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# **SELF-CARE IN PATIENTS WITH HEART FAILURE**

***WITH EMPHASIS ON WEIGHT  
MONITORING AND INTERACTIVE  
TECHNOLOGY***

Patrik Lyngå



**Karolinska  
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Cover picture: "Hjärta med törnekrans" by Esmé Alexander

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*“How wonderful it is that nobody need wait a single moment  
before starting to improve the world”*

Anne Frank (1929-1945)



## ABSTRACT

Heart failure is a condition which often means living with physical impairment. Research indicates that self-rated health among patients with heart failure is lower than in a healthy population. Self-care activities may improve the situation for patients with heart failure and the overall aim of this thesis was to investigate if quality of life, readmission and mortality rates were affected when using telemonitoring and interactive technology to strengthen the self-care ability in patients with heart failure.

In **study I** 57 patients with heart failure were followed for 12 months after completing an interactive patient education programme in self-care. Three validated questionnaires, Quality of life index, Sense of coherence and European Heart Failure Self-care Behaviour Scale, were used as outcome measures. The results showed that the degree of Sense of coherence did not influence quality of life and self-care ability after the patient education. A trend towards poorer self-care ability over time was observed. In **study II** 31 patients with heart failure, all with an implantable cardioverter-defibrillator, were observed during 2 months with emphasis on potentially dietary non-compliance. A significant increase in body weight (mean 550 g) and a decrease in thoracic impedance (mean 1.4 Ohm) were noted after Midsummer Eve, indicating deterioration in heart failure. A cluster of minor events suggests that, even after short episodes of dietary non-compliance, there might be an increased risk for adverse outcomes in patients with heart failure. **Study III** was a randomised controlled trial that included six hospitals in Sweden. The hypothesis was that telemonitoring in terms of daily transmission of body weight to a heart failure clinic would reduce cardiac readmission from 40 to 25%. A total of 344 patients recently hospitalised for heart failure were followed for 12 months or until reached endpoint. No significant differences were found for the primary endpoint, cardiac re-admission (70/153 control group, 70/166 intervention group, hazard ratio 0.90, 95% confidence interval 0.65-1.26,  $p = 0.54$ ) nor for any of the secondary endpoints. In **study IV** 20 patients from the intervention group in study III were interviewed regarding their experiences of telemonitoring and the transmission of body weight. The interviews were analysed with a phenomenographic approach. Patients' experiences were mainly positive; they conceived themselves as safe and increased their self-care activities. Five categories emerged and each was assigned a metaphor as a description; "the routine-building patient", "the worrying patient", "the technically relating patient", "the security-building patient" and "the self-caring patient".

In conclusion, telemonitoring of body weight did not decrease hospitalisation or death in patients with heart failure but increased self-care activities and safety. Thus, telemonitoring may be used as a complement to personal contacts between patients and caregivers. The hypothesis that the patients' internal resources, defined as the degree of Sense of coherence, influenced the outcomes of an interactive patient education intervention were not confirmed. Health care providers should take an active approach concerning dietary advice in heart failure.

*Key words: Body weight, Diet, Heart failure, Interactive, Patient education, Quality of life, Sense of coherence, Self-care, Telemonitoring.*

## LIST OF PUBLICATIONS

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## LIST OF ABBREVIATIONS

ACC	American College of Cardiology
ACE	Angiotensin-converting enzyme
AF	Atrial fibrillation
AHA	American Heart Association
ARB	Angiotensin receptor blocker
BW	Body weight
CI	Confidence interval
CG	Control group
CRT	Cardiac resynchronisation therapy
ECG	Electrocardiogram
EHFScBS	European Heart Failure Self-care Behaviour Scale
ESC	European Society of Cardiology
HF	Heart failure
ICD	Implantable cardioverter-defibrillator
IG	Intervention group
ITT	Intention-to-treat
LVAD	Left ventricular assist device
LVEF	Left ventricular ejection fraction
NYHA	New York Heart Association
PP	Per protocol
QLI	Quality of life index
QoL	Quality of life
RCT	Randomised controlled trial
SCHFI	Self-care Heart Failure Index
SD	Standard deviation
SOC	Sense of coherence
TM	Telemonitoring
VT	Ventricular arrhythmia



# **1 Introduction**

Caring for patients with heart failure (HF) in an outpatient setting not only means to support and educate patients in performing self-care in order to improve or maintain their situation but also for optimisation of the pharmacological treatment. In my clinical work as a specially trained HF nurse I have met several patients with HF and sometimes it has been difficult to succeed in this task. I have reflected over the variations in how an individual deals with a potentially difficult situation when having a severe condition such as HF and where the prerequisites for living a normal life may change. This has made me interested in how to provide and organise the best care to support self-care management for patients with HF.

In the HF team involving nurses, physicians and other professionals we have had many discussions on how to improve and optimise care. The special focus for me as a nurse in the HF team is the education of patients in self-care. A particular goal in my work and in my research has been to employ the patients own resources in strengthening the self-care ability and by that improve the outcomes. My interest in using interactive technology in which patients can take an active part and the opportunity to develop new methods for follow-up has also been an inspiration in this thesis.

## **2 Background**

### **2.1 Living with HF**

Living with HF means often to live with physical impairments such as breathlessness, fatigue and pain<sup>1,2</sup>. Patients have described that this limitations causes significant changes in their daily life<sup>3</sup>. For many patients, it is not possible to do the things they did before and they might lose contact with social networks and even their role in society. Patients with HF can also feel uncertain concerning how much they can do on a particular day in that their strength and energy to perform activities vary from day to day<sup>1</sup>. To be hindered by their symptoms has been described by patients as being trapped in the illness<sup>4,5</sup>. Because HF is a chronic condition, the future of the patients often means living with these physical limitations and having to find strategies to make

that possible<sup>3</sup>. For some patients this is difficult and thus depression is more common in patients with HF than in healthy individuals, especially in patients with severe HF (e.g., NYHA-class III-IV)<sup>6-9</sup>. Sleeping disorders in patients with HF have a negative effect on quality of life (QoL) and may cause daytime sleepiness<sup>10,11</sup>. Patients with HF also reported lower self-rated health than healthy controls as well as to other chronically ill patient groups, especially in physical functioning<sup>12,13</sup>. A correlation between NYHA-class and self-rated health was reported in which the higher the limitation on physical ability the lower the self-rated health<sup>14</sup>. Interestingly, a qualitative study reported a serious impact on QoL, i.e., physical symptoms but despite this most patients reported good overall QoL<sup>15</sup>. This finding is in line with those of Ekman et al.,<sup>4</sup> where elderly patients with HF, despite severe symptoms, did not feel hampered by their physical condition. Middle-aged patients, on the other hand, seem to be more negatively affected by physical impairment<sup>5</sup>.

There are similarities as well as differences between genders in how they conceive their situation living with HF<sup>16,17</sup>. Both men and women felt a lack of energy. Reduced physical capacity made women feel insecure and not to be able to support persons in their surroundings. For men, limited physical capacity led to a feeling of resignation with respect to not be able to influence their own situation. HF is also a condition that affects not only the patients but also the family. Spouses are often involved in the care by just being available and to ease suffering. In addition, they provide help with medication and support to adhere to the overall treatment<sup>1</sup>.

## **2.2 Definition of HF**

HF is not a disease in itself but a syndrome with an underlying cause. It has been defined as follows:

*A syndrome in which the patient should have the following features: symptoms of HF, typically shortness of breath at rest or during exertion, and/or fatigue; signs of fluid retention such as pulmonary congestion or ankle swelling, and objective evidence of an abnormality of the structure or function of the heart at rest (Dickstein et al. p 935, 2008)<sup>18</sup>.*

The origin of HF in the majority of patients is ischemic heart disease which includes previous myocardial infarction or angina pectoris<sup>19</sup>. Other major causes of HF are hypertension, valve disease, high alcohol intake and arrhythmias. These are defined as non-ischemic. For some patients the aetiology of their HF remains unknown<sup>20</sup>. The prevalence of HF is from 1-2 % in developed countries with higher numbers with increasing age reaching about 10% in patients over 70 years of age<sup>19</sup>. Hospitalisations are common and the major part of the costs for HF is related to hospital care<sup>21,22</sup>.

The severity of HF has been described by the New York Heart Association (NYHA)<sup>23</sup> who have classified HF into four levels based on physical functioning: the higher the NYHA-class the greater the severity of HF symptoms. NYHA I means that the patients have no limitations in physical functioning while patients in NYHA II feel some limitations with respect to normal physical activity. Further, patients in NYHA III are comfortable at rest but even activities less than normal (e.g., walking up stairs), causes tiredness, breathlessness or palpitations. Finally patients in NYHA IV have symptoms of HF even when they are at rest. Although the NYHA-classification is a subjective measure most commonly made by the caregiver, it has been proven useful both in clinical practise and in research<sup>20</sup>.

## **2.3 HF treatment**

HF treatment in the current European Society of Cardiology (ESC) guidelines<sup>20</sup> is divided into three parts: pharmacological therapy, non-pharmacological management and devices and surgery. In this thesis telemonitoring (TM) has been added as a fourth part of the treatment of patients with HF.

### **2.3.1 Pharmacological therapy**

Pharmacological therapy is based on the patients NYHA-class. Drugs are added with increased severity of HF (see Table 1)<sup>20</sup>. Recently, flexible diuretic doses, ruled by the patients and based on actual HF symptoms, have become more frequent.

Table 1. New York Heart Association Classification (NYHA), symptoms of HF and drugs used in HF treatment as recommended in ESC guidelines<sup>20</sup>.

<b>NYHA-class</b>	<b>Symptoms</b>	<b>HF drugs</b>
NYHA I	No physical limitation	ACE-inhibitor or ARB
NYHA II	Comfortable at rest. Bounds at normal physical activity such as breathlessness, fatigue or palpitations.	ACE-inhibitor or ARB Beta-blocker Diuretics (if needed)
NYHA III	Comfortable at rest. Less than ordinary physical activity results in breathlessness, fatigue or palpitations.	ACE-inhibitor or ARB Beta-blocker Diuretics (if needed) Aldosteron-antagonist Digoxin
NYHA IV	Symptoms at rest are often present. All physical activity results in breathlessness, fatigue or palpitations.	ACE-inhibitor or ARB Beta-blocker Diuretics (if needed) Aldosteron-antagonist Digoxin Inotropic drugs

The introduction of angiotensin-converting enzyme (ACE) inhibitors in the late 1980:s opened up for outpatient HF clinics where optimisation of pharmacological treatment could be performed by specially trained nurses. The first HF clinic in Europe started in Linköping, Sweden in 1990<sup>24</sup>. In some European countries (e g., Sweden and the Netherlands) such clinics have been frequently established and a survey showed that HF clinics with specially trained nurses existed in 59 of the 86 hospitals in Sweden<sup>25</sup>. At these clinics, patients received adequate doses of ACE-inhibitors or the equivalent angiotensin receptor blocker (ARB) within 2-3 outpatient visits together with checks of blood pressure and blood samples. The introduction of beta-blockers in the early 1990:s fitted well with the concept of outpatient HF clinics. However, the important factor is not the location or structure of the treatment but the treatment itself and that guidelines are followed<sup>20</sup>. One example is that HF clinics were not feasible for elderly patients who might benefit more from other types of follow-up (e g., home visits)<sup>26</sup>.

### 2.3.2 Non pharmacological management

In the guidelines for HF treatment there are recommendations based on expert consensus and research<sup>20</sup>. The most important factor in self-care management of HF is to adhere to the pharmacological treatment. It might be helpful for patients to know the effects/side effects of HF drugs, especially since modern HF treatment includes flexible intake of diuretics. It is also well known that when introducing beta-blockers to a patient with HF it is frequent that patients may experience increased symptoms, including fatigue and oedema sometime before a positive effect is achieved<sup>18</sup>. Another aspect is symptom recognition in order to detect possible deterioration in HF. Weight monitoring can be seen as the most important factor in symptom recognition in that weight gain can be associated with a worsened heart condition, which is most likely due to fluid retention<sup>27,28</sup>. It is also possible for patients to get an objective measurement of their body weight (BW) on a scale and patients are recommended to contact their health care team or take action on their own if they experience a weight gain of >2 kg in 3 days<sup>20</sup>.

Lifestyle changes including dietary advices should be given to all HF patients. This includes sodium and fluid restriction in patients with symptomatic HF, reduced alcohol intake to 10-20 g/day (e.g., 1-2 glasses of wine) or in case of alcohol-induced cardiomyopathy total abstinence, smoking cessation, immunisation for influenza as well as pneumococcal vaccine and exercise training recommendation<sup>20,29,30</sup>. The sodium intake in the general Swedish population is estimated to be more than double the recommended level of 5-6 g of table salt a day (2 g of sodium is comparable to 5 g of table salt)<sup>31</sup>. There are reasons to believe that the recommendation by the ESC patient care committee to avoid extra salt with food is of importance especially since pre prepared food already contains high sodium levels<sup>30</sup>. Interestingly, the American College of Cardiology/ American Heart Association (ACC/AHA)<sup>29</sup> guidelines gives a consumption limit of no more than 2 g of sodium/day (=5 g of table salt) for patients with symptomatic HF whereas the ESC<sup>20</sup> guidelines do not find evidence for such a recommendation though patients are recommended to avoid an excessive intake of salt. Fluid restriction in symptomatic HF is based on expert consensus. The only study addressing this issue is a small single centre study that provided no support for fluid restriction<sup>32</sup>. Another study that focused on patients with stable HF also did not find evidence of a fluid restriction of 1500 ml/day for all patients with HF<sup>33</sup>. As a

consequence the recommendation for fluid restriction is now based more on the individual patient's BW and only in patients with severe and symptomatic HF<sup>20</sup>. Another issue that may be difficult to deal with concerns the small positive effects reported in low to moderate alcohol consumption in patients with left ventricular dysfunction and ischemic origin of their HF in contrast to those patients with alcohol induced cardiomyopathy who also may have left ventricular dysfunction but should avoid alcohol intake<sup>34-36</sup>. In other areas of self-care a more individual approach is recommended for traveling, sexual activity, sleep disorders and unintentional weight loss<sup>20,30</sup>.

Non-pharmacological management mainly includes self-care activities in order to maintain or improve health according to patient's condition, as well as to avoid actions that can negatively influence the patient's situation<sup>37</sup>. The HF clinics where patients were seen for titration of medication after being diagnosed with HF provide the opportunity for both patients and nurses to discuss important topics in the treatment of HF. For patients it might be of interest to ask questions related to their own specific situation and for nurses to inform and educate patients about self-care (e.g., taking medication, diet recommendations and exercise).

Apart from written and oral information to educate patients about self-care management a computer with an interactive education programme has been used for the same purpose<sup>38</sup>. As a complement to routine care, patients could, by themselves or together with a relative or partner, learn more about HF, especially topics of particular interest to the individual. Because the education programme is interactive the patients can choose particular parts of it by simply placing a finger on the touch screen and focusing on what they want to know more about. This programme, which has been evaluated using a self-administered questionnaire, was found to be effective in increasing knowledge of self-care management in HF, but not to compliance of self-care activities<sup>39</sup>. It was believed to be essential to use a touch screen though not all patients had used a computer before. Since 2007, the ESC has its own web-page where patients can educate themselves in HF online<sup>40</sup>. Keeping the programme online makes it easier to update the information frequently and patients can use the information at home.

Various disease management programmes, including HF clinics, home care programmes and telephone follow-up programmes has been evaluated, some with favorable effects on hospitalisations<sup>41,42</sup> and even on mortality<sup>43</sup>. Recently, more intense follow-ups that include visits to cardiologists, HF nurses, telephone contacts and home visits were the focus in a large randomised controlled trial (RCT) in which patients were randomised to three groups<sup>44</sup>. However, there were no differences in the combined endpoint (death or hospitalisation due to HF) for the intensive support group who received four visits to a cardiologist, 18 contacts with a HF nurse, two home visits and two multiprofessional advice sessions, compared to the basic support group who had four visits to a cardiologist and nine contacts with a HF nurse and the control group. The study design could be criticised in the sense that the control group received regular follow-up with four scheduled visits to a cardiologist during the study period of 18 months which may have made it difficult to show any positive effects in the two intervention groups.

To summarise, the focus in non-pharmacological management research has been on the design of the programmes and the outcomes. So far little interest has been paid to the patient's own ability and internal resources in relation to patient education and self-care ability.

### **2.3.3 Devices and surgery**

The third part of HF treatment, devices and surgery, has witnessed a rather rapid development. Cardiac resynchronisation therapy (CRT) together with an implantable cardioverter-defibrillator (ICD) and, pharmacological treatment, has provided positive effects on physical functioning, QoL and mortality in an increasing number of patients with HF<sup>45,46</sup>. It has also been shown to be cost effective in reducing HF hospitalisations<sup>47</sup>. Left ventricular assist device (LVAD), a mechanic pump assisting the heart, which has been used previously as a bridge to heart transplant, will be applied more frequently in destination therapy for patients with end-stage HF<sup>48,49</sup>. Heart transplants are often successful for severely ill patients with no other treatment options and with no other serious co-morbidities. However, the limited availability of organs makes the number of transplants fewer than the actual needs. Various types of valve surgery can positively influence the patients' situation and, in some cases, are even

curative<sup>20</sup>. Recently, ultrafiltration which can be characterised as dialyses for HF patients is the object of ongoing studies<sup>50</sup>. The technical development has given opportunities to new methods for both sending and receiving information. This remote monitoring may involve information from patients' devices in order to check functionality but also to monitor changes in health status<sup>20</sup>.

### **2.3.4 Telemonitoring**

The concept of TM has been widespread and defined as the transmission of data from the patient to the caregiver<sup>51</sup>. In reality, this is often from the patient's home to a hospital, an outpatient clinic, a general practitioner or, in the larger multicentre studies, a study centre.

Early feasibility studies have tested the possibility of sending data e.g., blood pressure, BW, and electrocardiogram (ECG)<sup>52-54</sup>. During the past decade a number of TM-studies have been performed and a meta-analysis has concluded TM as effective in reducing HF readmission as well as all-cause mortality rates<sup>51</sup>. However, it has been argued that larger multicentre trials tend to show neutral results and the studies showing results in favour of TM are small<sup>55</sup>. The differences in design and the measures used make it difficult to compare studies and there is a lack of trials addressing guideline recommendations, in example, BW. Further, a frequent problem in TM studies has been low compliance rates particularly in the long run and also when more than one activity (e.g., BW in addition to blood pressure) is required from the patients<sup>55,56</sup>. Only one study has focused on patients' perceptions and experiences of TM describing predominantly positive experiences<sup>57</sup>. More knowledge in this particular topic would be of interest and further research is required.

## **2.4 Self-care**

Different self-care activities (e.g., eating, drinking and breathing) are required for a human being to maintain life and stay healthy. Self-care is of particular interest in nursing, especially when individuals are not in good enough condition to perform self-care on their own. A professional replacement of self-care when an individual needs



help can be categorised as nursing<sup>58</sup>. The concept of self-care has been defined as follows:

*“Self-care is the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health and well-being”* (Orem, p 43, 2001)<sup>59</sup>

#### **2.4.1 Orem’s theory of self-care**

In Orem’s theory of self-care<sup>59</sup> self-care is performed as a means of satisfying the individuals’ self-care requisites. These can be divided into three types: universal, such as breathing, drinking and eating; developmental, which is associated with an individual’s life cycle (e g., giving birth or getting divorced); and health-deviation, which includes various aspects of health, related to a particular disease or to side effects of the treatment.

Normally the universal and developmental self-care requisites are performed by the individuals without help from others with the exception of perhaps families and partners. However, when it comes to health-deviation self-care requisites there is a risk that a person’s own ability to perform self-care is not sufficient. The reason for that might be a lack of knowledge on how to handle self-care activities in relation to a disease or the treatment of it. Another reason might be that, because of the condition, the individual is physically unable to perform self-care. When a self-care limitation occurs in that way it is necessary to bridge the gap between the individual’s resources and the required needs. Thus, in such a circumstance professional care is authorised<sup>59</sup>. Depending on the severity of the individual’s condition it may also be necessary for professional help to perform universal self-care requisites such as eating, drinking and breathing.

In the concept of self-care, as defined by Orem, there is an ambition within the individual to regain independence from the professional care and to perform self-care on their own. One might question whether that is the case for all individuals in all types of situations. Orem’s theory of self-care is generic and not focused on a specific disease or condition of illness.

## 2.4.2 Riegel's and Vaughan Dickson's situation-specific theory of self-care in HF

Based on Orem's original and general self-care theory a situation-specific theory has been developed focusing on the condition of HF and its treatment<sup>60</sup>. One might refer to the theory as having one passive perspective where patients adhere to the treatment and observe potential changes in their condition in order to maintain physiologic stability. Thus, the first part (i.e., self-care maintenance) includes adherence to treatment and symptom recognition. This part is followed by a more active perspective in which patients have to deal with decision making regarding the meaning of the observed symptoms and how to act. The second part, self-care management, can be seen as a longitudinal continuation of the individual's self-care involving evaluation of symptoms, treatment implementation and treatment evaluation (Figure 1).

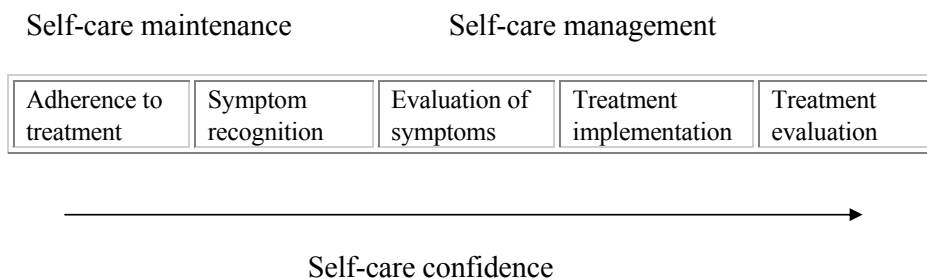


Figure 1. Representation of a situation-specific theory of self-care in heart failure. (Riegel & Vaughan Dickson 2008).

One example of self-care maintenance could be if the patients note that their legs become more swollen and contact their health care team and leave it up to the team to make the decisions. In contrast, self-care management involves taking an extra dose of diuretics as well as evaluating the effect of the treatment. The situation-specific theory by Riegel and Vaughan Dickson<sup>60</sup> reasons that if patients succeed in both self-care maintenance and self-care management, self-care confidence in turn grows within the patients and influences self-care in a positive and important way.

### 2.4.3 Self-care interventions

It has been shown that knowledge in self-care does not automatically lead to improvement in self-care activities and that personal values may affect the level of performed self-care<sup>39,60</sup>. Further, having extensive experience with HF (defined as having HF for > 2 months) and being able to recognise symptoms quickly, led to earlier treatment and better self-care management<sup>60</sup>. This is in line with Orem's conception of the individual's ambition to regain independence from the caregiver. Thus, the more experienced the individual becomes, the more decisions in self-care management the individual is likely to take.

Because non-compliance to self-care activities is associated with worsened outcomes in HF in terms of morbidity and mortality, self-care, is unquestionably an important task in HF treatment<sup>61,62</sup>. The two most common reasons for unplanned hospitalisation are non-adherence to prescribed medication or diet and not seeking care in time<sup>63-65</sup>. Overall compliance to medication is estimated to be about 70% in patients with HF which means that 30% do not receive optimised pharmacological treatment<sup>66</sup>. A delay of between 1-2 weeks from the debut of HF symptoms such as dyspnoea and oedema before seeking care, indicates that patients do not recognise symptoms or believed that they were not serious and rely on a "wait and see" strategy in the hope that the symptoms will disappear<sup>63,67</sup>.

Patient education is often given with the ambition to increase the knowledge of self-care in HF and thus improve self-care maintenance and self-care management<sup>68,69</sup>. The overall goal is to improve patient outcome. It has been suggested that patients and caregivers may have conflicting experiences on how patient education is performed and that, from a patient's perspective, the education should be tailored to the individual needs and that a dialogue between nurses and patients is essential for a successful outcome<sup>70,71</sup>. A recent study suggests that other strategies might be used as a complement: for example, better coordination of care, partnership approaches and the use of technology (i.e., TM)<sup>72</sup>. It has also been asserted that attention must be paid to those patients with cognitive dysfunction who might have difficulties to perform self-care<sup>62</sup>. Thus, other alternatives must be kept in mind for these patients.

#### 2.4.4 Sense of coherence (SOC) and coping

Internal resources have been the focus of attention in patients with HF. In particular, a high degree of SOC was found to have a more positive influence in the self-care management in patients with HF<sup>73</sup>. The concept of SOC, developed by Antonovsky,<sup>74</sup> can be defined as a person's overall capacity to respond and handle stressful situations. SOC refers to the ability to understand a situation and use internal resources to find a meaning in life<sup>74</sup>. The three components that constitute SOC are; Comprehensibility, which reflects the extent to which a person perceives stimuli in a structured way and to expect future stimuli to be predictable and explicit. Manageability, which reflects the extent to which a person perceives that he or she has the resources to meet the demands posed by the stimuli, and Meaningfulness, which reflects the extent to which a person, due to problems and demands, is able to commitment and engagement and to see the situation more as a challenge rather than as a burden<sup>74</sup>.

Being a chronic condition, HF affects several aspects of a person's everyday life. Physical limitations as well as the psychological distress require that patients use coping strategies in order to improve well-being<sup>75</sup>. Coping refers to how an individual deals with situations that can be seen as a threat<sup>76</sup>. The coping strategies can be defined as the techniques selected by the patients to deal with HF and its consequences.

The concept of SOC fits well as a model in nursing, as one important component is the individual's ability to perform self-care. This is of particular interest when patients with HF attempt to develop their self-care from self-care maintenance to self-care management, as shown in the situation-specific theory in HF.

SOC is assumed to be a relatively stable trait after young adulthood, which also has been confirmed in several studies<sup>77</sup>. However, it is suggested that SOC has a component that depends on a person's general condition, which may change over time<sup>78</sup>. In HF patients a positive association between SOC and QoL has been shown<sup>79</sup>. Patients' degree of SOC has been found to correlate with adherence to pharmacological treatment as well as to adaptation to a condition of illness<sup>80,81</sup>. Therefore, further interest should be paid to SOC as a potential mediating factor in self-care in HF.

### 3 Rationale

Successfully performed self-care may improve clinical outcomes in patients with HF. However, self-care activities are performed from 20-70% only. In particular, a self-care activity such as BW may be further investigated in that it has been shown to correlate well with deterioration in HF as well as with upcoming hospitalisation. To improve the current situation with poor QoL, high readmission and mortality rates in HF there is a need to develop methods to increase self-care activities in patients with HF. Research should address the question of whether the patient's own internal resources (such as SOC), could be a mediating factor and might influence the ability to perform self-care.

Yet, another possible strategy to increase self-care activities in order to improve the outcomes might be the use of interactive technology (i. e., TM). The rapid development of TM and interactive technology may be particularly applicable in patients with HF. The concept of TM has been frequently studied but has not specifically addressed the guideline recommendation that patients should contact their HF clinic in case of unexpected weight gain of  $>2$  kg in 3 days or take action on their own (e g., increase their diuretic dose). One obvious limitation in previous TM studies has been the rather low compliance rates of the required measures. It is therefore important to explore the patients' experiences of TM in order to understand what it means to them and how they conceive the TM and the transmission of BW. Such an approach may provide important information on how to plan and perform care for patients with HF using interactive technology.

## 4 Aims of the thesis

The overall aim of the thesis was to investigate whether QoL, readmission and mortality rates were affected when using TM and interactive technology to strengthen the self-care ability in patients with HF.

The specific aims were:

- I. To explore whether a person's degree of SOC was related to QoL and self-care ability after a patient education programme in HF.
- II. To describe the effect of dietary changes on measures of fluid retention in patients with HF.
- III. To test the hypothesis that daily electronic transmission of BW from the patients home to a HF clinic could improve clinical outcome in patients with HF.
- IV. To describe the variations of conceptions among a group of patients with HF and to understand what they experienced differently about the transmission of BW.

## 5 Material and methods

In this thesis a mixed method research was conducted using both quantitative and qualitative data. Study I and II are quantitative but in study III and IV, TM and the transmission of BW were studied from both perspectives.

### 5.1 Participants and design

An overview of the four studies in this thesis is presented in Table 2.

Table 2. Design, gender and age of participants, data collection, follow-ups and analyses are presented.

Study	Design	Participants	Data collection	Data analyses
Study I	Before-after	Total 57 Male 40 Female 17 Age/yrs 65	Questionnaires: SOC, QLI and EHFScBS. 3- and 12-month follow-up	Chi square test Students t-test Pearson's correlation coefficients
Study II	Observational	Total 31 Male 25 Female 6 Age/yrs 64	Daily weighing and intrathoracic impedance 30 days	Linear regression Pearson's correlation coefficients
Study III	RCT	Total 344 Male 239 Female 80 Age/yrs 73	Daily weighing and automatic transmission to a HF clinic for 12 months	Chi-square test Students t-test KM survival curves, Cox regression models
Study IV	Descriptive	Total 20 Male 15 Female 5 Age/yrs 74	Semi-structured interviews	Phenomenography

## **5.2 Subjects**

### **Study I**

In this study 57 patients with moderate to severe HF, defined as NYHA-class II-IV, were recruited consecutively from an outpatient HF clinic in a general hospital in Stockholm, Sweden. The 57 patients were followed for 12 months. The patients had to be pharmacologically treated and good command of the Swedish to complete self-administered questionnaires. Patients were excluded if they were <30 years of age, diagnosed with dementia and forthcoming interventions that could change the condition of HF positively (e.g., planned electrocardioversion, heart surgery or ablation) and therefore diminish the need for education in self-care. A total of 229 patients were referred to the HF clinic during a period of 21 months; of these, 132 met the inclusion criteria. At their first visit to the HF clinic, a HF nurse asked the patients to participate in the study: 83 patients accepted participation and of these 57 fulfilled the 12-month study period.

### **Study II**

Thirty-one patients with HF were recruited from an ongoing longitudinal study observing the relationship between two methods in monitoring HF: daily BW and intrathoracic impedance. All patients, 25 men and six women had a history of HF and had a primary preventive ICD.

### **Study III**

A total of 344 patients recently hospitalised (within a period of 2 months) for HF with NYHA-class III-IV at randomisation were included in the study (Figure 2). Further, the patients had to be able to use the scale in a safe way and had to have their own telephone. Other inclusion criteria were treatment with diuretics and at least one other HF drug (e.g., ACE-inhibitor, ARB, beta-blockers, digoxin or aldosteron-antagonist), ability to communicate in Swedish and having an impaired left ventricular ejection



fraction (LVEF) defined as <50%. Patients were excluded if they had diagnosed dementia or had difficulties using the scales or understanding instructions. Persons living in nursing homes or similar institutions were also excluded because of the risk of uncertainty regarding who was responsible for the patients' clinical care. Finally, patients with unstable angina pectoris or myocardial infarction within 2 months of enrollment, patients suffering from advanced kidney disease (dialyses or pre-dialyses) and other serious conditions with a life expectancy of less than 12 months were also excluded from participation in the study.

#### **Study IV**

Of the 179 patients randomised to the intervention group in study III, a sample of 20 were strategically selected for gender, civil status, age, educational background, study centre and being hospitalized vs. not hospitalised during study III (Figure 2). The reason for using a strategic sample was to obtain variation among the participants.

### **5.3 Methods**

#### **Study I**

All patients underwent an educational programme that included oral and written information about HF at the first visit to the HF clinic given by a HF nurse. At the next visit, normally within 1-2 weeks, the patients were introduced to an interactive computer-based education programme in HF with emphasis on self-care issues: for example, adherence to treatment (including what is HF and pharmacological treatment), symptom recognition, exercise recommendation, smoke cessation and diet (moderation of salt, fluid and alcohol intake). The programme is easily managed with a touch-screen so that patients can work by themselves or together with a relative.

Three validated self-rated questionnaires were used as outcomes measures at baseline and at 3- and 12-month follow-ups. The 13-item SOC-scale ranged from 13-91, with

high scores indicates a high degree of SOC. The SOC-scale has been translated and used in 33 languages with satisfactory cross cultural applicability and validity<sup>77</sup>.

The 34-item generic version of the Quality of Life Index (QLI) containing a total scale and four subscales: Health and functioning, Socio-economic, Psychological and spiritual and Family. The QLI has been found to be a valid and reliable questionnaire<sup>82</sup>. All subscales range 0-30 where higher scores indicate better QoL. The answers from patients of how satisfied they are vary from 1 (very unsatisfied) to 6 (very satisfied) for each item. Next, the responses are weighted, within the same item, regarding level of importance from 1 (not at all important) to 6 (very important) in order to find an individual perspective<sup>82</sup>.

The European Heart Failure Self-care Behavior Scale (EHFScBS) is a validated instrument containing 12 items, ranging from 12-60 for the total scale<sup>37</sup>. The EHFScBS consists of items related to the patients' knowledge in issues regarding self-care and to self-care activities performed by the individual. Patients can score from 1 (I agree) to 5 (I disagree), with low scores reflecting high self-care ability<sup>37</sup>. It has been widely used in Europe and some Asian countries and translated into 14 languages<sup>83</sup>.

The patients' answered the QLI questionnaire at baseline and again at the 3- and 12-month follow-up. The SOC scale was administered at baseline and at the 12-month follow-up and the EHFScBS at the 3- and 12-month follow-up. Questionnaires filled in at baseline were given to the patients at the first visit and brought back to the HF clinic at the next visit; the questionnaires for the 3-months follow-up were sent to patients and returned by regular mail. Finally, questionnaires were sent to the patients who brought them back at the 12-month follow-up visit (Table 3).

Table 3. Overview of questionnaires and follow-ups for study I.

Baseline	3 months	12 months
QLI	QLI	QLI
SOC	----	SOC
----	EHFScBS	EHFScBS

## **Study II**

The 31 patients received routine education for sodium restriction and limited fluid intake on an individual basis. The education took place before patients were included in a longitudinal study from which the actual sample of 31 patients was recruited. Daily BW was measured from digital electronic scales (the same type of scales was also used in study III) installed in the patients home and measures of thoracic impedance was made by storing the average daily value in the device memory of the patients ICD. Midsummer Eve was chosen because this is an important Swedish Holiday that often includes food and beverages not likely in accordance with diet recommendations in HF<sup>20</sup>. Median values from the 1-18 June for BW and intrathoracic impedance were used as baseline values. Data were collected for a period of 2 months (June and July 2009). All data were blinded to the physicians and nurses who were involved in the clinical management of the patients. However, patients were instructed to contact their health care team in case of a weight gain of >2 kg within 3 days according to current ESC guidelines<sup>20</sup>. BW was registered by one investigator not involved in the patients' care. If patients transmitted BW less than 5 times a week they were contacted by phone, to ensure compliance.

## **Study III**

Patients were randomised to either an intervention (IG) or a control group (CG) during their stay in hospital or at the follow-up visits. The randomisation had to take place within 8 weeks after discharge from hospital. In accordance with HF guidelines<sup>20</sup> all patients were recommended to weigh themselves on a daily basis, preferably in the mornings after emptying their bladder but before having breakfast. Patients in the CG were informed to call a special telephone number where they could leave a message to the study nurses. Patients in the IG were given electronic scales (Zenikor medical systems AB) in which they could place anywhere in their homes. After weighing, a wireless signal was sent to a modem plugged in the patients' telephone and the weight was then automatically transmitted to the HF clinic. The system gave an alarm if there were a weight gain of >2 kg from the targeted weight or if there were an upward trend of >2 kg in 3 days. The weight on the computer screen (IG) and the telephone messages (CG) were checked on Mondays, Wednesdays and Fridays. Because of the opening

hours at the HF clinic, a special schedule was followed during holidays, though information from the patients was always checked within 4 days. If information on weight gain was received by the study nurses, patients were contacted by telephone and asked questions from a special protocol. If one or more of the following symptoms occurred, patients were prescribed an additional dose of diuretics (e.g., furosemide 40 mg) for two consecutive days: increased tiredness, swollen legs, increased breathlessness or difficulties lying flat in bed. If the patients did not have any symptoms no actions were taken from the study nurses at this time. Patients in the CG were instructed to call back in case of continuous weight gain and patients in the IG were again checked on schedule within 2-3 days. Patients without improvement after increased doses of diuretics were offered an extra visit to the HF clinic. To ensure that no technical problems had occurred (telephone) contact was taken after 4 days, if no weights were received from patients in the IG. All patients were excluded from further follow-up in the study after reaching the primary endpoint, i.e. cardiac re-hospitalisation. Both groups had follow-up visits after 6-8 weeks and after 12 months (Figure 2).

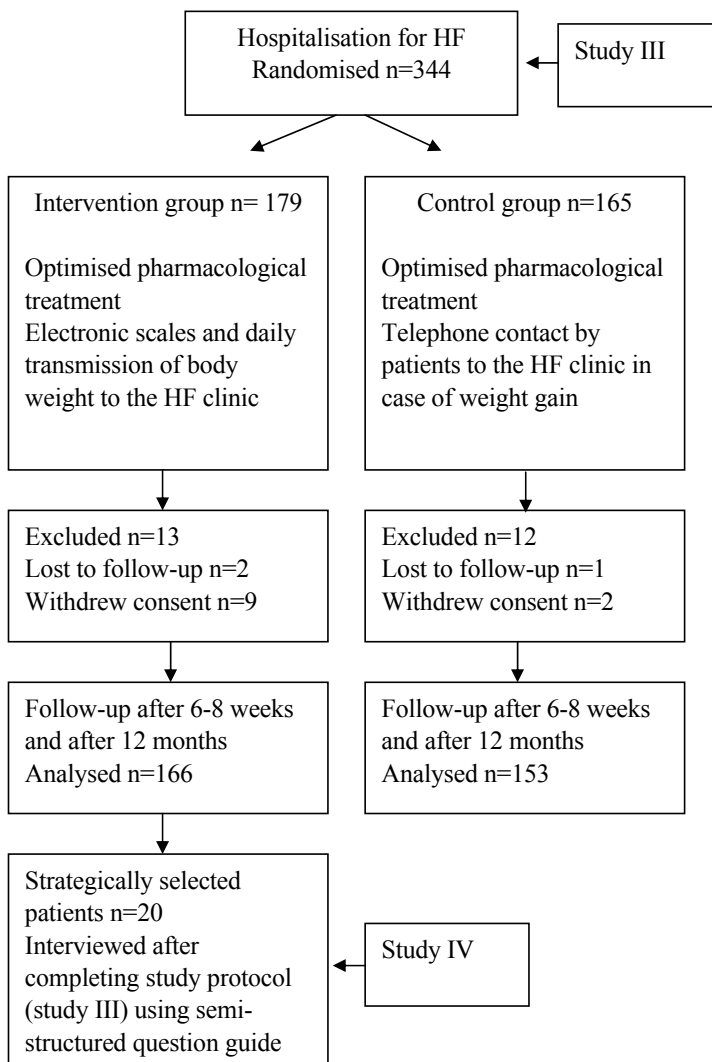
The primary endpoint in study III was cardiac re-hospitalisation and secondary endpoints were all-cause hospitalisation, death from any cause or the composite endpoint of cardiac re-hospitalisation and death from any cause. Because the study was a randomised controlled trial, the study was registered at the Karolinska Clinical Trials Registry (CTR) (no: CT200110072).

#### **Study IV**

After completing study III patients in the IG were contacted by phone and sent written information about the study. If they agreed to participate patients were interviewed either in their homes or at the hospital. The interviews were done by investigators who had not been involved in the clinical care of the specific patient. Thus, the potential risk for bias, in case of an existing nurse-patient relation between the interviewer and the informant, could be avoided. Two pilot interviews were made to test the semi-structured interview guide. These pilot interviews were both included in the analyses. Open questions were used and all interviews started with the question: *“You have participated in a study where you have weighed yourself and your BW has been*

transmitted to a HF clinic. What did the transmission of BW mean to you”? This question was, followed by the questions: “How did the transmission of BW become obvious to you in your self-care”? Finally, the patients were asked: “Can you state any positive or negative aspects of the transmission of BW”? Probing questions such as: “Could you tell more about that”? and “How, In what way”? were used to obtain additional information. The interviewer summarised the interview at the end of the interview session. The conversations were recorded and transcribed verbatim.

Figure 2. Flowchart for study III and IV.



## 6 Analyses

### 6.1 Statistical analysis

PASW statistics version 18 (IBM Corporation 2010, IBM Corporation, Route 100 Somer, NY 10589) was used to perform the statistical analyses for study I, III and IV and R v 2.9.2 (R Foundation for Statistical Computing, Vienna, Austria) was also used in study III.. Statistica (Tulsa, OK, USA) was used for in study II. A p-value of <0.05 (two-sided), was considered as significant for all analyses.

To present data for categorical variables e.g., gender, civil status, Fisher's exact test and Chi-square test were used. Continuous variables (e.g., age and laboratory results) are given as mean values and standard deviation (SD) and differences were analysed using Student's paired t-test or t-test for independent groups. Pearson's correlation coefficient was used to examine relations between variables.

In study I both non-parametric and parametric statistical methods were used in the analyses. Although data were approximately normally distributed and the results did not differ, it was decided to present the results from the parametric methods. A linear regression analysis was used in study II to analyse daily measures of BW and thoracic impedance. In Study III Cox regression models were used to analyse primary and secondary endpoints.

### 6.2 Qualitative analysis

In study IV a qualitative design with a phenomenographic approach was used to analyse the interviews. The focus was on how the phenomenon was conceived and the variations in the conceptions among the participants<sup>84,85</sup>. The text was then analysed in seven steps according to Larsson and Holmström<sup>86</sup>. The whole text was read several times individually by the researchers and marks were made at answers that corresponded to the aim of the study. The marks were then discussed and identification on how the phenomenon was described in a dominant way was made, i.e., what was the main focus on the phenomenon (the transmission of BW). The descriptions, similarities

and differences, were put into categories and then non-dominant, i. e., other ways of understanding the phenomenon were identified<sup>86,87</sup>. The descriptive categories were structured in order to create a structure in the outcome space. The marked descriptions from patients were compared with the original text until a final classification was agreed upon<sup>88</sup>. Finally, a metaphor was assigned to each category as a description<sup>86,87</sup>.

## **7 Ethical considerations**

Research should always be connected with ethical considerations and conducting studies in patients with a severe condition faces several ethical challenges. A researcher is responsible to practice and develop evidence-based care for the patients. On the other hand, patients might be in a weak position and perhaps dependent on the researcher who asks them to participate in a study. This was the actual case in this thesis in that the researchers in study I, II and III also provided the clinical care for the patients. This was avoided in study IV where the interviews were made by a researcher not involved in the clinical care of the informant and the interviews took place after the intervention in study III.

It was emphasised in the written information that was given to the patients that their participation in the studies was voluntary and that it was possible for them to withdraw their consent at any time, without giving any explanation, and that this would not influence their future care. Still, it is probably difficult for patients to say no and the researcher must be very sensitive when dealing with such matters. After giving information the researcher should preferably leave the patient alone to think and perhaps discuss with relatives before addressing the question of participation. However, if the researcher makes a decision not to ask a patient who seems to be too vulnerable to participate in the actual study, this could bias the result and thus reduce their generalisability.

In study II data were collected from patients with HF by a researcher not involved in the clinical care of the patients. These data were not used in the clinical care of the patients. However, patients were told to contact the HF clinic in case of weight gain or other HF symptoms.

In this thesis patients were given both verbal and written information about the studies. In study I and IV oral consent was obtained and in study II and III written consent was signed by the patients. For all studies confidentiality was guaranteed for all patients regarding the information that was collected and that no individuals could be identified.

Ethical approval for study I was obtained from the research committee south, Karolinska Institutet and for study II-IV from the Regional Ethics committee in Stockholm.



## 8 Results

### 8.1 Study I

Of the 83 patients who accepted participation at baseline, 57 fulfilled the study period of 12 months. Descriptive data and baseline characteristics did not differ between those that completed the study and those that dropped out (Table 4).

Table 4. Descriptive data for study I. Number, percentages and p-values are presented. Mean and standard deviation for age are also given.

	<b>Study group n=57 n (%)</b>	<b>Drop-outs n=26 n (%)</b>	<b>P-values</b>
<b>Gender</b>			
Male	40 (70)	21 (81)	0.42 <sup>1</sup>
Female	17 (30)	5 (19)	
<b>HF</b>			
Previous HF	9 (16)	5 (19)	0.76 <sup>1</sup>
New onset HF	48 (84)	21 (81)	
<b>NYHA-class</b>			
NYHA II	42 (74)	15 (58)	0.43 <sup>2</sup>
NYHA III	15 (26)	11 (42)	
NYHA IV	0 (0)	0 (0)	
<b>Age (yrs)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
Male	64.1 (10.0)	61.0 (12.8)	
Female	67.6 (12.0)	73.2 (12.5)	
Total	65.1 (10.6)	63.4 (13.4)	0.73 <sup>3</sup>

<sup>1</sup>Fishers exact test, <sup>2</sup>Chi-square test, <sup>3</sup>Students t-test for independent groups.

The mean value of the SOC score did not change significantly over the 12-months study period (67.9, 68.0 respectively,  $p=0.94$ ). The QLI score were stable over time, except for a significantly higher score in the Socio-economic subscale at the 3-month follow-up compared with both baseline and the 12-month follow-up.

Self-care as measured by the EHFScBS showed a tendency ( $p = 0.06$ ) to a decrease in the total scale from the 3- to the 12-month follow-up. Of the individual items in the scale the patients rated decreased self-care ability for, rest, fatigue and low salt diet ( $p = 0.01-0.05$ ). Compliance to medication, however, significantly improved over time ( $p = 0.04$ ).

The patients' physical ability (NYHA-class) remained stable and did not change over time. The positive significant correlations ( $r = 0.36-0.46$ ,  $p = 0.001-0.006$ ) between a patients degree of SOC and the total QOL scale at baseline, as well as after 3 and 12 months, suggests that the higher the SOC the higher the perceived QOL. No significant correlations were found between SOC and EHFScBS scores or NYHA-class.

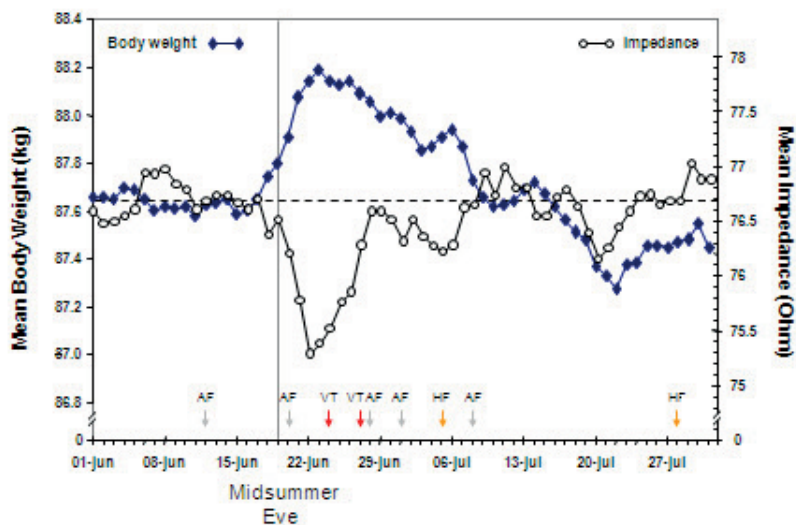
## 8.2 Study II

Both BW and thoracic impedance were stable from 1 to 19 June when Midsummer Eve was celebrated. A marked increase in BW and a decrease in thoracic impedance occurred after the 19 June (Figure 3) with BW peaking (mean 550 g) after 4 days and thoracic impedance (mean 1.4 Ohm) after 2 days. Further, the Opti-vol fluid index showed a marked increase with a peak after 9 days. BW gradually returned to normal baseline values in 20 days and thoracic impedance after 8 days. The time to recovery was 12 days for Opti-vol fluid index.

During the study period a number of minor events were registered. The majority of them (7 of 9 events) were observed within a period of 19 days after Midsummer Eve as illustrated in Figure 3. Two patients experienced symptoms of deterioration in HF which led to an increased prescription of diuretics. In addition, two patients suffered from fast ventricular tachycardia (VT) with appropriate ICD-shocks (another five had self-terminating VT, not shown in Figure 3). Finally, five episodes of atrial fibrillation (AF) were seen in three patients. However, no patients were admitted to hospital during

the study period. A weight increase of  $>2$  kg in 3 days occurred on 37 occasions in 21 patients but not one of these episodes led to any contact from the patients to their health care team.

Figure 3: 19 June (Midsummer Eve), Atrial fibrillation (AF), symptoms of heart failure (HF), ventricular arrhythmia with ICD-shock (published with permission from European Journal of Heart Failure).



### 8.3 Study III

Of the 344 randomised patients, 25 did not fulfill the inclusion criteria and were excluded from further analysis. The most common reason for not fulfilling the inclusion criteria were having an LVEF  $>50$  (examined after randomisation), not being hospitalised for HF or suffering from myocardial infarction within 2 months before inclusion. Two patients also moved to nursing homes shortly after enrollment. Thus, 319 patients were included in the final analysis. Baseline characteristics did not differ

between the IG (n=166) and the CG (n=153). Fourteen patients, of whom 11 withdrew their consent and 3 were lost to follow-up, were included in the analyses until their drop-out date.

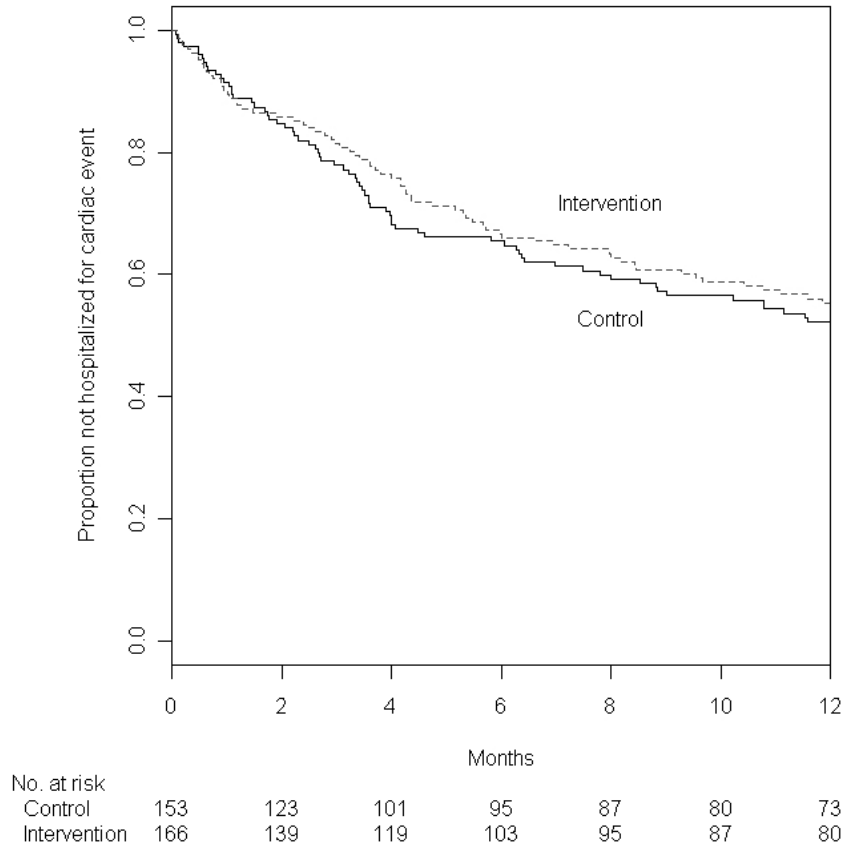
No significant differences were found between the IG and the CG for the primary endpoint (i.e., cardiac re-hospitalisation) or for the secondary endpoints (i.e., all-cause hospitalisation, death from any cause or the composite endpoint of cardiac hospitalisation and death from any cause) (Figure 4, Table 5).

Outcome	Control group n=153 n (%)	Intervention group n=166 n (%)	Hazard ratio (95% CI)	P-value
Cardiac hospitalisation	70 (45.8)	70 (42.2)	0.90 (0.65-1.26)	0.54
All cause hospitalisation	84 (54.9)	79 (47.6)	0.83 (0.61-1.13)	0.24
Death from any cause	8 (5.2)	5 (3.0)	0.57 (0.19-1.73)	0.32
Death from any cause or cardiac hospitalisation	78 (51.0)	75 (45.2)	0.90 (0.65-1.26)	0.54

References: control group, 95% CI =Confidence Interval

A statistically significant increased risk for cardiac re-hospitalisation (hazard ratio (HR) 2.24, 95% confidence interval (CI) 1.25-4.01, p = 0.01) was seen among patients in the IG who had a weight gain of >2 kg in 3 days prior to hospitalization, in contrast to those patients who experienced no such weight increase. Patients' mean compliance to daily weighing was 75% (range 0-100%, median value 83%). The absolute majority of all 428 monitoring occasions (e.g., telephone contact between patients and study nurses) took place for patients in the IG (398 vs. 30 in the CG). A complete intention-to-treat (ITT) analysis was also performed with all 344 patients as well as a per protocol (PP) analysis that included 305 patients. The results did not differ from the published result with 319 patients.

Figure 4. Kaplan-Meier curves illustrating time-to-event for the primary endpoint (published with permission from European Journal of Heart Failure).



## 8.4 Study IV

After reading the interviews several times and looking for passages that corresponded to the aim of the study (i.e., to explore patients' conceptions of transmitting BW from their home to a HF clinic) five categories emerged. Each category was then assigned a metaphor as a description. In table 6 an overview of the categories and the patients' dominant and non dominant ways of understanding the phenomenon are presented.

The patients experienced the transmission of BW as a kind of a routine. Something they just did and did not think that much about it. As one patient (No 16) stated: "It (the

scale) *stood beside the bed, so it was just to step up on it...*". It was also described as a morning ceremony, a ritual, taking medication and weighing them. It was a rather simple activity that was easy to perform. The metaphor that emerged in this category was "the routine-building patient".

One experience that also was expressed was a concern about forgetting to do the weighing in the morning. Another thing mentioned was the fear of relapse in HF and a concern among patients of getting on the scale for that purpose "*...I am a little frightened to step up on the scale, if I have gone up*", said one patient (No 4). Another conception was stress because the patient had to weigh themselves. Still, it was believed that the pressure to do the daily weighing was something good. According to the patients, there were situations when the system did not work and they did not know if the signal (the transmitted weight) had been sent to the HF clinic. On these occasions, when the system failed, the patients were worried if they had done something wrong. This led to the metaphor "the worrying patient".

The patients experienced the technical equipment very differently. Statements from patients that the technical solution was excellent occurred as well as it sometimes did not work. As one patient put it "*sometimes it worked well and sometimes it did not. Well...no, then you got tired of it*" declared one patient (No 15). The system was easy to use and even though there were problems with the transmission now and then it was described as positive. However, the patients expressed they required support to install the equipment. From these conceptions the metaphor of "the technically-relating patient" emerged.

The transmission of BW and the contact between patients and caregivers, made the patients safe. As one patient (No 12) stated, "*Yes, they are probably keeping an eye on me. If something happens there is somebody on the other end that will see...*". It was also important for the patients to know where to address if the need for contact came up. The metaphor that emerged in this category was "the security-building patient".

The patients experienced how their self-care activities were enhanced by having the electronic scales in their homes. They wanted to do the weighing and were interested in their self-care. Some patients co-operated with the study nurses in managing their HF and it was expressed that patients learned about symptom recognition (e g., swollen

legs). One patient (No 13) stated that the advantage was that he could more effectively keep an eye on himself: “*A few times I guess, I noticed I had put on too much and it was fluid*”. Still, another patient told that the transmission of BW did not mean anything to him because he was already in control on his own. The metaphor “the self-caring patient” represented this category.

Table 6. The 20 patients different ways of understanding the transmission of body weight (BW) in a dominating (++) and non- dominating (+) way.

Participants m = male f = female	The routine- building patient	The worrying patient	The technically relating patient	The security- building patient	The self- caring patient
1 (m)		+	+	++	+
2 (m)	+		++	+	+
3 (m)	+	++	+		+
4 (m)		+		++	
5 (m)	+		+	++	
6 (f)	+		+	++	
7 (m)	++			+	+
8 (m)			+	++	+
9 (m)		+	+	+	++
10 (m)		++		+	
11 (f)	+	++		+	+
12 (m)	+		++	+	+
13 (m)	+			+	++
14 (f)	++			+	
15 (m)			++	+	+
16 (f)	+				++
17 (f)	++	+			
18 (m)	++		+	+	+
19 (m)	+				++
20 (m)	++		+		+

## 9 Discussion

The main findings in this thesis were that TM, in the form of the transmission of BW and monitoring three times a week from a HF clinic, did not decrease hospitalisations or death in patients with HF. However, TM did increase self-care activities and safety. The hypothesis that the patients' internal resources, defined as the degree of SOC, influenced the outcomes of an interactive patient education was not confirmed. There may also be an increased risk for patients with HF not to follow diet recommendations.

### 9.1 Interactive patient education

The degree of SOC did not influence the self-care ability of patients with HF as measured by the EHFScBS. Few studies have investigated the possible influence of degree of SOC on the outcome of patient education. Our study (study I) showing no correlation between the scores of SOC and knowledge and information scores is consistent with a study concerning patient education in patients waiting for dialyses<sup>89</sup>. The degree of SOC did not change between baseline and the 12-month follow up. As in most other studies, the significant correlation between SOC and QoL indicates that individuals with a low degree of SOC are at risk of perceiving low QoL<sup>90,91</sup>.

The total score of the 12-item EHFScBS questionnaire showed a tendency to lower self-care ability at 12 months compared with the 3-month follow-up. Of the three items showing a significant decrease in self-care ability, one item ("taking a rest during the day") is no longer recommended to patients with HF as a part of their self-care<sup>30</sup>. In the revised version of the EHFScBS (EHFScBS-9) this item has been removed<sup>83</sup>. Instead only patients' with unstable HF are advised to rest whereas all other patients with stable HF are recommended to be physically active. Another item, "not reporting fatigue" to health care providers, is a risk factor for patients with HF in that increased fatigue has been related to a higher risk for HF re-admissions<sup>92</sup>. Finally, "not following a low salt" diet might suggest a higher risk for an adverse outcome in terms of increased symptom burden<sup>93</sup>. A positive factor for self-care ability was that "adherence to prescribed medication" increased over time. However, it must be noted that almost 100% of the patients in the present study answered that they took medication as prescribed in



contrast to other studies showing compliance rates of about 70%<sup>66</sup>. It must be considered that, because the EHFScBS is a self-administered questionnaire, it may lead to false positive results in that individuals might overestimate their own actions<sup>94</sup>.

Follow up strategies for patients with HF that included frequent clinical visits, home visits and telephone contacts have proven to increase EHFScBS scores over time<sup>95,96</sup>. The concept of bi-monthly clinical visits, more frequent in some cases, was successful in increasing self-care behavior in restricted fluid intake but not in following a low salt diet. Further, patients improved in reporting fatigue, shortness of breath, swollen legs and weight gain. However, the action of daily weighing did not increase<sup>95</sup>. Even in patients with long-term previous HF (mean duration of 6.2 years) some improvement was observed in the total scale of the EHFScBS, for the 12-month follow-up that included home visits (on average 2.8) and telephone contacts (on average 8.4) as a complement to clinical visits<sup>96</sup>. This observation indicates that a patient education consisting of two sessions as in study I, is less effective than more intense follow up and that repeated education in self-care is necessary maintaining and improving self-care ability.

## **9.2 The importance of diet**

The significant self reported decrease in following a low salt diet in study I was partly emphasised in study II where the findings indicated that non-compliance to guidelines diet recommendations can be a risk factor for patients with HF. The increase in BW and the simultaneous decrease in thoracic impedance strongly suggest that a temporary higher consumption of salt and fluids (including alcohol) during Midsummer Eve account for these findings. The exact amounts could not be measured within the design of study II, but even a moderate consumption of typical food and beverages would far exceed the guideline recommendations. For the study we estimated a moderate midsummer meal to contain approximately 5 g of sodium and 40 g of alcohol compared with the recommended amount of 2 g and 10-20 g, respectively<sup>20,29</sup>. A daily intake of 2 g of sodium is equivalent to 5 g of table salt (comparable to one teaspoon), whereas 10-20 g of alcohol are equivalent to 1-2 glasses of wine.

Two recent studies recommend a maximum intake of 3 g of sodium a day for patients with HF because higher consumption is a risk for adverse clinical outcomes<sup>93,97</sup>.

Another study shows that a normal consumption of sodium is preferable to a low salt diet<sup>98</sup>. However, in that study the normal diet included 3 g of sodium, which is far from the estimated consumption of 5 g in the Swedish general population<sup>31</sup>. The ESC guidelines give no such recommendation in sodium restriction, but that patients should avoid excessive intake, particularly symptomatic patients<sup>20,30</sup>. In a small study patients with HF were served bean-soup with three salt concentrations (low, medium and high). Compared with the healthy controls that preferred the medium level, patients with HF liked the soup with the highest salt concentration best<sup>99</sup>. The increased risk for adverse outcomes in study II, as in other studies<sup>93,97</sup> indicate the need for educating patients with HF on this particular issue. This is especially important in that prepared frozen meals, often served to elderly persons in home care, contains high sodium levels with up to two thirds of the recommended daily intake.

Furthermore, a truly important Swedish tradition (such as Midsummer Eve) should be considered when educating patients with HF on the importance of diet. In study II two of 31 patients had ventricular tachycardia with appropriate ICD -shocks in combination with increased BW and decreased thoracic impedance (Figure 3). For patients with no such ICD, this could have been fatal and therefore we should not hold back information about the potential adverse impact of dietary non-compliance.

Consumption of alcohol in agreement with the guideline recommendation of 1-2 glasses of wine/day is not considered harmful to patients with HF and may even be a reducing risk factor for myocardial infarction<sup>20,35</sup>. On the other hand, heavy consumption of alcohol may increase the risk of alcohol induced cardiomyopathy and atrial fibrillation<sup>34,100</sup>. In study II we estimated a higher consumption of alcoholic beverages than is recommended. If two beers were consumed there was up to one extra litre of fluid for each patient on this particular day. The guideline recommendations of a fluid restriction of 1500-2000 ml/day in patients with severe symptoms may well be exceeded during Midsummer Eve<sup>20,29</sup>. However, the lack of evidence of the effect of fluid restriction must be considered and the few studies addressing this question did not find support for beneficial effects in fluid restriction<sup>32,33</sup>. There is a lack of consensus in dietary recommendations to patients with HF. Study I and II support a more active approach to dietary advice in order to improve self-care. This might be beneficial in that a recent study showed that patients were able to reduce the intake of both sodium and fluids<sup>101</sup>.

### 9.3 TM and transmission of BW

To support patients in self-care the concept of TM was used in study III. We hypothesised that daily electronic transmission of BW from the patients' home to a HF clinic would reduce cardiac morbidity rates from 40 to 25%. Patients were then monitored according to current guidelines<sup>20</sup>. Despite a rather high compliance rate to daily weighing (mean 75%, Md 83%) and more monitoring occasions in the IG (398) compared with the CG (30), the hypothesis was not confirmed. A small though insignificant advantage in favour of the IG was noted and even if it had been significant, with a substantially larger sample size, the difference between the groups (3.6%) for the primary endpoint (cardiac re-hospitalization), would not be of clinical relevance.

No significant impact on the outcomes was found for any of the subgroups defined as: Gender, age, sinus rhythm/atrial fibrillation, LVEF  $\leq 25\%$  or  $>25\%$ , previous HF/new onset HF and previous hospitalisation due to HF in the past 12 months prior to enrollment. The result in study III contradicts a Cochrane review<sup>51</sup> that concluded that TM is effective in reducing HF-related hospitalisation as well as reducing mortality. However, looking at the larger RCT:s, defined as  $>300$  patients only one<sup>102</sup> could show beneficial effects in terms of re-admission rates whereas the others failed to show any beneficial effects<sup>103-109</sup>. The two largest RCTs so far were powered to detect a difference in mortality rates but no such effect was seen in favour of the IG compared with the CG<sup>106,108</sup>.

There are difficulties comparing TM studies because the only thing all studies have in common is the actual transmission of data from the patients' home to the caregiver<sup>51,110,111</sup>. Both the transmitted data (e.g., BW, oxygen saturation, ECG, blood-pressure and HF symptoms) and the measures taken in the studies vary as shown in Table 7. In some trials, particularly large multicentre studies, data were sent in to a central study center from which data were either communicated to the treating physician/clinic<sup>106</sup> or used in the management of patients by the study centre physicians in collaboration with the patients' local physician<sup>108</sup>. In study III BW was transmitted to the HF clinics and in case of weight gain symptom questions were asked and actions taken by HF nurses at each of the six study centres. Giordano et al.,<sup>102</sup> who were successful in reducing re-admission rates, used one parameter for the TM (single-led

ECG). On the other hand, patients with severe HF were contacted every week from the study centre for further measures (e.g., self-care activities that included diet, sodium and fluid restriction, pharmacological treatment and symptom recognition). It cannot be ruled out that it was merely the intensive follow-up and the actions taken from the HF clinic that were the important factors rather than the TM per se.

Further, a smaller study showed a trend to a decrease in re-admission rates by combining BW, blood pressure and heart rate that were transmitted daily by the patients followed by, contacts or home visits by the patients' General practitioner together with telephone follow-up from specially trained nurses at a HF clinic if the values were outside pre-determined limits<sup>112</sup>.

In study III BW was transmitted to HF clinics and, in case of weight gain, protocol-lead symptom questions were asked and action was taken by HF nurses. One parameter was used namely, BW, with the intention to make it as easy as possible for patients to be compliant. Cleland et al.,<sup>103</sup> used daily BW with a compliance rate of 84%. When adding blood pressure as a second parameter the compliance rate dropped to 55%. This finding indicates that the more activities required, the higher the risk for patients to be non-compliant. In study IV the patients' experiences were very different in terms of using the equipment and the functionality of it. The transmission of BW (in study III) was described as easy to do for the patients but also that the TM system did not always work and in those cases they got "tired of it". This raises questions whether technical problems occurred in other TM studies and if that perhaps influenced the compliance rates.

In conclusion TM can be designed and performed in two major ways. Data can be transmitted and actions taken from the health care providers as in study III and most other studies<sup>51</sup>. Still, this has not proven very successful. Another possibility, perhaps more promising, is to use the options given in the TM context and design the TM to make patients more active and take greater responsibility for their own care in collaboration with health care professionals.

Table 7. Randomised multicentre TM-studies (>300 patients).

Numbers and follow-up (months)	TM measures (data sent from patient to caregiver)	Main actions taken from the caregiver	Differences for the outcomes hospitalisation or death
Cleland et al 2005 <sup>103</sup> n=418 8 months	BW Blood-pressure ECG	Advice from nurses and changes in treatment by primary care physicians	ns
Soran et al 2008 <sup>104</sup> n=315 6 months	BW Symptom questions	Data reviewed by nurses and changes in treatment by primary care physicians	ns
Mortara et al 2009 <sup>105</sup> n=461 12 months	ECG, vital signs including: BW, blood pressure, dyspnoea and oedema scores	Telephone contact with nurses and/or physicians	ns
Giordano et al 2009 <sup>102</sup> n=460 12 months	ECG	At least weekly telephone contact with HF-nurses regarding self-care topics	Cardiovascular hospitalisation p=<0.01 55 (24%) Intervention, 83 (36%) Control, (RR=0,56, 95% CI: 0.38-0.82)
Chaudhry et al 2010 <sup>106</sup> n=1653 6 months	HF-symptoms	Measures taken by local physicians	ns
Tompkins et al 2011 <sup>107</sup> n=390 6 months	BW, blood pressure, heart rate, oxygen levels	Measures taken by HF nurses	ns
Koehler et al 2011 <sup>108</sup> n=710 12 months	BW, ECG, blood pressure	Contacts with study centre physician or local physician	ns
Wade et al 2011 <sup>109</sup> n=316 6 months	Blood pressure BW, HF-symptoms	Case manager via physician prescription	ns
Study III 2012 n=344 12 months	BW	Telephone contact with HF nurses and changes in diuretic doses	ns

ns = not significant

## 9.4 BW as a self-care activity

The results in study II strengthen the evidence for the use of BW as a self-care activity that is easy for patient to perform as a routine part of their self-care maintenance.

However, the use of BW as a self-care activity in order to recognize symptoms is not

without complications. Previous research has shown low self-reported levels, where only one third of the patients, complied with daily weighing<sup>113</sup>. In study II the threshold for weight increase >2 kg in 3 days<sup>20</sup> was frequently exceeded but with no actions taken from the patients to contact the HF clinic. Having electronic scales in the patient's home with automatic transmission of BW increased the number of compliant patients as well as the contacts with the HF clinic but without significant improvement in clinical outcome.

The more than doubled risk for patients with a weight gain of >2 kg in 3 days to be hospitalised in study III compared with those with no such weight gain confirms the relation between weight gain and deterioration in HF, but indicates that the ESC recommendation<sup>20</sup> might be a too generous limit to prevent hospitalisation. Other studies have reported weight gain ranging from 0.9-2.3 kg before hospitalisation<sup>114,115</sup>. However, it might be difficult for patients to follow a recommendation to contact their health care team or increase diuretic doses if they experience a lower weight gain (e.g., 1 kg or less). There may be a greater risk for bias and over utilisation of health care resources. As a consequence the use of a moving algorithm has been suggested because weight gain before hospitalisation in HF is not always linear<sup>114,115</sup>. Such a moving, or dynamic, algorithm could focus on weight gain over a longer period where the weight might fluctuate. Still, today daily weighing should be recommended according to current guidelines<sup>20</sup> as a self-care activity to patients with HF, although not alone but in conjunction with other measures.

## **9.5 Future aspects on self-care**

The role of self-care is well established in the treatment of patients with HF. HF nurses or other health care professionals have educated patients in self-care. Education sometimes, but not always, increases knowledge in self-care for these patients. However, such education does not automatically result in improvement in the accomplishment of self-care activities<sup>39</sup>. In study III self-care was strengthened by TM but did not decrease hospitalisation or death. HF is a complex syndrome and well performed self-care will not remove the need for support from caregivers.

If the concept of TM will change towards a more interactive approach, this change would be in line with the theory of Riegel and Vaughan Dickson<sup>60</sup>. They argued that when a patient makes progress from self-care maintenance i.e. adheres to treatment and recognises symptoms, toward self-care management and is able to evaluate symptoms and implement as well as evaluate treatment, the self-care confidence increases.

In a study mobile-phones were used to send daily weight and blood pressure which was followed-up by symptom questions. Such an approach was experienced positively by the patients though there were still rather low compliance rates to the daily measures<sup>57, 116</sup>. A more interactive approach in which patients use the system when they consider it appropriate might be more beneficial and help a to further individualise the care.

### **9.5.1 Health literacy**

Health literacy is important when making decisions concerning the patient's own health and whether individuals are supposed to take a greater responsibility. Moreover, the ability to make proper decisions is of importance<sup>117</sup>. In study IV one patient insisted that the TM did not mean anything to him in that self-care was already being performed. Such an individual might be considered to have high health literacy<sup>117</sup>. On the other hand there are persons who have difficulties understanding medical and self-care information and thus have potential difficulty in making correct health decisions<sup>118</sup>. These individuals may be defined as having low health literacy. It cannot be ruled out that this was the case for those patients in study III who were in need of the support given by the HF clinic when deterioration in HF occurred.

The literature suggests that health literacy is not only a polarised phenomenon between low and high health literacy but also a more complex phenomenon containing several aspects of knowledge in society, science and culture<sup>119</sup>. The consequence of that might be that one individual can have high health literacy in one specific situation but not in another<sup>117</sup>. The design in study III supported patients with potentially low health literacy. This was expressed in study IV, where patients conceived that they were being cared for by the nurses at the HF clinic which was experienced as a positive event.

## 9.6 Methodological considerations

Generally the research question asked in a study will help to decide which methods to use in the investigation<sup>94</sup>. In study I a before-after design was used, to explore whether a person's degree of SOC was related to QoL and self-care ability after a patient education programme. All patients followed the same programme and no control group was included in the study. One limitation of the study was the rather high drop-out rate (31%). Only two questionnaires are validated to measure self-care in HF, namely, the EHFSBS and the Self-care Heart Failure Index (SCHFI)<sup>120</sup>. The EHFSBS is available in Swedish and was ready to use when study I was carried out. The 12 items of the EHFSBS are added to obtain the total scale. The focus within the EHFSBS lies in the knowledge in and compliance to self-care matters in HF and measures the level of self-care maintenance among the individuals<sup>120-122</sup>. The SCHFI consists of three parts measuring self-care maintenance, self-care management and self-care confidence. Because self-care maintenance involves dealing with deterioration and symptoms of HF, that part may only be used if patients have been symptomatic in the past month<sup>122</sup>. The EHFSBS was chosen for the purpose of study I. However, if patients are newly diagnosed and have not yet received patient education the questions about being compliant might be confusing. Therefore the EHFSBS was not used as a baseline measure.

The reason for using the QLI as a QoL instrument was the possibility for patients to assess level of importance for a specific topic<sup>82</sup>. The use of QLI might be criticised in that the level of QoL was equal between the participants in study I and a healthy Swedish population<sup>123</sup>. The use of a complementary disease-specific questionnaire to the QLI would have been preferable. It has also been argued that the importance-weighted scores in the QLI do not have advantages over more easily managed instruments<sup>124</sup>.

For the purpose of observing effects of a potential dietary non-compliance during an important Swedish holiday (in this case, Midsummer Eve), an observational design was chosen in study II. One obvious limitation is that the actual amounts of salt, fluids and alcohol that were consumed at Midsummer Eve are not known. However, it was believed that it would be difficult to avoid bias in terms of underreporting if patients were asked to fill in a diary of what they consumed. A strength in the design was the



use of two parameters, BW and thoracic impedance, both of which have proven able to detect deterioration in HF<sup>27,125</sup>. One could argue about the ethical dilemmas in study II in which patients knew that they were observed during the study period but were not specifically reminded of dietary recommendations before Midsummer Eve. However, before enrollment, all patients were, informed about dietary recommendations on an individual basis.

Study III was a multicentre RCT involving six hospitals in Sweden. The design makes the results possible to generalise. Further, the study hypothesised a reduction in cardiac morbidity from 40 to 25%, with a power calculation base on that assumption. The rather large reduction in hospitalisations might be criticised but was done deliberately to ensure that the result reflected the effect of the TM. A limitation in study III is that the numbers of all eligible patients is unknown. Another limitation is that 25 patients were randomised despite not fulfilling all inclusion criteria. However, this limitation did not influence the results of the study in that these patients were equally distributed between the two groups.

A qualitative design with a phenomenographic approach was used in study IV for the purpose of describing patients' conceptions of TM. To ensure rigor in the data the concepts of credibility, dependability, confirmability and transferability were used<sup>126</sup>. Strength in the design was the use of a semi-structured interview guide that allowed that all patients were given the same opening question. The credibility in the study was also increased as each category was described by several patients. Dependability was increased because one of the authors is very experienced with the method. The risk for bias due to the first author's pre-understanding was avoided by clarifying the actual role in the interview situation (i.e., being a researcher and not a clinician), but also as the other three authors did not possess such pre-understanding. Two of the authors are familiar with HF and the other two are not, which strengthens the confirmability of study IV. It is not possible to generalise the results from a qualitative study in the same way as in a RCT. The term transferability is often used and refers to what extent the result can be transferred to other settings<sup>126</sup>. In study IV the strategic selection of patients in study III strengthened the transferability of the findings.

## **10 Conclusions**

The patients internal resources defined as SOC did not influence the QoL or self-care ability after an interactive patient education programme in HF. Patients with a low degree of SOC are at greater risk of perceiving low QoL.

Deterioration in self-care over time was seen and might lead to adverse outcomes in patients with HF. Education in self-care ought to be given to patients with HF and health care providers should have an active approach concerning dietary advice.

TM in the form of daily electronic transmission of BW that included monitoring three times a week from a HF clinic did not decrease hospitalisation or death in patients with HF but increased the patients' self-care activities and safety. Weight gain was associated with an increased risk of hospitalization due to HF. TM is a source to acquire information from the patients and a means for personal contact between patients and caregivers.

## **11 Clinical implications**

Daily weighing and transmission of BW from the patients' home to a HF clinic did not improve clinical outcome. However, a significantly higher risk for hospitalisation was seen in patients with a weight gain of >2kg in 3 days just before hospitalisation.

Therefore, daily weighing may still be recommended to patients with HF as a self-care activity but in combination with other measures (e g., increased fatigue, breathlessness and swollen legs). These measures, as a complement to the contact between patients and their caregivers, are likely essential in the care of patients with HF.

Patients living with HF should receive special education by health care professionals about the potential risks in HF deterioration when consuming greater amounts of salt, fluids and alcohol than recommended. This might be of particular importance when patients are to celebrate a festivity like Midsummer Eve.

The neutral results in this thesis, which is in agreement with most other studies suggest that TM alone should only be used as a complement to frequent follow-up and repeated education in self-care which seems important to maintain and improve the self-care ability in patients with HF. On the other hand TM did increase self-care ability and safety among patients with HF. It is possible that new technical solutions will permit greater interaction between patients and caregivers. It may also be so that patients with HF might be more familiar with technology in their daily life in the future, which may lead to an increased use of TM in the clinical care of patients with HF.

## **12 Implications for future research**

As weight gain in patients with HF was associated with a greater risk for hospitalisation, the question of using other algorithms for weight gain in HF should be further investigated. A moving, or dynamic, algorithm has been suggested as an alternative to the today's recommendation (>2kg in 3 days) and should be considered in future research.

Although there are inherent methodological problems, there is a need for research to clarify which dietary recommendations to give to patients with HF. Issues like sodium and fluid restriction should be further studied as well as consumption of alcohol. Alcohol is believed to be beneficial for patients with ischemic heart disease which is the case for the majority of patients with HF. However, since alcohol also may have a negative effect on patients with HF, this issue is of substantial importance for future research.

TM gives the opportunity to transfer data from a patients' home to a caregiver and to monitor patients without physical visits to HF clinics or other health care providers. However, no general way to use the concept of TM has been successful so far. Future research should focus on TM together with the patient's own ability to use the information given and to develop an interactive co-operation between patients and health care professionals. The patients' different levels of health literacy may well be considered in this research.

## 13 Summary in Swedish – Svensk sammanfattning

### “Egenvård hos patienter med hjärtsvikt med inriktning på viktmonitorering och interaktiv teknologi”

Att leva med hjärtsvikt innebär för många att leva med en nedsatt fysisk funktionsförmåga vilket kan leda till en upplevelse av sämre livskvalitet jämfört med friska personer. Tidigare forskning har visat att förmågan att utföra egenvård är viktig och kan förbättra situationen för den enskilde individen men också att egenvårdsaktiviteter utförs i varierande grad, uppskattningsvis mellan 20-70%. En ökning av detta skulle kunna förbättra utfallet i form av livskvalitet, återinläggningsfrekvens och död hos patienter med hjärtsvikt.

Det övergripande syftet i avhandlingen var därför att undersöka om livskvalitet, återinläggningsfrekvens eller död påverkades av användandet av telemonitorering och interaktiv teknologi i syfte att stärka egenvårdförmågan hos patienter med hjärtsvikt.

Under **studie I** följdes 57 patienter under 12 månader efter en patientutbildning i egenvård vid hjärtsvikt innehållande muntlig och skriftlig information samt tillgång till ett interaktivt datorbaserat utbildningsprogram. Patienterna besvarade tre validerade frågeformulär, vid inklusionen samt efter 3 respektive 12 månader. Resultatet visade att en individs egna inneboende resurser att hantera svåra och stressfyllda situationer, definierat som graden av känsla av sammanhang, inte påverkade livskvaliteten eller egenvårdsförmågan efter genomgången patientutbildning. Det fanns en tendens till försämrad egenvård efter 12 månader, speciellt avseende att hålla en låg salt diet och att rapportera symtom som exempelvis trötthet.

I **studie II** observerades 31 patienter under 2 månader avseende vikt och thorakal impedans. Syftet var att observera eventuella effekter av en möjlig låg följsamhet till diätrekommendationer för patienter med hjärtsvikt. I patienternas hem användes digitala vågar för att registrera vikten automatiskt. Thorakal impedans mättes via patienternas inplanterbara defibrillatorer. Resultatet visade en signifikant uppgång i kroppsvikt (medelvärde 550 g) och en signifikant nedgång i thorakal impedans (medelvärde 1.4 Ohm) med början på midsommarafton. Detta kan indikera en försämring i hjärtsvikt. Ett kluster av händelser, kopplade till försämring i hjärtsvikt,

identifierades också i anslutning till midsommarafton och antyder att låg följsamhet till diätrekommendationer kan innebära ökade risker för patienter med hjärtsvikt.

**Studie III** var en randomiserad kontrollerad multicenter studie som genomfördes på sex sjukhus i Sverige. Hypotesen var att daglig viktöverföring från patientens bostad till en hjärtsviktsmottagning med monitorering tre gånger/vecka skulle minska antalet sjukhusinläggningar från 40 till 25%. Totalt 344 deltagare randomiserades till antingen en interventionsgrupp för daglig viktöverföring eller en kontrollgrupp som rekommenderades daglig vägning och att vid viktuppgång >2 kg inom 3 dagar kontakta hjärtsviktsmottagningen. Uppföljningstiden var 12 månader eller uppnådd primär endpoint dvs. hjärtrelaterad inläggning på sjukhus. Resultat visade ingen signifikant skillnad mellan grupperna avseende primär endpoint (kontrollgrupp, 70/153, interventionsgrupp, 70/166, hazard ratio 0.90, 95% konfidens intervall 0.65-1.26,  $p = 0.54$ ). Inte heller för sekundära endpoints som inläggning oavsett orsak, död eller kombinationen hjärtrelaterad inläggning och död påvisades signifikanta skillnader mellan grupperna.

I **Studie IV** intervjuades 20 patienter från interventionsgruppen i studie III om deras uppfattningar om viktmonitoreringen. Intervjuerna spelades in på band och skrevs ut ordagrant och analyserades med en fenomenografisk ansats. Patienterna erfarenheter var övervägande positiva. De beskrev sig som säkra och att de ökade sina egenvårdsåtgärder. Fem kategorier framstod och tilldelades varsin metafor som beskrivning: ”den rutinskapande patienten”, ”den orolige patienten”, ”den tekniskt relaterande patienten”, ”den säkerhetsskapande patienten” och ”den egenvårdande patienten”.

Slutsatserna i avhandlingen är att telemonitorering i form av daglig viktöverföring inte minskade sjukhusinläggningar eller död hos patienter med hjärtsvikt men patienterna uppfattade sig som säkra och ökade sin egenvårdsförmåga. Telemonitorering kan användas som ett komplement till personliga kontakter mellan patient och vårdgivare. Hypotesen att en patients egna inneboende resurser, i form av känsla av sammanhang, kunde påverka utfallet av en interaktiv utbildning i egenvård vid hjärtsvikt kunde inte bekräftas. Vårdgivare bör vara aktiva och ge råd till patienter om eventuella risker att inte följa diätrekommendationer vid hjärtsvikt.

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