<table>
<thead>
<tr>
<th>Survey SC acuto</th>
<th>Italiana (n=2870)</th>
<th>Europea (n=2467)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentazione</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Scompenso de novo</strong></td>
<td>44%</td>
<td>39.6</td>
</tr>
<tr>
<td>Riacutizzazione SC cronico</td>
<td>54.8%</td>
<td>60.4</td>
</tr>
<tr>
<td>Età media</td>
<td>73</td>
<td>70.5</td>
</tr>
<tr>
<td>Sesso femminile</td>
<td>40%</td>
<td>39%</td>
</tr>
<tr>
<td>Ipertensione</td>
<td>66%</td>
<td>63.2</td>
</tr>
<tr>
<td>Cardiopatia ischemica</td>
<td>46%</td>
<td>54.76</td>
</tr>
<tr>
<td>Diabete</td>
<td>38%</td>
<td>32</td>
</tr>
<tr>
<td>BPCO/asma</td>
<td>30%</td>
<td>18.9</td>
</tr>
<tr>
<td>Insufficienza renale</td>
<td>25%</td>
<td>16.7</td>
</tr>
<tr>
<td>Fibrillazione atriale</td>
<td>21%</td>
<td>33</td>
</tr>
<tr>
<td>Durata degenza mediana</td>
<td>9 [6, 13]</td>
<td></td>
</tr>
<tr>
<td>Mortalità intraospedaliera</td>
<td>7.3%</td>
<td>7.2%</td>
</tr>
</tbody>
</table>
Causes of decompensation
(n= 204 in 101 HF patients)

- Hypertension: 22%
- Low Compliance: 32%
- Pulmonary Infections: 6%
- Therapy: 11%
- Arrhythmias: 14%
- MR: 3%
- Others: 12%

Ghali et al, Arch Intern Med 1988
Causes of decompensation

- Arrhythmias (24%)
- Infections (22%)
- Therapy (10%)
- Angina (17%)
- Compliance (14%)
- Others (13%)

Opasich C et al, Am J Cardiol 1996
DECOMPENSATION

AHF De Novo

Assess what CMP

CHF Instab.

Assess
- Possible Cause
- Risk Factor
- Change Therapy

Acute Treatment

Discharge
Criteria for Clinical Stability Before Hospital Discharge

- Clinical Examination: no signs of congestion
- Systolic Arterial Pressure $> 90$ mmHg
- Plasma NA Level $> 134$ mEq/l
- Stable Creatinine levels
- No symptoms of HF at rest
- Absence of signs and symptoms of ischemia
- Absence of symptomatic arrhythmias
DECOMPENSATION

AHF De Novo

Assess what CMP

Acute Treatment

Assess
- Possible Cause
- Risk Factor
- Change Therapy

Discharge

Follow-up

CHF Instab.
Factors Causing Decompensation

- Anaemia, Infections, Distyroidism (amiodaron)
- Pulmonary hypertension, Sleep apnoea syndrome
- Electrolytes disorders, A.Fibrillation, Arrhythmias
- Myocardial ischemia
- Pulmonary embolism
- Renal failure, Diabetes
- Low compliance to therapy, no education
Congestion Precedes Hospitalization

Adamson PB et al. J Am Coll Cardiol. 2003; 41: 565
Follow-up

Parameters

- Weight
- SAP/SDP
- Heart rate
- Rhythm
- B.Temperature
- SaO2
- Creatinine
- NA+/K+
- Hb
- Score (dyspnoea)
- Score (fatigue)

Telemonitoring ECG/Vital Signs

Periodic controls

Hospital Heart Failure Clinic
**DEFINITION of Telemedicine**

Telemedicine is the use of electronic information and communication technologies to provide and support healthcare when distance separates the patient from the health care provider.
Telemonitoring is not a model of care

Communication Technology

GP

Hospital

patient
Telemonitoring setting

1. Phone and answering machine
2. E-mail and Instant messaging
3. Web based system
4. Internet video conferencing
5. Remote control of clinical parameters (web based or not)
Telemonitoring and Heart Failure

1. Use of specific architecture (phone/web based) to connect patients to their nurse, GP or hospital

2. Monitoring (daily, weekly) of vital signs such as weight, pressure, pulse and symptoms (breathlessness, fatigue, oedema)

3. Close monitoring of fluid status and therapy

4. Monitoring of brady and tachyarrhythmias

5. Advices by telephone on diuretic dosage, diet, training, behaviour
## Multidisciplinary HF Clinic

<table>
<thead>
<tr>
<th>Study (Year) (Ref.)</th>
<th>Length of Follow-Up (mos)</th>
<th>All-Cause Mortality (# Events/Total # Pts)</th>
<th>Risk Ratio (95% CI)</th>
<th>All-Cause Hospitalization Rates (# Re-Admitted at Least Once/Total # Patients)*</th>
<th>HF Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention Arm</td>
<td>Control Arm</td>
<td></td>
<td>Intervention Arm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>24/80</td>
<td>31/110</td>
<td>1.06 (0.68, 1.67)</td>
<td>22/56</td>
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<tr>
<td>Kasper et al. (2002) (18)</td>
<td>12</td>
<td>21/79</td>
<td>17/79</td>
<td>1.24 (0.71, 2.16)</td>
<td>48/79</td>
</tr>
<tr>
<td>Capomolla et al. (2002) (19)</td>
<td>6</td>
<td>19/100</td>
<td>24/97</td>
<td>0.77 (0.45, 1.31)</td>
<td>64/100</td>
</tr>
<tr>
<td>Stromberg et al. (2003) (20)*</td>
<td>12</td>
<td>7/102</td>
<td>13/98</td>
<td>0.52 (0.22, 1.24)</td>
<td>40/102</td>
</tr>
<tr>
<td>Ledwidge et al. (2003) (15)</td>
<td>3</td>
<td>3/112</td>
<td>21/122</td>
<td>0.16 (0.05, 0.51)</td>
<td>9/112</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7/52</td>
<td>20/54</td>
<td>0.36 (0.17, 0.79)</td>
<td>28/52</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3/51</td>
<td>3/47</td>
<td>0.92 (0.20, 4.34)</td>
<td>2/51</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.66 (0.42, 1.05)</td>
<td></td>
</tr>
</tbody>
</table>

## Multidisciplinary Team with specialized Follow-up

<table>
<thead>
<tr>
<th>Study (Year) (Ref.)</th>
<th>Length of Follow-Up (mos)</th>
<th>All-Cause Mortality (# Events/Total # Pts)</th>
<th>Risk Ratio (95% CI)</th>
<th>All-Cause Hospitalization Rates (# Re-Admitted at Least Once/Total # Patients)*</th>
<th>HF Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention Arm</td>
<td>Control Arm</td>
<td></td>
<td>Intervention Arm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Stewart et al. (1948) (11)*</td>
<td>0</td>
<td>13/142</td>
<td>17/140</td>
<td>0.75 (0.38, 1.49)</td>
<td>21/63</td>
</tr>
<tr>
<td>Stewart et al. (1999) (25)*</td>
<td>6</td>
<td>18/100</td>
<td>28/100</td>
<td>0.64 (0.38, 1.08)</td>
<td>41/142</td>
</tr>
<tr>
<td>Nayler et al. (1999) (12)*</td>
<td>6</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Blue et al. (2001) (27)</td>
<td>12</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<tr>
<td>Trochu et al. (2004) (37)*</td>
<td>12</td>
<td>28/102</td>
<td>42/100</td>
<td>0.89 (0.63, 1.25)</td>
<td>58/95</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.81 (0.65, 1.01)</td>
<td></td>
</tr>
</tbody>
</table>

## Telephone Follow-up with nurse/physician Care

<table>
<thead>
<tr>
<th>Study (Year) (Ref.)</th>
<th>Length of Follow-Up (mos)</th>
<th>All-Cause Mortality (# Events/Total # Pts)</th>
<th>Risk Ratio (95% CI)</th>
<th>All-Cause Hospitalization Rates (# Re-Admitted at Least Once/Total # Patients)*</th>
<th>HF Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention Arm</td>
<td>Control Arm</td>
<td></td>
<td>Intervention Arm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Rainville et al. (1999) (30)</td>
<td>12</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Pugh et al. (2001) (26)</td>
<td>6</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Jerant et al. (2001) (15)*</td>
<td>6</td>
<td>2/25</td>
<td>0/12</td>
<td>2.50 (0.13, 4.86)</td>
<td>8/25</td>
</tr>
<tr>
<td>de Lusignan et al. (2001) (31)</td>
<td>12</td>
<td>2/10</td>
<td>3/10</td>
<td>0.67 (0.14, 3.17)</td>
<td>9/25</td>
</tr>
<tr>
<td>Riegel et al. (2002) (33)*</td>
<td>6</td>
<td>16/130</td>
<td>32/228</td>
<td>0.88 (0.50, 1.54)</td>
<td>56/130</td>
</tr>
<tr>
<td>Laramee et al. (2003) (35)*</td>
<td>3</td>
<td>13/141</td>
<td>15/146</td>
<td>0.90 (0.44, 1.82)</td>
<td>49/134</td>
</tr>
<tr>
<td>Tsuyug et al. (2004) (36)*</td>
<td>6</td>
<td>16/140</td>
<td>12/136</td>
<td>1.30 (0.64, 2.64)</td>
<td>59/140</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.91 (0.67, 1.29)</td>
<td></td>
</tr>
</tbody>
</table>

Summary for specialized multidisciplinary team follow-up (clinical or non-clinical settings):

- Multidisciplinary HF Clinic: 0.76 (0.58-0.99)
- Multidisciplinary Team with specialized Follow-up: 0.72 (0.59-0.87)
- Telephone Follow-up with nurse/physician Care: 0.75 (0.57-0.99)
Readmission of older patients and meta-analysis of the effect on mortality or death.

HF or CV Readmission

The effect of readmission or death on mortality or death in older patients and meta-analysis.

0.70 (0.62-0.79)

0.82 (0.72-0.94)

0.88 (0.79-0.97)
Assumptions

Telemonitoring could reduce the frequency of hospital admission for a variety of reasons:

1. Monitoring weight and fluid balance allows diuretics to be adjusted
2. It may avoid over-diuresis and hypotension
3. Early detection of precipitating factors such as atrial fibrillation, persistent hypertension, infections
4. Better titration of ace-inhibitors and beta-blockers
5. Monitoring of transcutaneous SaO2 to detect sleep apnoea
Congestive Heart Failure (CHF) Home Care Telemedicine Study
SHL TeleMedicine Ltd
Tel Aviv, Israel
Noninvasive Home Telemonitoring for Patients With Heart Failure at High Risk of Recurrent Admission and Death
The Trans-European Network–Home-Care Management System (TEN-HMS) Study

John G. F. Cleland, MD,* Amala A. Louis, MD,* Alan S. Rigby, PhD,* Uwe Janssens, MD,†
Aggie H. M. M. Balk, MD,‡ on behalf of the TEN-HMS Investigators

Kingston Upon Hull, United Kingdom; Aachen, Germany; and Rotterdam, the Netherlands
Study: RCT

Inclusion Criteria:
- NYHA Cl. II-IV
- Furosemide > 40 mg/die
- LVEF < 40% e LVDD > 30 mm/m2
- One episode of HF in the previous 12 months or LVEF < 25% plus furosemide > 100mg/die

RANDOMIZATION 1 : 2 : 2

1) Usual care
2) Nurse by telephone: Specialist nurses who were available to patients by telephone.
3) Telemonitoring: Twice-daily self-measurement of weight, BP, heart rate and rhythm with automated device linked to a cardiology center
Figure 1. Diagrammatic representation of the telemonitoring system used in the trial. ECG = electrocardiogram.
Figure 3. Mortality in each of the randomized groups. A difference was found between usual care and either nurse telephone support or home telemonitoring (chi-squared test; $p = 0.0397$). The absolute difference in mortality at one year was 16% to 18%. Dashed line = usual care; dotted line = nurse support; solid line = telemonitoring.
Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis

Robyn A Clark, Sally C Inglis, Finlay A McAlister, John G F Cleland and Simon Stewart

BMJ 2007;334;942-; originally published online 10 Apr 2007;
doi:10.1136/bmj.39156.536968.55
### Effect of monitoring on all cause mortality

#### Structured telephone

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment group</th>
<th>Control group</th>
<th>Relative risk (random) (95% CI)</th>
<th>Weight (%)</th>
<th>Relative risk (random) (95% CI)</th>
<th>Risk difference (random) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleland et al 2005&lt;sup&gt;w1&lt;/sup&gt;</td>
<td>35/173</td>
<td>28/85</td>
<td>1.20 (0.40 to 0.94)</td>
<td>12.06</td>
<td>0.61 (0.40 to 0.94)</td>
<td>-0.13 (-0.24 to -0.01)</td>
</tr>
<tr>
<td>Gatzis et al 1999&lt;sup&gt;w2&lt;/sup&gt;</td>
<td>3/90</td>
<td>5/91</td>
<td>0.67 (0.15 to 2.46)</td>
<td>1.10</td>
<td>0.61 (0.15 to 2.46)</td>
<td>-0.02 (-0.08 to 0.04)</td>
</tr>
<tr>
<td>Rainville 1999&lt;sup&gt;ms&lt;/sup&gt;</td>
<td>1/17</td>
<td>4/17</td>
<td>0.25 (0.03 to 0.20)</td>
<td>0.50</td>
<td>0.25 (0.03 to 0.20)</td>
<td>-0.18 (-0.41 to 0.05)</td>
</tr>
<tr>
<td>Barth et al 2001&lt;sup&gt;w4&lt;/sup&gt;</td>
<td>0/17</td>
<td>0/17</td>
<td>0.25 (0.03 to 0.20)</td>
<td>1.00</td>
<td>0.25 (0.03 to 0.20)</td>
<td>-0.18 (-0.41 to 0.05)</td>
</tr>
<tr>
<td>Riegel et al 2002&lt;sup/ws&lt;/sup&gt;</td>
<td>16/130</td>
<td>32/228</td>
<td>0.60 (0.44 to 1.82)</td>
<td>6.90</td>
<td>0.60 (0.44 to 1.82)</td>
<td>-0.01 (-0.08 to 0.06)</td>
</tr>
<tr>
<td>Laree et al 2003&lt;sup&gt;ws&lt;/sup&gt;</td>
<td>13/141</td>
<td>15/146</td>
<td>0.74 (0.44 to 1.26)</td>
<td>4.35</td>
<td>0.74 (0.44 to 1.26)</td>
<td>-0.03 (-0.09 to 0.02)</td>
</tr>
<tr>
<td>DeBursk et al 2004&lt;sup&gt;w7&lt;/sup&gt;</td>
<td>21/228</td>
<td>29/234</td>
<td>1.30 (0.64 to 2.64)</td>
<td>4.29</td>
<td>1.30 (0.64 to 2.64)</td>
<td>0.03 (-0.05 to 0.10)</td>
</tr>
<tr>
<td>Tsuyuki et al 2004&lt;sup&gt;w8&lt;/sup&gt;</td>
<td>16/140</td>
<td>12/136</td>
<td>0.95 (0.75 to 1.20)</td>
<td>39.73</td>
<td>0.95 (0.75 to 1.20)</td>
<td>-0.01 (-0.04 to 0.03)</td>
</tr>
<tr>
<td>GESCA Investigators 2005&lt;sup&gt;ww9&lt;/sup&gt;</td>
<td>116/760</td>
<td>122/758</td>
<td>0.71 (0.26 to 1.91)</td>
<td>2.15</td>
<td>0.71 (0.26 to 1.91)</td>
<td>-0.04 (-0.14 to 0.07)</td>
</tr>
<tr>
<td>Riegel et al 2006&lt;sup&gt;ww0&lt;/sup&gt;</td>
<td>6/69</td>
<td>8/65</td>
<td>0.85 (0.72 to 1.01)</td>
<td>78.75</td>
<td>0.85 (0.72 to 1.01)</td>
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</tr>
</tbody>
</table>

#### Subtotal (95% CI) 1765 1777

Test for heterogeneity: $\chi^2=6.61$, df=8, $P=0.60$, $I^2=0\%$

Test for overall effect: $z=1.88$, $P=0.06$

#### Telemonitoring

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment group</th>
<th>Control group</th>
<th>Relative risk (random) (95% CI)</th>
<th>Weight (%)</th>
<th>Relative risk (random) (95% CI)</th>
<th>Risk difference (random) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleland et al 2005&lt;sup&gt;ww1&lt;/sup&gt;</td>
<td>36/168</td>
<td>28/85</td>
<td>1.20 (0.43 to 0.99)</td>
<td>12.31</td>
<td>0.65 (0.43 to 0.99)</td>
<td>-0.12 (-0.23 to 0.00)</td>
</tr>
<tr>
<td>De Lusigian et al 2001&lt;sup&gt;ww11&lt;/sup&gt;</td>
<td>2/10</td>
<td>3/10</td>
<td>0.89 (0.14 to 3.17)</td>
<td>0.89</td>
<td>0.89 (0.14 to 3.17)</td>
<td>-0.10 (-0.48 to 0.28)</td>
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<tr>
<td>Goldberg et al 2002&lt;sup&gt;ww12&lt;/sup&gt;</td>
<td>11/138</td>
<td>26/142</td>
<td>0.44 (0.22 to 0.85)</td>
<td>4.90</td>
<td>0.44 (0.22 to 0.85)</td>
<td>-0.10 (-0.18 to -0.03)</td>
</tr>
<tr>
<td>Woodend et al 2003&lt;sup&gt;ww13&lt;/sup&gt;</td>
<td>5/62</td>
<td>4/59</td>
<td>1.19 (0.34 to 4.22)</td>
<td>1.35</td>
<td>1.19 (0.34 to 4.22)</td>
<td>0.01 (-0.08 to 0.11)</td>
</tr>
<tr>
<td>Capomolla et al 2004&lt;sup&gt;ww14&lt;/sup&gt;</td>
<td>5/67</td>
<td>7/66</td>
<td>0.70 (0.24 to 2.11)</td>
<td>1.80</td>
<td>0.70 (0.24 to 2.11)</td>
<td>-0.03 (-0.13 to 0.07)</td>
</tr>
</tbody>
</table>

#### Subtotal (95% CI) 445 362

Test for heterogeneity: $\chi^2=2.22$, df=4, $P=0.70$, $I^2=0\%$

Test for overall effect: $z=2.93$, $P=0.003$
Effect of monitoring on HF Hospitalisation

### Structured Telephone

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment group</th>
<th>Control group</th>
<th>Relative risk (random) (95% CI)</th>
<th>Weight (%)</th>
<th>Relative risk (random) (95% CI)</th>
<th>Risk difference (random) (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Cleland et al 2003&lt;sup&gt;5&lt;/sup&gt;</td>
<td>32/110</td>
<td>23/55</td>
<td>8.87 0.70 (0.45 to 1.07)</td>
<td>90.02</td>
<td>0.78 (0.68 to 0.89)</td>
<td>-0.13 (-0.28 to 0.03)</td>
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<tr>
<td>Rainville 1999&lt;sup&gt;6&lt;/sup&gt;</td>
<td>4/17</td>
<td>10/17</td>
<td>1.81 0.40 (0.16 to 1.03)</td>
<td></td>
<td>0.35 (-0.66 to -0.04)</td>
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</tr>
<tr>
<td>Barth et al 2001&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0/17</td>
<td>0/17</td>
<td>Not estimable</td>
<td></td>
<td>0.00 (-0.11 to 0.11)</td>
<td></td>
</tr>
<tr>
<td>Riegel et al 2002&lt;sup&gt;5&lt;/sup&gt;</td>
<td>23/130</td>
<td>63/228</td>
<td>8.90 0.64 (0.42 to 0.98)</td>
<td></td>
<td>0.10 (-0.19 to -0.01)</td>
<td></td>
</tr>
<tr>
<td>Lamee et al 2003&lt;sup&gt;6&lt;/sup&gt;</td>
<td>18/141</td>
<td>21/146</td>
<td>4.72 0.89 (0.49 to 1.59)</td>
<td></td>
<td>-0.02 (-0.10 to 0.06)</td>
<td></td>
</tr>
<tr>
<td>DeBusk et al 2004&lt;sup&gt;7&lt;/sup&gt;</td>
<td>38/228</td>
<td>43/234</td>
<td>10.29 0.91 (0.61 to 1.35)</td>
<td></td>
<td>-0.02 (-0.09 to 0.05)</td>
<td></td>
</tr>
<tr>
<td>Tsuyuki et al 2004&lt;sup&gt;8&lt;/sup&gt;</td>
<td>37/140</td>
<td>38/136</td>
<td>10.83 0.95 (0.64 to 1.39)</td>
<td></td>
<td>-0.02 (-0.12 to 0.09)</td>
<td></td>
</tr>
<tr>
<td>GESICA Investigators 2005&lt;sup&gt;9&lt;/sup&gt;</td>
<td>128/760</td>
<td>169/758</td>
<td>37.94 0.76 (0.61 to 0.93)</td>
<td></td>
<td>-0.05 (-0.09 to -0.01)</td>
<td></td>
</tr>
<tr>
<td>Riegel et al 2006&lt;sup&gt;10&lt;/sup&gt;</td>
<td>21/69</td>
<td>22/65</td>
<td>6.66 0.90 (0.55 to 1.47)</td>
<td></td>
<td>-0.03 (-0.19 to 0.12)</td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>1612</td>
<td>1656</td>
<td>90.02</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: $\chi^2 = 5.13$, df=7, P=0.64, $I^2 = 0\%$
Test for overall effect: $z = 3.63$, P=0.0003

### Telemonitoring

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment group</th>
<th>Control group</th>
<th>Relative risk (random) (95% CI)</th>
<th>Weight (%)</th>
<th>Relative risk (random) (95% CI)</th>
<th>Risk difference (random) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleland et al 2005&lt;sup&gt;11&lt;/sup&gt;</td>
<td>38/106</td>
<td>23/55</td>
<td>9.98 0.86 (0.57 to 1.28)</td>
<td>100.00</td>
<td>0.86 (0.57 to 1.28)</td>
<td>-0.06 (-0.22 to 0.10)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>106</td>
<td>55</td>
<td>9.98</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: Not applicable
Test for overall effect: $z = 0.75$, P=0.45
A multi-country randomised trial of the role of a new telemonitoring system in CHF: the HHH study (Home or Hospital in Heart Failure). Rational, study design and protocol

Andrea Mortara\textsuperscript{a,*}, Gian Domenico Pinna\textsuperscript{b}, Paul Johnson\textsuperscript{c}, Henry Dargie\textsuperscript{d}, Maria Teresa La Rovere\textsuperscript{b}, Piotr Ponikowski\textsuperscript{e}, Luigi Tavazzi\textsuperscript{f}, Peter Sleight\textsuperscript{c}, on behalf of HHH Investigators

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\textsuperscript{b} Divisioni di Bioingegneria e di Cardiologia, Fondazione ‘‘S. Maugeri’’, IRCCS, Istituto Scientifico di Montescano (Pv), Italy
\textsuperscript{c} University of Oxford, Departments of Cardiovascular Medicine and Telemonitoring Research Center, Nuffield Department of Obstetrics, John Radcliffe Hospital, Oxford, UK
\textsuperscript{d} Cardiac Research Department, University of Glasgow, Western Infirmary, Glasgow, UK
\textsuperscript{e} Department of Cardiology, Clinical Military Hospital, Wroclaw, Poland
\textsuperscript{f} Divisione di Cardiologia, Policlinico S. Matteo, IRCCS, Pavia, Italy
Administrative coordination: 
University of Oxford UK

Medical and Technical coordination 
Fondazione “S.Maugeri” Montescano 
Policlinico di Monza

461 HF patients
Controls (n=160) → Usual Care

Group 2.1 (n=106) → Periodic telephone call and answering machine

Group 2.2 (n=94) → Weekly

Group 2.3 (n=101) → Weekly

- Weight
- Arterial Pressure
- Heart Rate
- Dyspnoea Score
- Fatigue Score
- Peripheral Oedema
- Blood Sample

ECG
Respiration
Movimento

Population N= 461

ECG
Respiration
Position
Self positioned by the patient
HHH Study

Clinical Parameters

- Digital Scales
- Automatic blood pressure monitor

24h ECG Recorder

ECG Respiration Position
### BASELINE CLINICAL DATA

<table>
<thead>
<tr>
<th></th>
<th>Controls (n=160)</th>
<th>Telemonitoring (n=301)</th>
<th>Strategy 1 (n=104)</th>
<th>Strategy 2 (n=96)</th>
<th>Strategy 3 (n=101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>60.4±11</td>
<td>59.6±11</td>
<td>59.5±11</td>
<td>60.2±12</td>
<td>59.1±11</td>
</tr>
<tr>
<td>Age &gt; 65 yrs (%)</td>
<td>40.6</td>
<td>36.6</td>
<td>39.6</td>
<td>39.3</td>
<td>30.7</td>
</tr>
<tr>
<td>Female (%)</td>
<td>16.8</td>
<td>13.6</td>
<td>14.2</td>
<td>10.6</td>
<td>15.8</td>
</tr>
<tr>
<td>Ischemic Aetiology (%)</td>
<td>59.4</td>
<td>54.2</td>
<td>57.5</td>
<td>55.3</td>
<td>59.5</td>
</tr>
<tr>
<td>NYHA (Cl.)</td>
<td>2.3±0.6</td>
<td>2.4±0.6</td>
<td>2.4±0.6</td>
<td>2.3±0.5</td>
<td>2.5±0.7</td>
</tr>
<tr>
<td>NYHA &gt; 3 (%)</td>
<td>33.7</td>
<td>42.8</td>
<td>43.4</td>
<td>36.2</td>
<td>48.5</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>29.5±7.0</td>
<td>28.5±7.4</td>
<td>28.7±7.7</td>
<td>28.8±6.8</td>
<td>28.4±7.3</td>
</tr>
<tr>
<td>LVEDD (mm)</td>
<td>65.9±9</td>
<td>67.4±8.9</td>
<td>66.3±7.8</td>
<td>67.8±9.3</td>
<td>67.3±9.1</td>
</tr>
<tr>
<td>Baseline HR (bpm)</td>
<td>73±14</td>
<td>75±15</td>
<td>75±17</td>
<td>73±14</td>
<td>75±15</td>
</tr>
<tr>
<td>Baseline SAP (mmHg)</td>
<td>117±17</td>
<td>117±18</td>
<td>117±16</td>
<td>119±20</td>
<td>116±17</td>
</tr>
<tr>
<td>Sodium level (mEq/L)</td>
<td>139.9±4.4</td>
<td>139.8±3.9</td>
<td>139.8±4.0</td>
<td>139.8±3.4</td>
<td>139.7±4.0</td>
</tr>
</tbody>
</table>
BASELINE CLINICAL DATA

Ace-Inhibitors

Beta-Blockade
### Vital Signs Transmission in Each Country across the Overall Study

<table>
<thead>
<tr>
<th>Country</th>
<th>Expected</th>
<th>Practicable</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>4227</td>
<td>3741 (89%)</td>
<td>3060 (82%)</td>
</tr>
<tr>
<td>Poland</td>
<td>3707</td>
<td>3019 (81%)</td>
<td>2261 (75%)</td>
</tr>
<tr>
<td>UK</td>
<td>1116</td>
<td>1000 (90%)</td>
<td>931 (93%)</td>
</tr>
<tr>
<td>All study</td>
<td>9050</td>
<td>7760 (86%)</td>
<td>6252 (81%)</td>
</tr>
</tbody>
</table>

**EXPECTED** = total number of expected transmissions  
**PRACTICABLE** = total n. of expected practicable transmissions, i.e. discounting hospitalisation, technical problems, or other personal problems  
**COMPLETED** = total n. of practicable transmissions received (global compliance)
Total cardiac death + Heart failure Hospitalization

<table>
<thead>
<tr>
<th></th>
<th>Controls (n.160)</th>
<th>Telemonitoring (n.301)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No event</td>
<td>130 (81.2%)</td>
<td>239 (79.4%)</td>
<td>0.63**</td>
</tr>
<tr>
<td>Event</td>
<td>30 (18.8%)</td>
<td>62 (20.6%)</td>
<td></td>
</tr>
</tbody>
</table>

** Test for Treatment by Country Interaction (p=0.05)
(This interaction led us to study the effect of telemonitoring within countries)
Total Cardiac Death + Heart Failure Hospitalization

Italy vs. Poland

Controls
Telemonitoring

Italy
Poland

p = 0.082

p = 0.11
Total Cardiac Death + Heart Failure Hospitalization (Patients enrolled in Italy)

Log-Rank = 6.7
p = 0.016
Patients enrolled in Italy
(follow-up of 12 months concluded 30/7/2005)
n = 215

Primary-Endpoint
Total cardiac death + Heart failure Hospitalization

<table>
<thead>
<tr>
<th></th>
<th>Controls (Str. 0)</th>
<th>Telephone (Str. 1)</th>
<th>Vital Signs M. (Str. 2)</th>
<th>NICRAM (Str. 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No event</td>
<td>57 (79%)</td>
<td>46 (87%)</td>
<td>39 (89%)</td>
<td>41 (89%)</td>
</tr>
<tr>
<td>Event</td>
<td>15 (21%)</td>
<td>7 (13%)</td>
<td>5 (11%)</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>Total</td>
<td>72</td>
<td>53</td>
<td>44</td>
<td>46</td>
</tr>
</tbody>
</table>

P < 0.05 only vs controls
HHH – CONCLUSIONS

Telemonitoring is not a treatment but rather a different way of organizing effective care.

HHH shows that it works (excellent feasibility and compliance) but since Telemonitoring does not mean Tele-Management, an integrated Disease Management Program needs to be implemented for a modern Heart Failure treatment.

Remote monitoring may be of particular benefit to patients who have difficulty accessing specialized care because of geography, transport or infirmity.
What next
Hemodynamic Monitor

Chronicle® System Components

- Implantable Hemodynamic Monitor
- Pressure Sensor Lead
- External Pressure Reference
- Programmer and software
- Remote Monitor
- Patient Management Information Network
Hemodynamic Monitor

Chronicle Data

- RV Pressures
  - RV systolic/diastolic pressure
  - Estimated pulmonary artery diastolic pressure
  - RV pulse pressure
  - Maximum +/- dP/dt
  - Pre-ejection and systolic time intervals

- Heart Rate
- Activity Level
- Core Temperature
- Barometric Pressure
Hemodynamic Monitor

COMPASS STUDY

<table>
<thead>
<tr>
<th></th>
<th>CHRONICLE (n =112)</th>
<th>CONTROL (n = 122)</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Pts with Events</td>
<td>35</td>
<td>51</td>
</tr>
<tr>
<td>Total HF Related Events</td>
<td>58</td>
<td>99</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>50</td>
<td>86</td>
</tr>
<tr>
<td>Emergency Department Visits</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Urgent Clinic Visits</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Event Rate / 6months</td>
<td>0.54</td>
<td>0.85</td>
</tr>
<tr>
<td>% Reduction in Event Rate</td>
<td>36%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(p=0.0061; p=0.0582)</td>
<td></td>
</tr>
</tbody>
</table>
Drier lungs means the intrathoracic impedance is higher.

Wetter lungs means the intrathoracic impedance is lower.
OptiVol™ Fluid Status Monitoring

![Graph showing fluid status monitoring over days with fluid index and impedance metrics.](image-url)
OptiVol™ Audible Alarme

SentryCheck™
CONSIDERATIONS

1. Telemonitoring facilitates titration of B-Blockers
   (Spaeder JA, Am Heart J 2006)

2. Telemonitoring predicts sustained response to exercise training
   (Smart N, Am Heart J 2005)

3. Telemonitoring improves control of fluid retention
   (Mueller TM, Heart Lung 2002)

Telemonitoring must be integrated in a new system of care with trained and expert nurses and physicians to reduce morbidity and mortality.
Telemedicine and Telemonitoring need to be considered carefully in the future. They reduce the distance which separates the patient from the health care provider.
How to Invest our Resources?

1° Step
To implement an integrated Disease Management Program

2° Step
To improve Communication Technologies (local network, Telemonitoring)

3° Step
To invest in more sophisticated Technologies and Monitoring system
Consensus Conference
The disease management of Heart Failure

Società Scientifiche Partecipanti

AIMEF
ANCE
AMNCO
APRO
ARCA
ATO
CONACUORE
FADOI
FIC
GICR
METIS
SIC
SICOA
SICP
SIGG
SIGOS
SIMEU
SIMG
SIMI
SNAMID

Italian Heart J 2006
200 patients studied
Home visit by nurse manager
Patient and family handbook
Telephone contact weekly or biweekly
Nurse manager available 24h/d and 7 d/wk
ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult

Stage A
High risk with no symptoms

Stage B
Structural heart disease, no symptoms

Stage C
Structural disease, previous or current symptoms

Stage D
Refractory symptoms requiring special intervention

Hospice
VAD, transplantation
Inotropes
Aldosterone antagonist, nesiritide
Consider multidisciplinary team
Revascularization, mitral-valve surgery
Cardiac resynchronization if bundle-branch block present
Dietary sodium restriction, diuretics, and digoxin
ACE inhibitors and beta-blockers in all patients
ACE inhibitors or ARBs in all patients; beta-blockers in selected patients
Treat hypertension, diabetes, dyslipidemia; ACE inhibitors or ARBs in some patients
Risk-factor reduction, patient and family education
3.8 million of annual ambulatory care visits due to HF in US
First admission over 12 weeks for any reason from the time of index admission discharge (tot. N=8463).