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Telehealth on heart failure: results of the Recap project

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Abstract

Telehealth has become a very important tool that allows the monitoring of heart failure patients in a home environment. However, little is known about the effect that such monitoring systems have on patients' compliance, evolution and self-care behaviour. In particular, the effect that the selected user interface has on these factors is unknown. This study aims to investigate this, and to determine some practicalities that must be considered when designing and implementing a telehealth programme for heart failure. To achieve this, daily measurements of blood pressure, pulse, SpO₂ and weight were collected from 534 patients suffering from heart failure. In addition, they were asked to fill in the European heart failure self-care behaviour scale questionnaire and the EQ-5D quality of life questionnaire, before and after the monitoring period. Two telehealth systems were used, the Motiva platform provided by Philips and the standalone unit provided by Docobo, the Doc@Home system. Significant differences were found between both systems concerning the compliance and adherence of patients. Moreover, a general, positive effect of telehealth was identified due to the fact that patients showed an increased self-awareness when managing their condition. These findings are supported by behavioural changes and a better understanding of heart failure from the patients' perspective.

Keywords

Heart failure, telehealth, education, compliance, self-care behaviour

Introduction

Heart failure (HF) is recognized as one of the most common diseases in Western Europe, with more than 10% of the people older than 65 years suffering from it.¹ HF represents the most common cause of readmission in industrialized countries, and more than 30% of patients hospitalized due to HF will die within 1 year.² It is well known that HF is often accompanied by several comorbidities such as coronary artery disease, hypertension, atrial fibrillations, and valvular heart disease.³ Therefore, it is not surprising that this disease strongly impacts social and economic systems in a large scale. For instance, it has been reported that the costs associated with HF represent more than 2% of the total cost of health care.¹ As a result, the use of alternative approaches such as telehealth tools that help improving the HF outcome, and reduce the costs, is imminent. Even though some telehealth programmes have been implemented for the monitoring of HF patients,⁴⁻⁷ their effect on the entire health care system is not yet understood. For example, it has been reported that telehealth seems to be more effective for more critical patients and patients with higher risk of hospitalization.⁸ Hence, it is crucial to identify effective protocols that allow to better manage HF.⁹ In this respect, the Recap (Regional Care Portals) project aims to improve and promote the implementation of telehealth systems in heart failure.¹⁰ This project brings 13 partners from the North West Europe region together, to work towards the analysis of new legal, financial, organizational and technological solutions in telehealth. These solutions aim to improve the communication between patients and care givers, and to increase the awareness of patients with respect to the importance of self-managing their condition. With this in mind, it is expected that new telehealth solutions could have a positive effect on the diagnosis and treatment of HF.

This manuscript deals with technological factors that need to be considered during the design and implementation of telehealth programmes in HF. For this reason, three partners worked together on the implementation of one of such programmes. One of the partners involved in this task is the North East London NHS Foundation Trust (NELFT) in the UK, where HF patients were recruited and followed up. Health Enterprise East also known as NHS Innovations East in the UK, is the second partner involved in this work, which took care of the business planning and commercial research on telehealth systems monitoring HF patients. The third partner is the KU Leuven in Belgium, where

the data analysis took place. Furthermore, KU Leuven evaluated and defined the technological practicalities that needed to be considered during the implementation of this telehealth programme.

In this study, two different telehealth systems were implemented, namely the Motiva platform offered by Philips (The Netherlands), and the standalone unit provided by Docobo (UK). Docobo model numbers were as follows: A&D UA-767PBT-C40 BT BP Monitor (3PM-A02 SN), A&D UC-321PBT-C40 BT Scales (3PM-A03 SN), HealthHUB 2 Roaming GPRS BT Kit (DCU-002-RGPRS-BT), and Nonin 9560 Bluetooth Oximeter (3PM-N06 SN).

The main differences between these two telehealth systems are the user interface, mobility, and the educational information. Therefore, it is possible to assess differences between these systems, and determine whether education and mobility have an impact on the evolution of HF patients. Another important point investigated in this work is the effect of telehealth on the self-care behaviour of patients. With this in mind, the general effect of education and self-management will be clarified and hopefully later used in the implementation of new telehealth programmes.

Methods

Ethics

The study was approved by Health research authority NRES east of England with reference number 12/EE/0137. Moreover, each patient signed a written consent form before starting the telehealth programme.

Patient population

The dataset used in this study consists of daily measurements of blood pressure, pulse, blood oxygen saturation (SpO₂), and weight, collected from HF patients referred to the North East London NHS Foundation Trust (NELFT) in the UK, from November 2012 to November 2014. All eligible patients were older than 18 years and they all had a confirmed diagnosis of left ventricular systolic dysfunction (LVSD) supported by a positive ECG. In addition, at least one of the following conditions was satisfied: sudden increase in weight of more than 1.5kg in 24 hours; systolic blood pressure lower than 90 mm Hg; sudden increase in shortness of breath; episodes of palpitation/tachycardia without collapse; change of medication within 48 hours of discharge from acute; or high Hospital Anxiety Depression Self-Assessment (HADS) score.¹¹ On the other hand, if any of the following conditions applied, the patient was excluded from the study: diagnosis without ECG; clinically stable NYHA I to II classification (New York Heart Association); Nil oedema; normotension (120/80 mm Hg); end of life with NYHA larger than II; or insufficient cognitive understanding to complete questionnaires or to use the telehealth equipment.

Study design

Once a patient was enrolled into the programme, the Hospital Anxiety and Depression Scale (HADS) was administered. Next, a demonstration of the use of the telehealth programme was provided by the HF nurses, together with the explanation of the EU Recap project and the benefits of the whole programme. In total 534 HF patients were eligible, with mean age 69.1yr±12.6yr. No record was kept of how many patients had declined to participate in the first place. Figure 1 presents the flow of participants in the study. All patients were randomized into two groups, one receiving the standalone unit

offered by Docobo (135 patients), and one receiving the Motiva telehealth platform offered by Philips (399 patients). The groups were unevenly split because less Docobo systems than Philips Motiva equipment were available for this study, hence more of the latter to give to patients. During the first days of monitoring, the patients were trained at home, to measure the 5 physiological parameters mentioned above, twice a day, on a daily basis. After 42 days of constant monitoring, the telehealth equipment was returned to NELFT and it was allocated to a different patient. A monitoring of 42 days was selected as the appropriate study period because it has been shown that HF readmissions are known to occur within 6 weeks at minimum to 6 months at maximum.¹²

Apart from the physiological measurements, patients were asked to fill in the European heart failure self-care behaviour scale (EHFScBS)¹³ and the EQ-5D¹⁴ quality of life questionnaires, at the beginning and at the end of the monitoring period. This was done in order to assess changes in self-care behaviour and quality of life followed by the telehealth programme. Additionally, the HADS was also administered at the end of each trial. Of the 534 patients, 411 (mean age 68.5yr±12.2yr) completed the 42 day programme, 123 were females and 288 were males, 105 patients received Docobo units, and 306 patients received the Motiva system. All data transferred to KU Leuven for analysis was completely anonymized.

Interventions like changes in medication, titrations, and withdrawals were annotated in the data. However, no information about type of medication or specific doses was available. It is important to mention that all of these interventions were the same for both groups, and they were made mainly by the nurses with input from cardiologists and GPs where appropriate. Additionally, both groups were monitored by the same healthcare providers.

The telehealth systems

As mentioned before, two different monitoring systems were deployed, the Docobo unit and the Motiva platform. Their main characteristics are indicated in Table 1. The most important difference between these two systems relies on the functions that they offer to the patients. For instance, the Motiva platform offers more educational material, and a more familiar interface, since it is a personal healthcare television channel. In this channel, patients can read reminders sent from the health providers, and access videos where the importance of a healthy diet, physical activity, and medication is highlighted. Even though this information is crucial to encourage patients to stay healthy, no record was kept of when and how often the patients accessed and reviewed this material.

On the other hand, the Docobo system used for this study is a stand-alone unit that does not provide educational information, but offers more mobility to the patients. The main goal of this study is to determine differences on the physiological parameters, and answers to questionnaires, for patients with different systems. In the same way, indirect effects of the user interface can be assessed.

Data analysis

In order to quantify the evolution of the physiological parameters of all HF patients that completed the monitoring period of 42 days, the slope (m) for each parameter was computed using linear regression. Each patient was then characterized by 5 slopes that describe the tendency of each parameter from day 1 to day 42. The slopes for each group were compared, and differences were assessed by means of the Kruskal-Wallis test with a 95% confidence interval. The reason to use this test is that it does not assume normality

in the variables, as for instance one-way Anova. Furthermore, the quality of life and the self-care behaviour for patients with decreased/increased trends were analysed. From this analysis the possible impact of the different telehealth systems on the compliance of patients to the programme was determined. Patients' compliance was also associated with the amount of missing data for each telehealth system, and the amount of additional data that was transferred to the telehealth programme. The additional data refers to the amount of days that patients measured themselves more than twice.

The amount of interventions and the differences between the initial and the final HADS per group were also compared. Moreover, differences in age and gender were also considered. Differences between proportions were evaluated using the Chi-square test.

All calculations were carried out in MATLAB R2013a on an Intel(R) Core(TM) i7, 2.4GHz, 8GB RAM, running Windows 8.1.

Results

Initial common problems

The first observations correspond to the initial common issues reported by the patients during the installation of the telehealth systems and during the first days of monitoring. For instance, patients using the Docobo unit had problems adhering to the monitoring times. Additionally, due to the characteristics of the unit, they needed to rely on a care giver to be able to collect and transmit the data. Therefore, initial issues concerning the daily transmission of the data were commonly reported. On the other hand, patients using the Motiva system complained about the portability of the unit. Furthermore, the installation of the platform was sometimes not straightforward due to the different TV technologies available at the patients' homes. This resulted in transmission problems of the first readouts of the physiological parameters.

It is important to point out that this information was obtained from the *free text* patients wrote on the surveys and from speaking to the patients. Hence, no statistics can be made on these observations.

Patient's compliance

An important factor to consider when implementing a telehealth system is the amount of data transmitted to the care provider, in this instance the HF nursing team. This is crucial for the design of algorithms that can predict decompensations related to HF. In this study, patients needed to measure themselves twice a day, but it was observed that patients using the Motiva system measured themselves significantly ($p < 0.05$) more times a day than patients using the Docobo unit. This is shown in Figure 2, where the amount of missing data per group is also indicated.

Effect of telehealth on the physiological parameters

The initial comparison was performed between the "baseline" parameters of both groups under investigation. Figure 3 indicates the physiological parameters at day 1, and the age of all patients. At this point, no significant differences ($p > 0.05$) were found.

The next step was to compare the evolution of the physiological parameters of both groups. This was done using the slopes during the monitoring period of 42 days. Figure

4 shows the differences for each physiological parameter. A decreasing trend was found in DBP, pulse and weight, however, only the first one was significantly different with $p=0.001$.

Effect of telehealth on quality of life

The questionnaire used to assess changes in the quality of life (QoL) consists of 5 questions that evaluate the following factors: anxiety/depression; pain/discomfort; usual activities (e.g. work, study, housework, and family or leisure activities); self-care; and mobility.¹⁴ Each factor gets scored according to the severity of the problems experienced by the patient. As mentioned before, two scores were obtained, one at day 1 and one at day 42. As a result, it was possible to determine whether or not changes in the QoL were caused by the telehealth system, and if they were influenced by the user interface. No significant differences ($p>0.05$) were found between the factors at the beginning and at the end for either all patients together or for the two groups separately.

A different way of evaluating the anxiety/depression factor is by means of the HADS. Here, these scores at the beginning and at the end were also evaluated, and no significant differences ($p>0.05$) were found.

When looking at patients that showed an improved QoL at day 42, no relationship was found between this improvement and their evolution during the 42 days of monitoring. In other words, these patients did not show a consistent evolution in the physiological parameters.

Effect of telehealth on self-care behaviour

To assess changes on self-care behaviour, the European heart failure self-care behaviour scale was used, and it consists of the following 12 items:¹³

- I1. I weigh myself every day
- I2. If I get short of breath, I take it easy
- I3. If my shortness of breath increases, I contact my doctor or nurse
- I4. If my feet/legs become more swollen than usual, I contact my doctor or nurse
- I5. If I gain 2 kg in 1 week, I contact my doctor or nurse
- I6. I limit the amount of fluids I drink (not more than 1.52 l/day)
- I7. I take a rest during the day
- I8. If I experience increased fatigue, I contact my doctor or nurse
- I9. I eat a low salt diet
- I10. I take my medication as prescribed
- I11. I get a flu shot every year
- I12. I exercise regularly

Each item was scored from “(1) I completely agree” to “(5) I do not agree at all”. As with the QoL questionnaire, two scores were obtained, one at the beginning and one at the end of the telehealth programme. Significant differences ($p<0.05$) were found in some of the items. Moreover, the telehealth programme showed a general improvement in the self-care behaviour. This can be seen in Figure 5, where the comparison between the scores at the beginning and end are indicated for the total score and for the items with significant differences ($p<0.05$). These results were equal for both telehealth systems, where no significant differences ($p>0.05$) were found.

An important observation here is the fact that significant differences ($p < 0.05$) were found in the scores for I1 and I6, which correspond to “measuring body weight every day” and “limiting the amount of daily fluid intake”. These two factors are very important in the monitoring of HF. Hence, when the patients with decreasing trend in DBP (136 patients), SBP (131 patients), and weight (91 patients) were analysed, and their scores at day 1 and day 42 were compared, it was possible to observe an improvement in their self-care behaviour. This improvement was more obvious in the daily weighing and in the daily fluid intake (see Figure 6).

Interventions

Different interventions were annotated in the dataset, and some significant differences were found between both telehealth systems. It was observed that patients using the Docobo unit received 2% more diuretic titration, 3% less titration of beta blockers, and 2% less titration of angiotensin-converting enzyme inhibitors than Motiva patients. Unfortunately, no information about the exact dose of medication nor differentiation between up- and down-titration was available.

Another important observation that can be made, is that 6 out of 135 patients using Docobo withdrew the programme, while only 2 out of 399 withdrew when using Motiva platform. After evaluating these proportions using the Chi-square test, a significant difference was found with $p = 0.004$.

Discussion

The results of this study indicate that the characteristics of the telehealth platform have an effect on the compliance of the patients to the telehealth programme. This is supported by the amount of missing data, and by the withdrawal rates of both systems. In other words, a platform such as the Motiva system, which offers educational information and a more user friendly interface, might increase the compliance and adherence of the patients to the programme, and this on its turn could have a long term effect on the evolution of the patients' condition. In this study, after only 42 days of monitoring, it was already possible to see differences in the evolution of blood pressure. Nevertheless, it may be speculated that these differences could have been caused by differences in titration between both telehealth systems. Unfortunately, no information on medication nor on exact doses was available during this study. Therefore, in order to draw stronger conclusions on the effect of either telehealth platform on patients' outcome, it is necessary to implement longer trials where information about medication changes is available. In addition, longer-term trials will also allow to assess changes in the quality of life of patients using telehealth.

Having considered the effect of the user interfaces on the evolution of the physiological parameters, it is now important to comment on the behavioural changes observed in this study. It was shown that a general improvement in the self-awareness, self-management and assistance-seeking was achieved by the telehealth programme. This is a remarkable finding, because it proves that by implementing a telehealth programme, it is possible to increase the awareness of patients of the importance of self-managing their conditions. For instance, daily weighing and limitation of daily fluid intake became an important factor for patients during the monitoring period. Hence, significant improvements in a long term can be achieved, such as better adherence to telehealth programmes that can result in a reduction of heart failure decompensations.

Despite the fact that patients were more aware of the importance of monitoring their weight, it was observed that measurements of this parameter were often missing. This was the case even for patients using the telehealth system more than twice a day. These findings are crucial, since weight is a very important parameter in HF, and it has been shown to be probably the most useful physiological parameter to predict decompensations.^{5,15} Therefore, it is important to keep in mind that patients tend to forget, or simply avoid to take daily measurements of weight, when developing telehealth systems, and when designing algorithms for risk prediction. It is worth noting that attention must be paid to the way weight measurements are integrated into the telehealth system. For example, a way where all sensors are integrated into one compact platform could be developed, as well as new protocols to attract and motivate patients to monitor themselves on a daily basis.

Two important points must be considered here. On the one hand, the Motiva unit uses a “well-known” interface, i.e. the television, and on the other hand, the mean age of the population under investigation was $69.1\text{yr} \pm 12.6\text{yr}$. These two points are crucial because elderly people of today are more used to the TV technology, while the HF population of 10 or 20 years will already be used to more portable devices, e.g. standalone units. Hence, it is believed that technological differences may cause that patients using the Motiva system are reminded more often to take daily measurements, while patients using standalone units tend to comply less with the monitoring times. However, these results will probably change in the future due to the fact that society is relying more and more on portable devices. These findings are in agreement with the increasing needs for personalized health informatics,¹⁶ where each telehealth system is specifically tuned to work for each particular patient.

Conclusions

This study assessed changes in the evolution of blood pressure, pulse, blood oxygen saturation, weight, and self-care behaviour caused by the implementation of a telehealth programme on HF patients. Two telehealth systems were used to monitor patients, namely the Motiva platform offered by Philips, and the Docobo unit. Both patient groups were monitored by the same healthcare providers, and the main difference between both systems was the user interface, and the amount of educational information that was presented to the patients. Significant differences were found between both systems, as well as a possible positive effect of education on the compliance and adherence of the patients to the telehealth programme. This effect will need to be confirmed in future studies, where information of how often patients access educational material is available.

A general improvement in the self-care behaviour was achieved by the use of telehealth, which appeared to also have a positive effect on the evolution of the physiological parameters. Therefore, an improved heart failure outcome can be achieved, which may lead to a reduced load in the healthcare system. Nevertheless, this is something that needs to be confirmed by longer-term trials, where hospitalizations are included as endpoints.

One of the main limitations of this study was the lack of information about types of medication and dose changes. For this reason, no links between changes in the physiological parameters and medication could be made. Furthermore, the short-term duration of this study, namely 42 days per patient, limited the possibility to observe clinical events. Therefore, no conclusions on the effect of each telehealth system on the outcome could be drawn.

The results obtained in this study allow to define some practicalities and technicalities that need to be considered when designing and implementing a telehealth system, and they will be listed next.

- The telehealth device needs to be considered because it has a direct influence in the compliance of the patients to the programme. For some patients the mobility of the unit is important, while for others the fact that they do not need to use or learn a “new” technology improves their compliance to the monitoring times.
- The educational and additional information presented to the patients should be included in the telehealth programme.
- A way to attract and motivate patients to take daily measurements of weight needs to be reconsidered. This is crucial for the design of algorithms that predict decompensation due to heart failure.
- It is of paramount importance to include information about medication and doses in order to assess the direct effect of telehealth on the evolution and final outcome of the patients.

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Table 1. Main characteristics of the telehealth systems

Docobo	Motiva
Stand-alone unit	Interactive telehealth platform
No video streaming	Personal healthcare channel
No educational information	Educational information to control and understand the condition
Blood pressure (systolic/diastolic)	Blood pressure (systolic/diastolic)
Pulse rate	Pulse rate
Oxygen saturation (SpO ₂)	Oxygen saturation (SpO ₂)
Body weight	Body weight

Figure 1. Heart failure patients on the telehealth programme.

Figure 2. Amount of data transmitted to the hospitals for each telehealth system. Note that patients with Motiva unit seem to comply better with the programme. Differences in DBP, SBP and Pulse for more than 2 measurements a day were significantly different ($p < 0.05$). Concerning the days without measurement, Weight indicated a significant difference ($p < 0.05$). The central mark of the boxplots is the median, and the edges correspond to the 25th and 75th percentiles.

Figure 3. Physiological parameters at day 1 (left) and age (right) of the patients in both groups under investigation. The central mark of the boxplots is the median, and the edges correspond to the 25th and 75th percentiles.

Figure 4. Slopes for each physiological parameter and for each telehealth system. Diastolic blood pressure tends to decrease in patients using Motiva ($p=0.001$). Pulse and weight also tend to decrease in those patients. However, no significant differences were found. The central mark of the boxplots is the median, and the edges correspond to the 25th and 75th percentiles.

Figure 5. Scores of the self-care behaviour questionnaire for all the patients under investigation. All differences were significant ($p<0.05$). The central mark of the boxplots is the median, and the edges correspond to the 25th and 75th percentiles.

Figure 6. Scores of items 1 and 6. Significant differences ($p < 0.05$) were found between the scores for patients with decreasing trends in DBP, SBP and Weight. The central mark of the boxplots is the median, and the edges correspond to the 25th and 75th percentiles.