easy to use	4.1 ± 0.53
	TOTAL	**28.6 ± 3.35** (max = 42)
	TOTAL TAM	**59.1 ±7.43** (max=84)

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Pilot test: heart failure KPI results

Outcomes		Improvement indicator	Results
Primary outcome			
Improvement of the quality of life	EuroQoL5D	10% increase of the QoL score at the end of in-house pilot study	✔ Mobility = 10% ✔ Self-care = 17% ✔ Pain/disconfort = 30% ✔ Daily activities = 18% ✔ Anxiety/depression = 23%

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Pilot test: heart failure KPI results

Outcomes	Improvement indicator	Results
Secondary outcome		
Reduction of risk factors		
Daily number of steps	improve at least by 10%	✔ The minimum improve in the number of steps was 7% and the maximum was 84%. The average number of steps increased was 32%
Weekly time spent exercising	improve at least by 10%	✔ Increased by 12%
Weekly number of corrective e-learning lessons		X Not all patients watched the e-learning materials
Changes in weight loss	Expected to aproach during Pilot Test towards normal body-mass index.(BMI)	X There were small variations in the weight of the patients, but the objective of having a normal BMI was not reached
Medication adherence	Blood pressure values should be under 140mmHgs for systolic blood pressure and 90mmHgs to express medication adherence and dietary risk factors control	✔ All patients maintained their blood pressure value below 140/90 mmHg
Number of cigarettes smoked	expected to decrease during Pilot Test	✔ 2 out of 3 patients stopped smoking and 1 patient reduced his addiction by 50%
Cholesterol levels reduction	more than 15% reduction	✔ Decrease with 30%

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Conclusion

- The use of the vCare system:

  ✓ improve the clinical condition

  ✓ increase the quality of life

  ✓ a safe and efficient solution for ensuring continuity of medical care and access to personalized cardiac rehabilitation for patients with cardiac disease

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Thank you for your attention!

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VIRTUAL COACHING ACTIVITIES
FOR REHABILITATION IN ELDERLY

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