

# The effects of a tailored telemonitoring system in patients with heart failure

## The TEHAF-study

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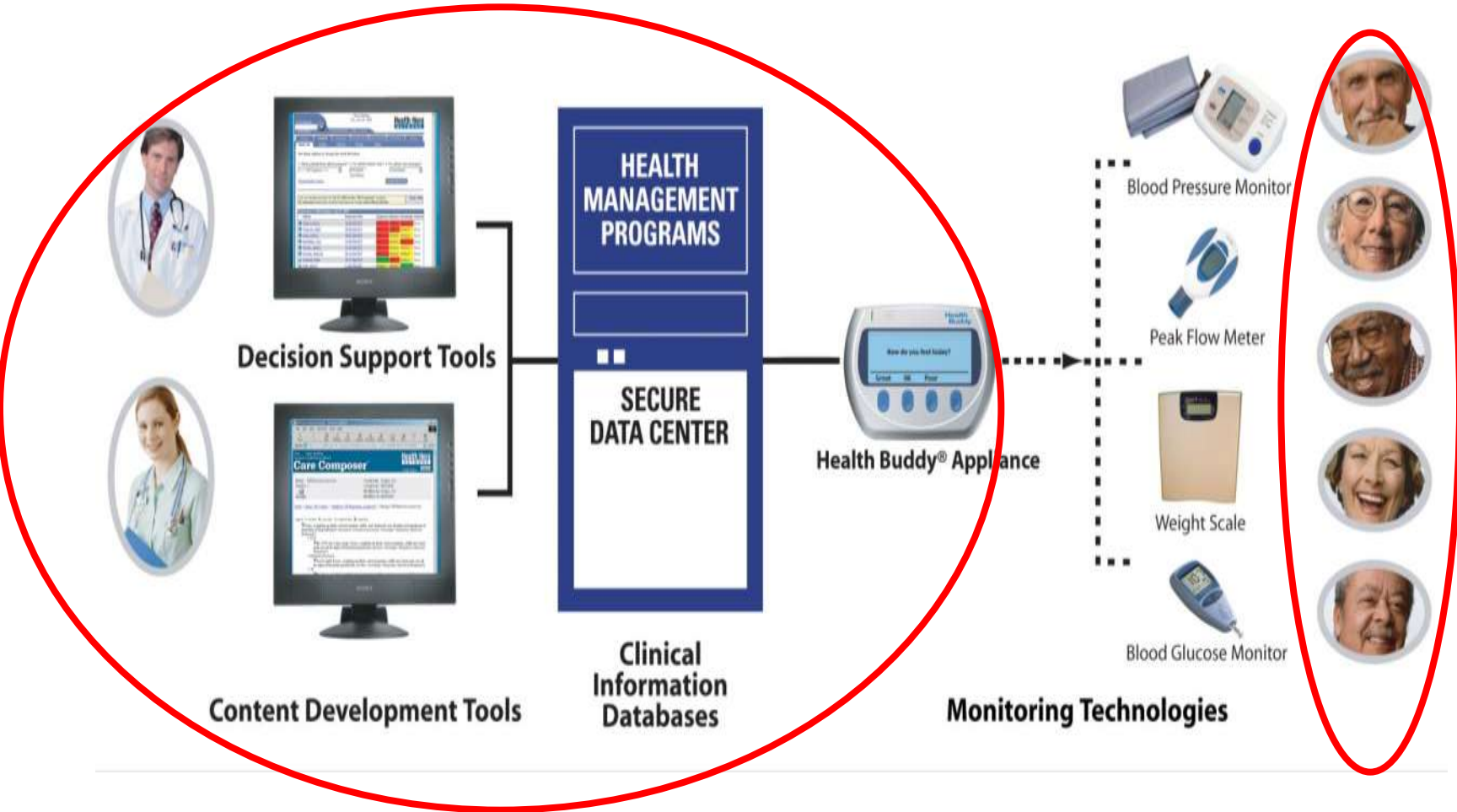
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Presenter disclosure information  
no conflicts of interest.

# The TEHAF-study

The TEHAF-study is a multicentre randomised controlled trial, studying the effects of telemonitoring in patients with heart failure

# The Health Buddy<sup>®</sup> system



## CAPHRI School for Public Health and Primary Care

Programme 1  
Focus on SKB  
90 days  
•At start  
•Instable HF  
Low DS education

Programme 2  
Focus on S  
30 days  
•Instable HF  
Well DS education  
•After HF-admission

Programme 3  
Focus on KB  
90 days  
•No symptoms  
Low DS education

Programme 4  
Maintenance  
180 days  
•No symptoms  
Well DS education

## Study design

- To detect a reduction of 50% in HF-admissions with a two sided significance level of 0.05 and power of 0.80, with a lost to follow up of 10%, a sample size of 195 patients was needed per group
- Follow-up of 1 year
- Analyses based on intention to treat

# In- and exclusion criteria

- Inclusion
  - Diagnosed for HF
  - NYHA classification 2-4
  - >18 years
  - Capable to give IC
  - Treated by a HFN and a cardiologist team
- Exclusion
  - Physically and/or cognitively unable to use the HB<sup>®</sup>
  - Expected lifespan <1 year
  - COPD Gold classification 3-4
  - Haemodialysis

# Endpoints

- Primary endpoint:
  - Time to first admission for heart failure
- Secondary endpoints:
  - Number of heart failure (re)admissions and admission days
  - Cardiovascular and other cause admissions and admission days
  - Number of contacts with caregivers
  - Mortality

# Results : baseline characteristics (1)

	<b>Intervention (197)</b>	<b>Usual Care (185)</b>	<b>P-value</b>
<b>Gender / male*</b>	<b>115 (58)</b>	<b>111 (60)</b>	<b>ns</b>
<b>Married or partner*</b>	<b>122 (62)</b>	<b>123 (66)</b>	<b>ns</b>
<b>Age</b>	<b>72 (62-81)</b>	<b>74 (64-80)</b>	<b>ns</b>
<b>Duration of HF (mnths)</b>	<b>17,5 (6-42)</b>	<b>14,5 (4-40)</b>	<b>ns</b>
<b>NYHA 2</b>	<b>110 (56)</b>	<b>105 (59)</b>	<b>ns</b>
<b>NYHA 3 &amp; 4</b>	<b>87 (44)</b>	<b>76 (41)</b>	<b>ns</b>
<b>LVEF</b>	<b>36 (28-50)</b>	<b>35 (26-46)</b>	<b>ns</b>
<b>% LVEF ≤ 45%*</b>	<b>117 (60)</b>	<b>112 (62)</b>	<b>ns</b>
<b>Heart rate</b>	<b>75 (68-85)</b>	<b>72 (65-85)</b>	<b>ns</b>
<b>Systolic BP</b>	<b>120 (110-140)</b>	<b>125 (110-140)</b>	<b>ns</b>
<b>Diastolic BP</b>	<b>70 (64-80)</b>	<b>73 (65-80)</b>	<b>ns</b>

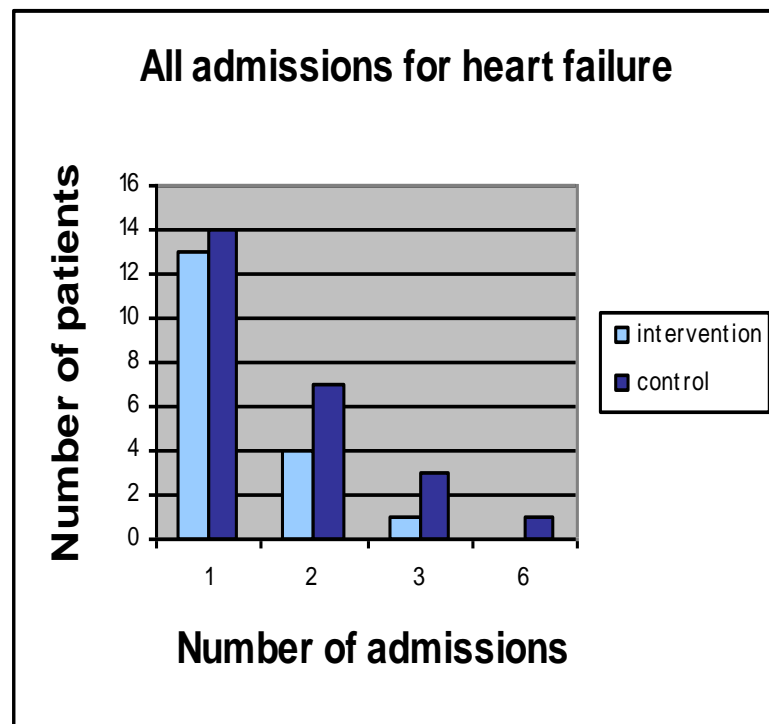
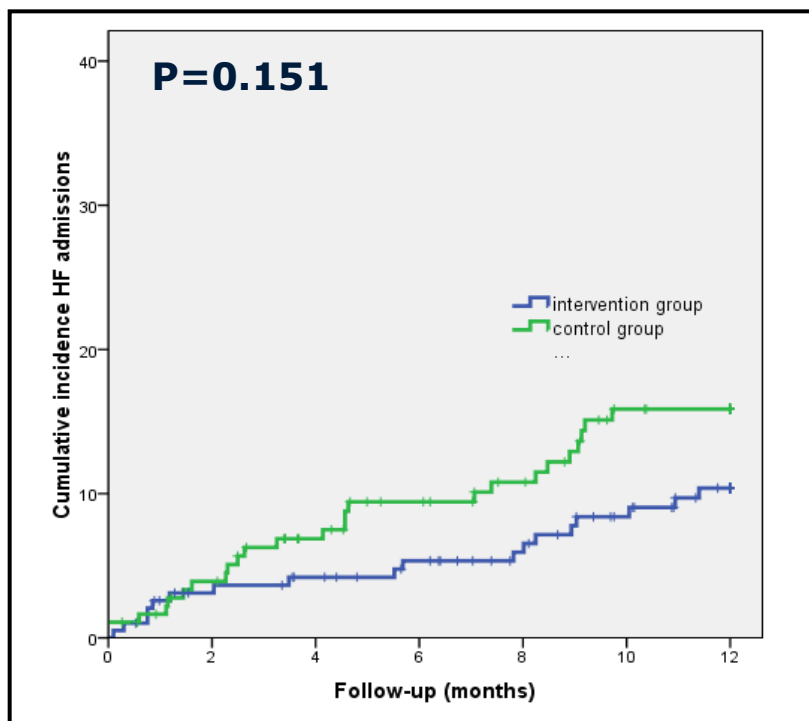
median (IQ 25-75) (\*number (%)) P=MW-test

# Results : baseline characteristics (2)

	<b>Intervention (197)</b>	<b>Usual Care (185)</b>	<b><i>P</i>-value</b>
<b>Ischemia</b>	<b>99 (50.3)</b>	<b>91 (49)</b>	<b>ns</b>
<b>Pacemaker</b>	<b>59 (30)</b>	<b>53 (29)</b>	<b>ns</b>
<b>Atrial fibrillation</b>	<b>62 (32)</b>	<b>35 (19)</b>	<b>0.007</b>
<b>Diuretics</b>	<b>170 (86)</b>	<b>163 (88)</b>	<b>ns</b>
<b>ACE-inhibitors</b>	<b>113 (58)</b>	<b>104 (57)</b>	<b>ns</b>
<b>ATII-antagonists</b>	<b>67 (35)</b>	<b>56 (31)</b>	<b>ns</b>
<b>Beta-blocker</b>	<b>161 (83)</b>	<b>149 (81)</b>	<b>ns</b>
<b>Ace/ATII and BB</b>	<b>161 (82)</b>	<b>143 (77)</b>	<b>ns</b>

**MW-test (%)**

# Primary endpoint



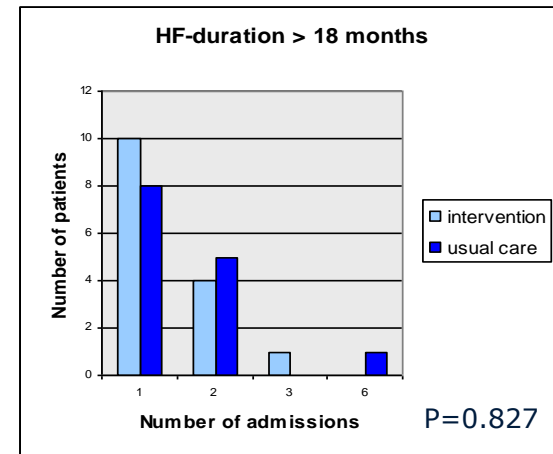
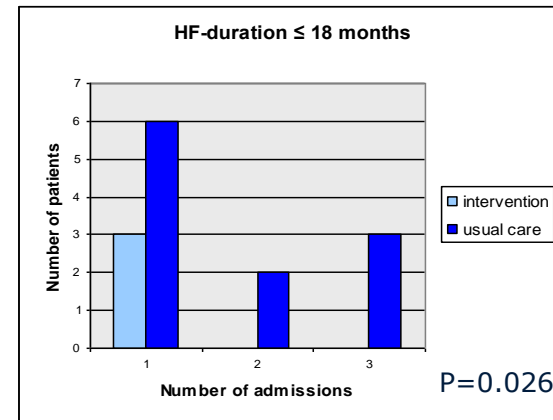
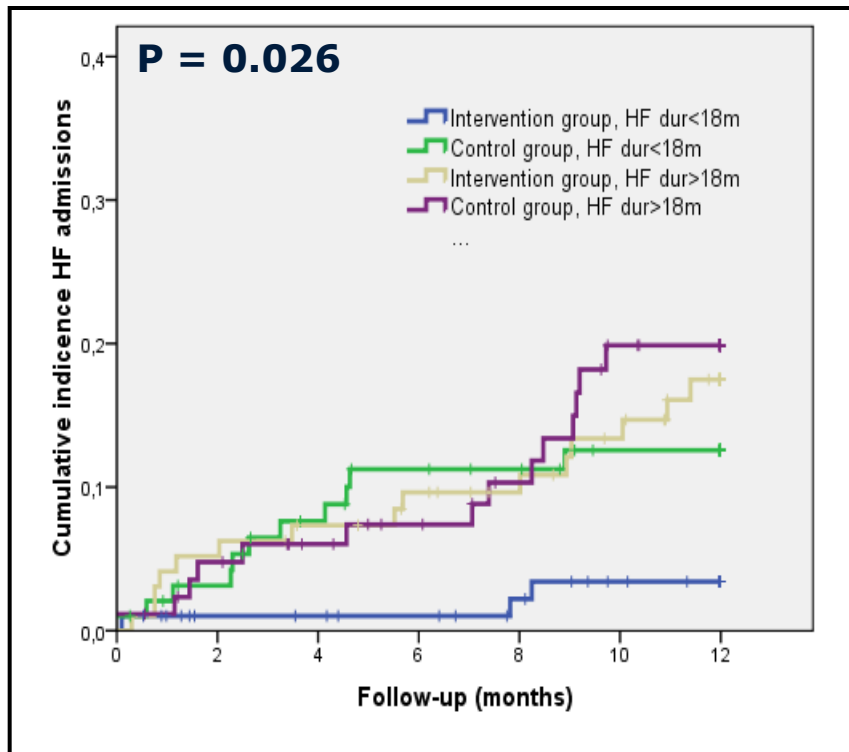
- 18 patients had 24 admissions
- 25 patients had 43 admissions

## Univariate and Cox regression analysis of primary endpoint

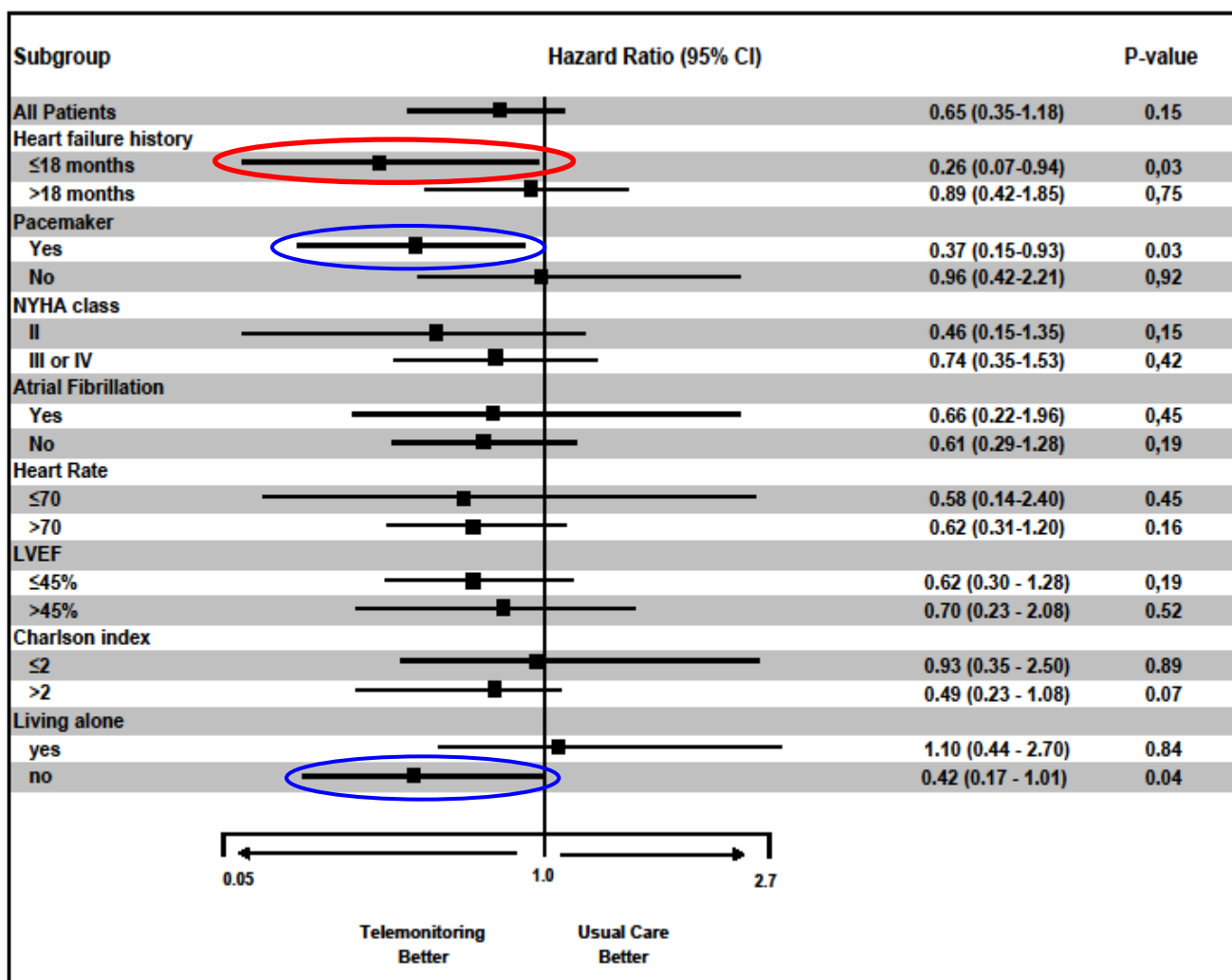
	<i>P</i> - value	Hazard	Lower	Upper
<b>Univariate analysis</b>				
Group (intervention / usual care)	0.151	0.65	0.35	1.18
<b>Cox regression analysis</b>				
Group (intervention / usual care)	<0.001	4,96	2.022	12.181
Group * Duration of HF	.007	0,98	.970	.995
NYHA 2	.020			
NYHA 3 vs 2	.006	0,00	<0.001	.183
NYHA 4 vs 2	.216	0,00	<0.001	49.205
BP systolic	<0.001	0,94	.909	.968
History of HF	.001	1,02	1.007	1.024
Ischemia	.022	2,14	1.113	4.098
Urea	.001	1,08	1.031	1.122
Haemoglobin	.004	0,64	.474	.867
Heart Rate	<0.001	1,05	1.023	1.068
NYHA 2 * BP-sys	.011			
NYHA 3 vs 2 * BP-sys	.004	1,06	1.018	1.095
NYHA 4 vs 2 * BP-sys	.094	1,08	.987	1.183

Hazard = Cox Regression Effect

# Sub-analysis for HF-duration $\leq$ or $>$ 18 months



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Subgroup Analysis of time to first admission for heart failure

# Secondary endpoints

	Intervention (N = 197)	Usual care (N = 185)	p-value*
<b>Total heart failure hospital days</b>	253	330	0.18
median (IQR)	11 (5,75-22,5)	11 (5,5-19,5)	
≤18 months	29	176	0.02
>18 months	224	154	0.95
<b>Re-admissions for heart failure</b>	5	11	0.10
≤18months	0	5	0.02
>18months	5	6	0,6
<b>Patients with cardiovascular admissions<sup>†</sup></b>	26 (13.2) <sup>‡</sup>	18 (9.7)	0.29
1 admission	24 (12.2)	15 (8.1)	
2 admissions	2 (1.0)	1 (0.5)	
>2 admissions		2 (1.1)	
<b>Total cardiovascular hospital days</b>	155	101	0.28
median (IQR)	2,5 (2-7)	2 (2-7,3)	
<b>Patients with other cause admissions</b>	49 (24.8)	35 (18.9)	0.16
1 admission	35 (17.1)	30 (16.2)	
2 admissions	11 (5.6)	3 (1.6)	
>2 admissions	2 (1.0)	2 (1.1)	
<b>Total other cause hospital days</b>	720	435	0.21
median (IQR)	5 (1-20,5)	5 (5-14)	
<b>Mortality</b>	18 (9.1)	12 (6.5)	0.82**
<b>Contacts with heart failure nurse</b>	267 ±1.36 <sup>‡</sup>	321 ±1.74	<0.01
median (IQR)	1 (0-2)	1 (1-3)	

\* Mann-Whitney test \*\* Cox regression \*\*\* Kaplan-Meier

† Cardiovascular or heart failure therapy related

‡ (percentage)

# Conclusions

- Trend to less admissions for heart failure in favour of the intervention group
- In sub analysis a significant reduction of heart failure hospital first and re-admissions, and admission days in the intervention group with HF  $\leq 18$  months
- A reduction in number of face to face contacts with the heart failure-nurse



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# Differences between heart failure duration $\leq$ en $>$ 18 months HF

	HF $\leq$ 18mnths	HF $>$ 18mnths	<i>p</i> -value
	196	186	
NYHA 2	113	92	ns
NYHA 3&4	69	83	0.076
pacemaker	47	65	0.02
no pacemaker	149	121	ns
age $\leq$ 75	96	112	ns
age $>$ 75	100	74	0.027
living alone yes	66	67	ns
living alone no	127	119	ns

# Combined EP for HF <&>18 months

	HF≤18mnths	HF>18mnths	p-value
	196	186	
admissions for heart failure	14	29	
death	15	15	
primary EP	HR 0.47	CI 0.25-0.88	0.02
combined EP	HR 0.66	CI 0.40-1.09	0.11

# Living alone or together

	living alone	living together	p-value*
	n=62	n=115	
daily compliance	90%	88%	ns
admission for heart failure	11 (18%)	7 (6%)	0.03
*chi <sup>2</sup>			

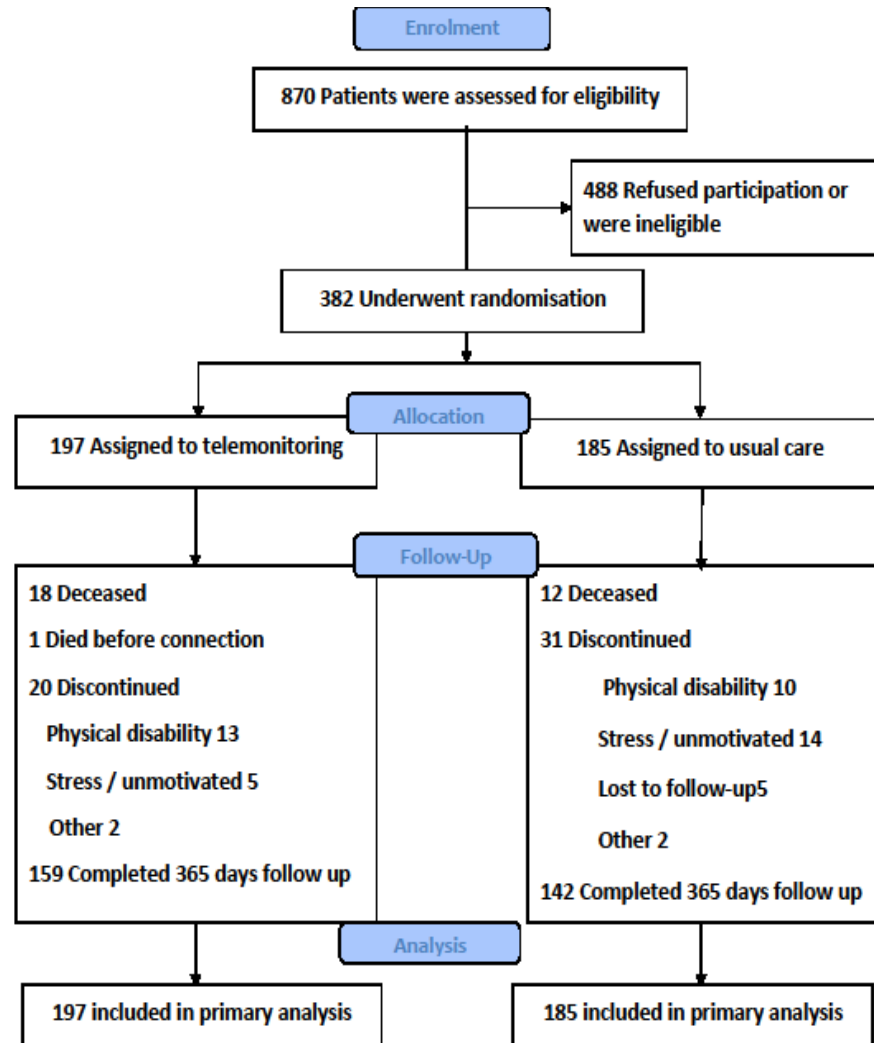
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	both groups		telemonitoring		usual care		p-value
	no of pat	mean mg	no of pat	mean mg	no of pat	mean mg	
<b>ACE</b>							
captopril	16	93	8	98,5	8	87,5	ns
quinapril	84	23	41	21	43	25,5	ns
fosinopril	12	17	4	27,5	8	12	0.07
lisinopril	12	15	6	13	6	17	ns
perindopril	61	4,6	34	4,8	27	4,5	ns
enalapril	16	23,5	10	26	6	19	ns
ramipril	14	5,3	9	4,7	5	6,5	ns
<b>ATII</b>							
candersartan	15	13,9	9	16,9	6	9,3	ns
irbesartan	25	250	15	256	10	241	ns
losartan	25	73	11	73	14	73	ns
valsartan	43	169	24	173	19	163	ns

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	both groups		telemonitoring		usual care		p-value
	no of pat	mean mg	no of pat	mean mg	no of pat	mean mg	
<b>DIURETICS</b>							
bumetanide	186	4,2	85	5	101	3,6	ns
furosemide	133	81	75	87,5	58	72,5	ns
chloorthalidon	3	40	2	50	1	20	na
hydrochloorthiazide	11	29	8	33,5	3	16,6	ns
<b>BBLOCKER</b>							
carvedilol	122	38	68	46	54	27,5	ns
metoprolol	123	98	53	101	70	95,5	ns
bisoprolol	22	4,6	13	4,7	9	4,4	ns
atenolol	6	82,2	4	73,5	2	100	na
nevigolol	5	176	3	140	2	230	na
labetolol	18	4,8	13	4,9	5	4,5	ns

# Screening and follow-up



## Daily compliance using the system

- Mean percentage number of daily responses is 89%
- Median 96 (IQ 84-98)
  - First 3 months 93% (progr.1)
  - Repeated first program 94% (re-progr.1)
  - Focus on symptoms 87% (progr.2)
  - Focus on education 87% (progr.3)
  - Maintenance program 87% (progr.4)