ICT PSP – Accessibility, Ageing and Social Integration Programme

elDeRly-friEndly Alarm handling and MonitorING

(Grant Agreement No 225023)

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Abstract

This deliverable reports the initial trial evaluation of all pilot sites emphasizing the different initial deployment results and the lessons learned of it.

Key Word List

Trial evaluation, RCT, Help desk, Contact centre

Executive Summary

This deliverable D7.3 Initial Trial Evaluation Report describes the initial deployment results of each pilot site:

- Denmark
- Estonia
- Germany
- Italy
- Spain
- Sweden

While there is a detailed description of each pilot site (sections 2 – 7), some general statistics and conclusions can be drawn (sections 8 & 9).

Population involved

From the total 341 patients, 44% are male and 56% female.

Estonia and Spain youngest population vs. Germany and Denmark the oldest.

Drop-outs: high in percentage terms Estonia and Scandinavian Countries, low in Germany and Mediterranean countries.

Chronic Heart Failure is the most frequent disease, followed by Diabetes Mellitus (54%).

Equipment

The most frequent medical sensors deployed are the blood pressure meter (25.04%), the weight scale (13.24%) and the pulse oxymeter (11.81%), which all together make more than 50% of all sensors. Meanwhile the less frequent sensor is the asthma monitor (2.15%).

Through the use of the equipment, some general technical problems have been identified highlighting the following weaknesses:

- Set-up box and Central Unit:
  - Frequent disconnections.
  - Power plug very sensitive to disconnection.
  - Nightly beeps.
  - TV unwanted connections.
  - Set up box and Central Unit heating.
  - Null and erroneous measures. It is not the same.
  - Commented Central Unit measure does not correspond with portal sent one (Glycaemia).

- Ello Video-conference system:
  - Very poor video quality.
  - Sound lag.
  - Minimum bandwidth.
  - Webcam image/video resolution.
  - For elderly is a common problem to use TV channel for calling (answering and making). This is a bigger problem in TV installations with only a euroconector (scart).
- Devices
  - Generally it has been identified to establish best practices stating When? Where? and How? to use the medical sensors.
  - Blood pressure meter: It needs calibration as there is a tendency to slightly higher values. In a case it showed 20 mmHg above the normal value which lead to mistrust. It seems important to establish best practices deciding when, where and how to take the measurement.
  - ECG: We have not received any quality set until now. Here again, it seems important to establish best practices deciding when, where and how to take the measurement.
  - Glucometer: Downward trend in the measurements.
  - Oximeter / Pulsioximeter: batteries need to be frequently removed.
  - Weight scale: problems of stability.
  - Asthma monitor: no incidents.
  - Domotic sensors: no incidences.

Contact Centre

Half of the partners have chosen a private management model where there has been chosen a shared centre. In the public environment, it has been more common to establish a specific centre to deal with Dreaming. All operate 24 x 7, 365 days a year, except in Estonia which has a more restrictive schedule limited to working days.

The centres are mainly managed by mixed organisations of social and healthcare nature; only in two cases they are controlled by pure healthcare organisations.

Helpdesk

All have local first level support, which at second level depends on at least one external technology enterprise. All have identified a contact person responsible for the help desk.

Sensor fitted homes

Patient's Safety: All partners have considered the legislation which protects patient's data. Some partners are considering clinical safety as a result of the reliability of the measurements obtained, calibration and sensitivity of devices and good practices by taking measurements.

The ADSL and voice communications have been mainly negotiated and centrally paid by the organisation of each pilot site.

Running costs, for either or both electric consumption of devices or telephone line costs have been a worry in some cases, where compensation has been negotiated.

With regards to the deployment organisation and training there has been an unintentionally agreement among several partners. It has been decided to deploy in 3 stages. Italy has been the only one who has made training in a different way.

Set-up

There is a high degree of consensus on minimising the time spent to install equipment in the patient's home. Seeking for this goal, it seems necessary to do a preliminary visit to plan the installation.

The joint responsibility of family members, if any, and of the elderly in the preliminary visit is important for a successful participation in the project.

In all pilot sites, there have been formed multidisciplinary teams for the set-up. In the Swedish model, technicians work along staff of social services, whereas the rest have been working with healthcare staff.

Installation time is between 1 ½ hours and 3 hours

Portal

Partners are equally divided on the need to install a local portal and to integrate it with their clinical history information systems.

The portal is accessible for professionals of specialised care, except in the Scandinavian pilot sites.

For professionals of primary care, it is available in all pilot sites except in the Estonian model.

Social services have access to the portal only in German and Swedish pilots.

A great majority of partners felt the need to include a guide on good practices.

Change History

Version History:

0.1	5th January 2009	Initial TOC draft
0.3	18th December 2009	
0.4	11th January 2010	
0.5	5th April 2010	
0.6	19th May 2010	
1.0	19th May 2010	Version for release

Version Changes

0.1 Initial TOC
0.2 Text for Aragon added
0.3 Text for Sweden added
0.4 Text for Denmark, Italy, Germany and Estonia added
0.5 Text revised after PSC5 meeting, new sections “Installation issues” and section 8 “Global Data” introduced and section “Implementation Conclusions” revised
0.6 Executive Summary added, minor revisions prior to issue
1.0

Outstanding Issues

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1. Introduction

1.1 Purpose of this document

This document provides an initial evaluation of the trials of the DREAMING services in the various pilot sites. It focuses on the start up of the trials, including recruitment of users and their assignment to trial (treatment) or control group, any issues on use of equipment, staffing, and any lessons learned and corrective actions needed. Furthermore, it presents additional details to deliverables D6.2 Sensor fitted homes, D6.3 Contact Centre Environment and D6.4 Help Desk, highlighting similarities and differences between the pilot sites, and extracting useful information for future installations, good practices and recommendations.

Other documents that contain relevant information are:

- D6.2 Sensor fitted homes.
- D6.3 Contact centre environment.
- D6.4 Helpdesks.

This evaluation report will be followed by D7.4 Intermediate Trial Evaluation Report and D7.5 Final Trial Evaluation Report.

1.2 Glossary

For each country, there are tables giving the demographic details of all the patients, both in the treatment group and control group, together with an indication of specific aspects of their health condition. The abbreviations used in these tables are as follows.

- **Init**: patient's initials, assigned to be unique in each country.
- **S**: Gender (M/F)
- **Age**: in years
- **DM**: Diabetes mellitus (yes/no)
- **CHF**: Chronic heart failure (yes/no)
- **COPD**: Chronic obstructive pulmonary disease (yes/no)
- **HMF**: History of myocardial infarction (yes/no)
- **HST**: History of stroke (yes/no)
- **HF**: History of falls (yes/no)
- **Hosp**: Hospitalisation within the last two years (yes/no)
- **HC**: participant enrolled in home care program (yes/no)
- **IC**: informed consent signed
- **NE**: none of the exclusion criteria present

- **L**: current living situation of the participant: (A = alone, C = with caregiver, G = group of elderly residents).

Other terms are:

CHF	Chronic heart failure
COPD	Chronic obstructive pulmonary disease
DM	Diabetes mellitus
CC	Contact Centre
ICT	Information and Communication Technologies

2. DENMARK - REGION SYDDANMARK

2.1 Clinical protocol and preparation for trials

2.1.1 Recruitment of the users and random allocation to the test or control group

The Danish trial originally required 30 participants in each group. However, due to a difficult randomisation process, it became clear that this number would be impossible to reach. Therefore it was accepted that the Danish site should only have 22 patients in the trial and control groups.

One of the randomisation drawbacks was that the patients should be a part of the established home and social care system. The reason for this was that the patients could thereby be integrated more easily into the project and normal working procedures locally at Langeland. However, this meant that the patients already had a medical history severe enough to be a part of the home, social and health care system at Langeland.

1. Initially, 22 citizens, already a part of the system at Langeland, were asked to participate in the project. They all accepted.
2. However, due to the medical history and high age of the patients, six have dropped out before they have had the equipment installed, thus leaving only 13 patients in the test group. Dropouts were caused by either death, simple unwillingness to participate or transfer to nursing home.
3. A second randomisation will take place at the end of April 2010. This randomisation will include as many new potential participants as possible.
4. The same problem applied to the control group, where four out of the original 22 patients have dropped out.

As a part of the start-up of the trial, an Excel sheet has been developed for the purpose of information gathering. The Excel sheet contains information regarding the patients from both groups: their pathologies, practical information, types of equipment to be or already installed, a sheet per patient with relevant information regarding their current status, and a logging system with information regarding failures in and comments on the equipment.

The Excel sheet is the main tool used by all professional users, be they from MedCom or Langeland, to track changes in the situation at Langeland. It is furthermore possible to use the sheet to documentation the number of errors which occurred during installations and trials. The sheet also documents if and how errors with the equipment influence the project.

2.1.2 Informed consent form signature

A patient folder has been made containing:

- An informed consent form to be signed by the patient by installation at the latest.
- Contact information for professional users, i.e. project management, nurses, etc.
- An information document about the project to be used by the patient as well as relatives in case of questions.
- An information sheet containing information about the equipment installed, including pictures and short descriptions.
- A diary, where the patients can note instances where they have had to visit the doctor, the hospital, etc. This data will also be available after the project for extracting data from the relevant health data networks, GPs, etc.

The informed consent form has to be signed before the equipment is installed.

2.1.3 Description of the resulting trial population

The trial site is Langeland as well as one near-by Island, called Strynø. The age distribution of the population goes from 66 to 93. The randomisation of the population follows the standards from the project, but has been expanded a bit in the sense that no patients from outside the established health and social care network have been included. This is the main reason for the high dropout rate, because the group of patients before entering the project had to be in a very bad shape – in Denmark, patients will not be a part of the health and social care network before they are very ill.

The demographic and health profile of the trial population are given in Table 1 (test group) and Table 2 (control group).

Table 1: Denmark: Demographic / health profile – test group

Init.	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
A.C.	M	84	NO	NO	YES					YES			
VM	M	65	YES	NO	YES					YES			
K.H	M	81	NO	YES	YES					YES			
E.M.	F	75	YES	NO	NO					YES			
I.B	F	90	YES	NO	NO					YES			
S.F.	M	83	YES	NO	NO					YES			
M.C.	F	77	YES	YES	NO					YES			
D.R.	F	82	YES	NO	NO					YES			
B.L.	F	68	YES	NO	NO					YES			
R.A.	F	85	YES	YES	NO					YES			
R.R.	M	76	NO	YES	NO					YES			
Å.M.	M	67	YES	NO	NO					YES			
K.M.	M	73	YES	YES	YES					YES			
B.N	M	82	NO	YES	NO					YES			

Init.	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
K.E.	F	82	YES	YES	NO					YES			
H.N.	M	82	NO	YES	NO					YES			
G.J	F	78	NO	YES	NO					YES			
J.N.	F	76	NO	YES	NO					YES			
I.H.	F	85	NO	NO	YES					YES			
L.H.	F	68	NO	NO	YES					YES			
O.L.	M	88	NO	YES	NO					YES			
T.W.	M	66	NO	NO	YES								

Table 2: Denmark: Demographic / health profile – control group

Init.	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
V.M.	M	84	NO	NO	YES					YES			
I.S.	F	82	NO	NO	YES					YES			
E.H.	M	77	YES	NO	NO					YES			
R.M.	M	82	YES	NO	NO					YES			
I.O.	F	71	YES	NO	YES					YES			
T.M.	F	77	YES	NO	NO					YES			
B.V.H.	M	75	YES	NO	NO					YES			
I.A.	F	80	NO	NO	YES					YES			
T.K.	F	86	YES	NO	YES					YES			
L.P.	F	74	NO	YES	NO					YES			
E.B	F	87	YES	YES	NO					YES			
L.F.	F	75	NO	YES	NO					YES			
I.S.	M	74	NO	YES	NO					YES			
O.J.	M	83	NO	YES	NO					YES			
A.H.	M	84	NO	YES	NO					YES			
E.N.	F	83	NO	NO	YES					YES			
B.J.	M	79	YES	YES	NO					YES			
A.H.	F	76	NO	NO	YES					YES			
H.F.	M	78	YES	NO	NO					YES			
K.W.	M	73	YES	YES	YES					YES			
K.N.	F	83	NO	YES	NO					YES			
H.C.	F	93	YES	NO	NO								

Notes:

- Red = deceased
- Blue = left project
- Yellow = Nursing home

Mean age test group:

The mean age of the test group is 77.68 excluding the pre-trial dropouts.

Mean age control group:

The mean age of the control group is 79.44 excluding the pre-trial drop-outs.

Distribution by gender is shown in Figure 1 below.

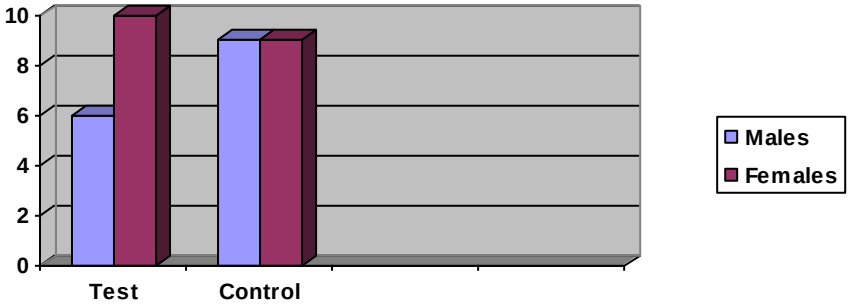


Figure 1: Denmark: Distribution by gender

The profile by pathology is shown in Table 3.

Table 3: Denmark: Profile by pathology

	COPD	DM	CHF
Test group	4	9	7
Control-group	6	9	8

Note that many patients have more than one pathology.

2.1.4 Interventions in test group

Training of patients has been done in their own homes by the healthcare team and by the project assistant installing the equipment. Ongoing training and support is also being conducted to secure the acceptance and satisfaction with the project.

2.1.5 Interventions in control group

Check-ups and controls to this group will be carried out in their own healthcare centres; for any emergency case, the elderly belonging to this group will go to the emergency service of the hospital as they have usually been doing. They will keep the classical healthcare system with the 112 emergency call service. The information gathering during follow-up will be passive by means of extracting data periodically from the Danish Health Data Network, from GPs' records, and from social information systems.

2.2 Personnel involved in trials

2.2.1 Authority staff: planners, financial and management

The authority staff involved in the Dreaming project are:

- To some extent the Danish Regions (participants in the reference group).

- To some extent Local Government Denmark (participants in the reference group).
- Local GP (participant in the reference group).
- The municipality of Langeland (main authority staff):
  - Service director, Thomas Rosenqvist.
  - Director of prevention, Anne Marie Hedegaard.
  - Head Nurse, Helle Holm.
  - Financial manager, Heidi Kieler.
- MedCom.

2.2.2 Health & social care staff

One of the first things done in the Danish pilot was to identify some primary persons from the health and social care staff. This task was managed by MedCom in cooperation with the local authority personnel responsible in Langeland Municipality.

These primary persons have so far handled all communication with patients.

The next step will be to include more health and social care staff members as primary persons. This task is expected to be started during the first months in the New Year (2010).

2.2.2.1 Training of social care staff

Portal and ello! client

The health and social care staff, i.e. nurses and assistants at Langeland, had their first training on 17th September 2009. Here the responsible nurse, Helle Holm, made a PowerPoint presentation, describing the portal and how to use it in detail.

The nurses and assistants are granted access to the portal and are now able to use it.

The ello! client will also be installed on the personal computer of each health and social care staff member. The staff can thereby use the ello! and HIS systems as a natural part of their daily work.

A training session will be held early in 2010 to teach the staff about how to use the ello! video conferencing equipment.

2.2.3 Technical staff

The technical staff involved in the project of Langeland municipality are composed of the representative from MedCom (Casper Marcussen) as well as the head nurse (Helle Holm). Both representatives receive direct support from the two system providers. Another person will be hired in January 2010 to take care of the technical installations and support functions connected with implementation of equipment.

A representative from HIS was in Denmark in August 2010 to show Casper and Helle how the installations and support functions worked. On the same occasion, Casper and Helle were trained in use of the Portal.

2.3 Equipment

Table 4: Denmark: Distribution of sensors

No	Initials	DM	CH	COPD	IEM Stabilograf	IEM weight scale	HMM Glab	Viasys	Nonin Avant 400
	A.B.	Y/N	Y/N	Y/N	BP-meter	Weight	Glucose	PEF	PO2
1	A.C.	NO	NO	YES				x	X
2	VM	YES	NO	YES	X		x	X	x
3	K.H	NO	YES	YES	X			X	X
4	E.M.	YES	NO	NO			X		
5	I.B	YES	NO	NO			X		
6	S.F.	YES	NO	NO	X		X		
7	M.C.	YES	YES	NO	X	X	X		
8	D.R.	YES	NO	NO			X		
9	B.L.	YES	NO	NO			X		
10	R.A.	YES	YES	NO	X	X	X		
11	R.R.	NO	YES	NO	X	X			
12	Å.M.	YES	NO	NO	X		X		
13	K.M.	YES	YES	YES	X	X	X	X	X
14	B.N	NO	YES	NO	X				
15	K.E.	YES	YES	NO	X		X		
16	H.N.	NO	YES	NO					
17	G.J	NO	YES	NO	X				
18	J.N.	NO	YES	NO	X				
19	I.H.	NO	NO	YES				X	X
20	L.H.	NO	NO	YES				X	X
21	O.L.	NO	YES	NO	X				
22 # →	T.W.	NO 10 (7)	NO 11 (5)	YES 7 (2)	13 (8)	4 (3)	11 (9)	X 7 (4)	X 7 (5)

In (..): # of patients still in the project
Without (..): Number of patients originally

2.4 Installation issues

2.4.1 Sensor fitted homes

Biomedical and domotic signals will always be gathered via distributed devices at the domiciles of our patients who are living in Langeland Municipality. A central unit will receive the values obtained at the domicile and transmit these to a central server which will be located in the service centre at Langeland. In the pilot or test phase we will use the HIS Portal.

The system will be able to automatically analyse the data and send alarms to the virtual nursing unit, located at the service centre at Langeland, which will react to these following the locally established protocols.

Equipment is currently installed in 13 homes. By the end of May 2010 (after the 2nd randomisation), hopefully 22 homes will have equipment installed. Unfortunately, the second randomisation seems to run into the same problems as the first, i.e. that it is extremely difficult to find patients within the Danish public sector's health or social services that can fulfil the requirements set up by the DREAMING project.

Training is performed at the patient's domicile, during a session at the start. Later, on-line care will be provided by web or videoconferencing or telephone. The home nurse will furthermore be available in case of questions.

2.4.2 Help desk

A patient's folder has been made containing instructions about how patients or relatives should act in certain situations. Basically, they are instructed to follow the existing procedures already established prior to the project (e.g. in case of very high values or emergencies: call alarm service 112).

Patients as well as relatives have received a contact list for the local helpdesk.

Regarding professional users such as nurses, GPs or home carers who deal with the technical equipment, a contact list has been distributed for the local helpdesk. Super users have also been trained to perform and assist on the most basic technical issues. Working procedures have been established for dealing with alarms, failing equipment and other issues.

2.4.3 Contact Centre

The Contact Centre (CC) is staffed with a rota of nurses on duty at the Danish site at Langeland.

The modules of the DREAMING environment are installed in the CCs and integrated with the existing ICT infrastructure.

The solution, designed for the location of reception and management of events or alarms coming from the Dreaming project, is based on the existence of an existing tele-assistance CC, which is already in place at Langeland to deal with alarm systems for elderly people at home.

This CC is a network of District Nurses, who are available via phone or internet/mail. The phone is always with the nurse on duty; mail and online interaction is possible through broadband connections, which are available throughout the island. The CC is therefore a mobile centre that is online 24/7.

The CC has points where the head nurse and other relevant representatives can access the portal, the video conference and the mailing system. These locations are equipped with personal computer, telephones, acoustical alert, headset microphone

connected to the PC, mobile phone, internet connections and anything else necessary for the operators. Premises comply in addition to national requirements for security of workers, and the legislation on privacy. The CC at Langeland is thus built on an already existing ICT structure.

At Langeland, the locations for the Dreaming CCs are as shown in Table 5 below:

Table 5: Locations of the CC for the Danish partner

Body	Framework	Location	Operators
Head Nurse at Langeland	Public sector	Danahus in Rudkøbing at Langeland	1 operator during weekdays
DN	Public sector	North Langeland	1 during workdays (24/7)
DN	Public sector	Middle of Langeland	1 during workdays (24/7)
DN	Public sector	South Langeland	1 during workdays (24/7)
MedCom representative	MedCom	Odense	1 operator during workdays

2.5 Initial trial results

2.5.1 Use of equipment / Findings of test implementation with HIS / ello!

Challenges, DK Pilot site	Solutions
HIS:	
Voice output missing when measurements are taken	HIS is still working on this issue, but has promised that it is top priority and will be dealt with asap.
Lost Bluetooth connection to glucose devices (very sensitive)	New device installed. Result of this action is still waiting.
Internet has to be installed (difficult in a rural area such as Langeland)	Many solutions have been tested and all citizens are either with a connection or about to have it installed
In some cases equipment have lost connection after having been used some time	Re-connection and troubleshooting together with HIS / New device installed
Weak batteries in the glucose devices	Batteries changed to a new model

Challenges, DK Pilot site	Solutions
General installation:	
Equipment and manuals are easy to understand and Christian Pohl has been very helpful during installations	Ongoing fruitful communication with Christian Pohl as support
Connections lost because end user turns off the switch for the TV or Internet to save electricity	Set up a dedicated switch for ello!, HIS and Internet.
Ello!:	
Users need to have two SCART plugs in their TV if they have a video or other equipment which uses SCART	Possible to buy extra SCART box with more connections
Poor video quality	TMR upgraded the system and it now works much better
Somewhat difficult installation / set-up for relatives	Manual sent to relatives and ongoing support from Casper/TMR
Equipment is quite easy to set-up and TMR provides great support	Ongoing communication with Antonia from TMR

2.5.2 SF-36 (Health related quality of life) and HADS (Depression) questionnaires

Patients were asked to answer to the SF-36 and HADS questionnaires during a domiciliary visit. The patients have a dedicated project assistant to assist filling out the questionnaire. The first few patients have filled out the questionnaires on their own, but this does not seem to have caused any problems.

Patients are asked to fill out the questionnaire a short while after they have equipment installed.

Since only a limited number of patients have had equipment installed, no results are ready at this moment.

2.6 Lessons learned & corrective actions

Recruitment issues:

Much time and troubles could have been saved if the inclusion criteria had been more loosely defined for the pilot site. Since the patients had to be a part of the established health and social care system, natural limits on the available number of potential recruits in a small municipality like Langeland quickly became apparent.

Furthermore, the recruitment criteria had meant that a significant share of the patients have been lost prior to installation of equipment. This is only natural when

only selecting patients who already are in the system and suffering from at least one chronic illness. The patients in such a group are extremely fragile.

Internet issues:

Due to many problems with establishing proper internet connections, the project has been delayed. This could have been avoided if the selection criteria said that only patients with an established internet connection could participate. On the other hand, this would of course have limited the available test group even more.

Equipment issues:

A dedicated person, taking care of the technical installations, should have been hired from the start.

A local training session with representatives from the ello! provider could have been beneficial. It was extremely helpful in the case of HIS.

A dedicated employee, taking care of the data collection, should have been hired from the start.

Other:

The use of a reference group with relevant experts from major organisations has proved to be a very useful idea. The group is very good at giving feedback and to help disseminate the results.

It has been a very good idea to assign some local role models to the project. In the municipality, this has been a nurse, and at the patient level, we had a test person, trying out the equipment prior to a complete roll out. This has helped to catch problems early on, and the role model at the municipality has served as a gatekeeper to the rest of the employees.

3. ESTONIA - TALLIN

3.1 Clinical protocol and preparation for trials

3.1.1 Recruitment of the users and random allocation to the test or control group

The Estonian trial originally required 30 participants in each group. Due to a long delay in the process, it became clear that Estonian site would not obtain the necessary number of patients in the test group.

9 patients dropped out before they had equipment installed, thus leaving 21 patients in the test group. Dropouts were caused by death (one patient), transfer to nursing home, or simply they were unwilling to continue due to their serious health condition.

So far the equipment has been installed at 20 patients out of 21 in the test group. Efforts have been made in order to find new patients to participate; at the moment there are four potential patients who fulfilled the inclusion criteria and have agreed to participate in the project.

We did not have any dropout problems in the control group; all patients, who were randomised in the control group, agreed to participate.

3.1.2 Informed consent form signature

All participants, who agreed to participate in the project and who were assigned to the control or test group, signed the informed consent form.

First the nurse contacted the patients in order to agree on a visit to their homes. During the visit the nurse explained to the patient the nature of the Dreaming project, and the use of equipment; patients were also asked to sign the informed consent form during the first visit.

Taking into account the special needs of elderly users, and the fact that earlier in their lives they might not have used ICT so often, the patients were also provided with a user manual on how to use the Dreaming equipment. The user manual, containing information about the equipment, pictures and short descriptions, was intended to be helpful material for the elderly or their relatives in case of questions.

3.1.3 Description of the resulting trial population

The mean age of all participants (both test and control group), both male and female, stands at 75,1.

The participating elderly in the treatment group are between 66 and 89 years of age. The mean age of the treatment group is 74,8, excluding the pre-trial dropouts. 18 of them are female and 12 male.

Table 6: Estonia: Demographic / health profile – treatment group

Initials	Sex	Age	DM	HF	COPD
J.G.	F	83	N	Y	Y
T.S.	F	66	N	Y	N
E.S.1	M	89	N	Y	Y
I.N.	F	75	N	Y	N
H.H.	F	72	N	Y	N
V.K.1	F	81	N	Y	N
E.N.	F	67	N	Y	Y
L.S.	F	76	N	Y	N
M.J.	F	71	Y	Y	N
S.B.	F	88	Y	Y	N
Z.R.	F	78	Y	Y	N
A.M.1	F	76	N	Y	N
A.T.	M	68	Y	Y	N
E.T.	M	81	N	Y	N
M.L.	F	73	N	Y	N
H.L.	M	72	N	Y	N
V.O.	M	72	N	Y	N
T.T.	F	76	N	N	Y
N.P.	F	81	N	N	Y
S.L.	F	68	Y	N	Y
T.A.	F	70	Y	N	Y
E.P.	F	72	Y	N	Y
U.H.	M	79	N	N	Y
K.S.	F	81	Y	N	Y
A.K.	M	67	N	N	Y
I.S.	M	69	Y	N	N
V.L.	M	70	N	N	Y
S.T.	M	75	N	N	Y
R.M.	M	72	N	Y	N
K.E.	M	76	N	N	Y
Sum/Mean	**18 F, 12 M**	**74,8**	**9**	**18**	**14**

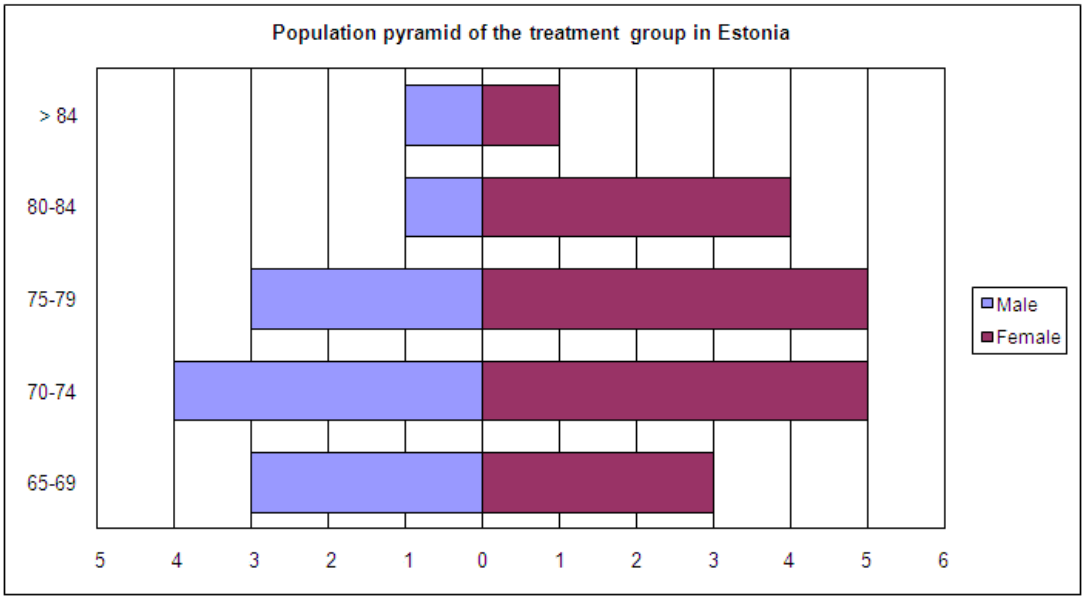


Figure 2: Estonia: Distribution by age & gender – treatment group

The participating elderly in the control group are between 65 and 88 years of age. Mean age of control group is 75,4 excluding the pre-trial dropouts. 18 of them are female and 12 male.

Table 7: Estonia: Demographic / health profile – control group

Initials	Sex	Age	DM	HF	COPD
H.A.	M	77	N	Y	Y
B.D.	M	65	Y	N	Y
L.S.	F	68	N	Y	N
A.P.	F	69	Y	Y	N
V.A.	F	78	Y	Y	N
H.R.	F	77	N	Y	N
A.V.	F	68	Y	Y	N
H.R.	M	79	N	Y	N
V.H.	F	76	N	Y	N
T.R.	M	66	N	Y	N
U.P.	F	69	N	Y	N
V.Z.	F	75	Y	Y	N
V.K.2	F	74	N	Y	N
V.T.1	F	75	N	Y	N
A.Z	M	75	N	Y	N
E.K.	F	70	N	Y	N
V.T.2	F	77	N	Y	Y
A.R.	F	72	N	Y	N
E.S.2	M	79	N	N	Y
A.N	M	88	N	N	Y

Initials	Sex	Age	DM	HF	COPD
H.S.	M	74	N	N	Y
M.K.	F	79	Y	N	Y
H.T.	M	84	N	N	Y
R.K.	F	67	Y	N	N
R.R.	M	73	N	N	Y
P.L.	F	78	N	N	Y
A.M.2	M	86	N	N	Y
H.J.	F	86	N	N	Y
H.V.	F	82	Y	N	N
E.R.	M	76	N	N	Y
Sum/Mean	**18 F, 12 M**	**75,4**	**8**	**17**	**13**

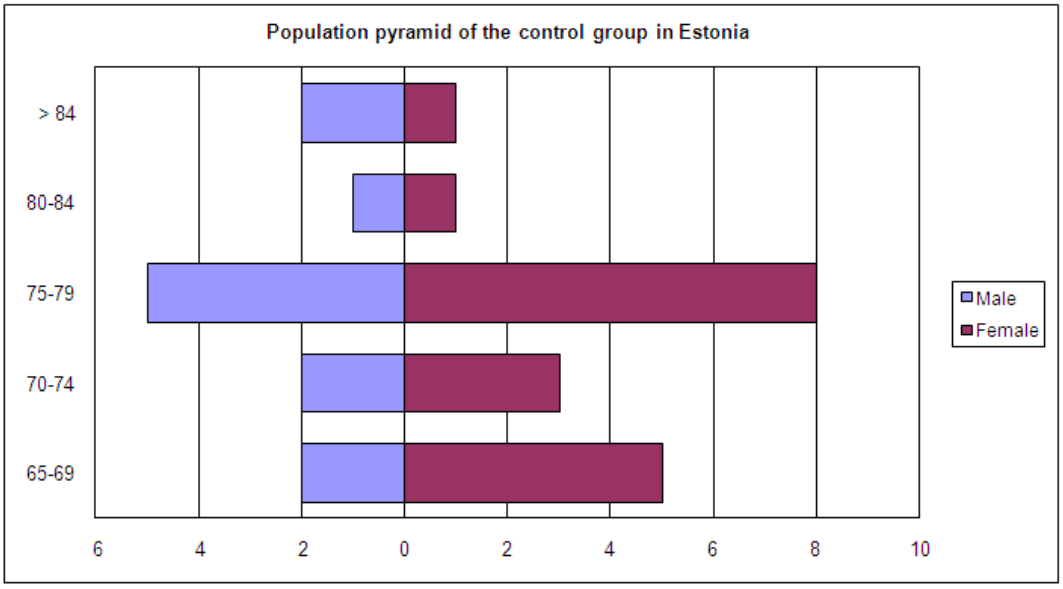


Figure 3: Estonia: Distribution by age & gender – control group

The profile by pathology of the patients is shown in Table 8 below.

Table 8: Estonia: Profile by pathology

	COPD	DM	CHF
Test group	14	9	18
Control-group	13	8	17

Note that some patients have more than one pathology – eleven in the test group.

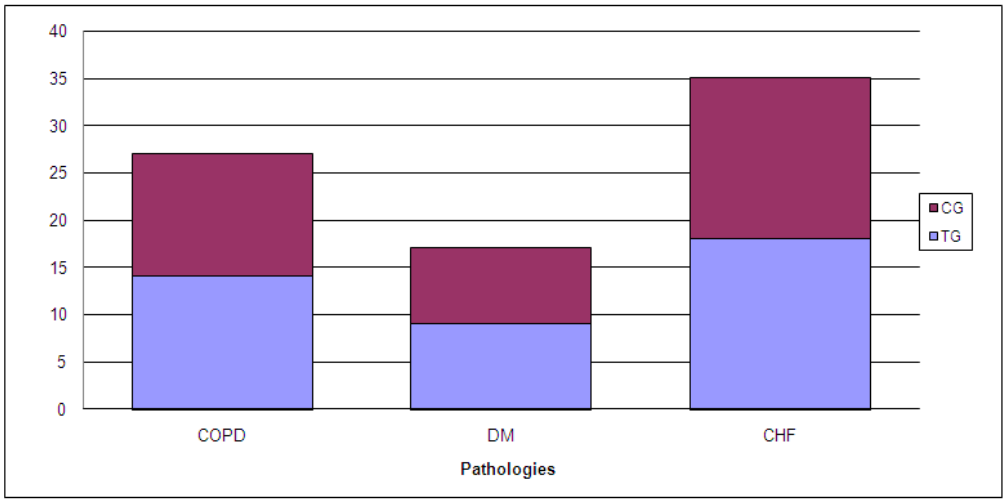


Figure 4: Estonia: Profile by pathology

3.1.4 Interventions in test group

Training of patients has been done in their own homes by the healthcare team during one session. Ongoing training and support is also being provided in order to ensure satisfaction with the project.

3.1.5 Interventions in control group

Check-ups and controls to this group will be carried out in their own healthcare centres; in the case of emergency, the elderly belonging to this group will go to the emergency service of the hospital as they have usually been doing. They will keep the classical healthcare system with the usual 112 emergency call service. The information collection during follow-up will be passive by means of extracting data periodically from the healthcare and social information systems. An interview by the healthcare team with these patients during the midterm and final evaluation will complete existing data.

3.2 Personnel involved in trials

3.2.1 Authority staff: planners, financial and management

In East Tallinn Central Hospital there is one project manager, who coordinates the work. One person is responsible for ICT matters. There is also a financial director of the hospital attached to the Dreaming project, who keeps track of the budget. The Director of R&D and Nursing Director are also active participants in the project in order to ensure effective functioning of the project.

3.2.2 Health & social care staff

The first aim to carry out the Dreaming project in the Estonian site was to identify the clinical staff. The person responsible for the clinical side then formed a team of nurses, who were recruited based on their patient care experience and knowledge of elderly care. They have been responsible for the recruitment of participants and have managed all communication with the patients. Currently three nurses are actively monitoring the patient's parameters; if necessary they advise and contact the patient by telephone.

They were trained in a one day intensive session about configuration and alarms set-up related to the vital monitors.

3.2.3 Technical staff

The technical staff involved in the project of the East Tallinn Central Hospital are composed of the staff of medical engineering department and software group.

Three persons were actively involved in the technical installation and support functions connected with implementation of equipment. If necessary, they contacted HIS in order to solve technical problems.

3.3 Equipment

The medical sensors have been distributed shown in Table 9 below.

Table 9: Estonia: Distribution of sensors

Initials	DM	COPD	HF	ECG	Blood Pressure Meter	Weight Scale	Pulse oxymeter	Glucometer
J.G.	N	Y	Y	X	X	X	X	
T.S.	N	N	Y	X	X	X		
E.S.1	N	Y	Y	X	X	X	X	
I.N.	N	N	Y	X	X	X		
H.H.	N	N	Y	X	X	X		
V.K.1	N	N	Y	X	X	X		
E.N.	N	Y	Y	X	X	X	X	
M.J.	Y	N	Y	X	X	X		X
Z.R.	Y	N	Y	X	X	X		X
A.M.1	N	N	Y	X	X	X		
A.T.	Y	N	Y	X	X	X		X
M.L.	N	N	Y	X	X	X		
H.L.	N	N	Y	X	X	X		
V.O.	N	N	Y	X	X	X		
N.P.	N	Y	N	X	X		X	
T.A.	Y	N	N	X	X			X
U.H.	N	Y	N	X	X		X	

Initials	DM	COPD	HF	ECG	Blood Pressure Meter	Weight Scale	Pulse oxymeter	Glucometer
K.S.	Y	Y	N	X	X		X	X
A.K.	N	Y	N	X	X		X	
I.S.	Y	N	N	X	X			X
T.T	N	Y	N	X	X		X	

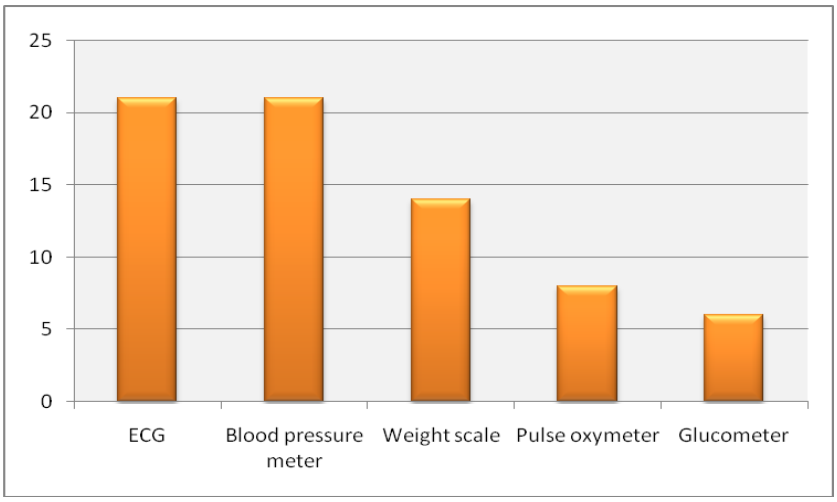


Figure 5: Estonia: Distribution of sensors

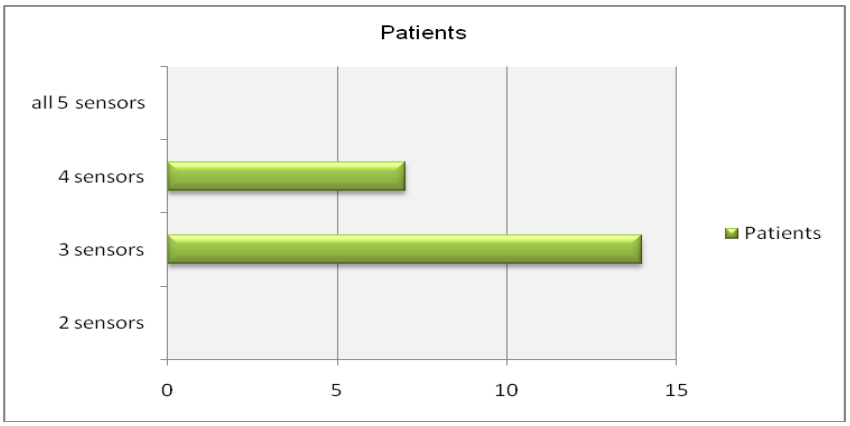


Figure 6: Estonia: Dreaming sensors distribution per patient

All patients belonging to the treatment group at this moment have been given ECG and blood pressure meter.

Six diabetics received the glucometer and seven patients with COPD received pulse oxymeter (one patient received both). 14 patients received weight scales.

The different sensors have been distributed to patients in the following manner:

- No patients have just one or two sensor.
- At this moment no patient has more than 4 sensors.

- From all patients, 13 patients have received 3 sensors and 7 patients received 4 sensors.

3.4 Installation issues

3.4.1 Sensor fitted homes

The ADSL have been negotiated with the Estonian ISP provider Elion and are centrally paid by our organisation.

Before installation, it is important to do a visit together with the company technician to the elderly's home, as technicians must know how devices must be connected and what is needed (cables, power strips, additional sockets, etc.). If it is possible, our engineer installs the previously lab tested and sensor connected equipment to the site. After connection, we test the installed equipment and perform measurements in order to see if the set is working. If everything is working, a hand-over protocol is signed by the patient and our representative.

Then afterwards the nurse schedules training of the installation with the patient.

Equipment is installed in 21 homes currently (March 2010). By the end of 2nd randomisation, we will hopefully have more homes equipped.

3.4.2 Help desk

Technical helpdesk consists of three nurses. They forward the difficult cases which are not solved by restart or battery change to our three technical site engineers. Engineers solve the problems on-site or do it remotely together with HIS. Weekly we have 1-2 cases or problem to resolve.

In the case on alarm, the nurses are the first ones to respond; if necessary, they will address the problem to the physician. The nurses check clinical data daily. If required, the nurse will ask the patient to repeat the measurements and, if necessary, the nurses consult with the physician. The patients are in contact by phone with the nurses at least once a week. If necessary, the treatment is adjusted by telephone; alternatively the patient will be ask to see their physician by appointment, and if needed the patient will be hospitalised. In the case of emergency, the patients will call the emergency centre.

3.4.3 Contact Centre

Contact Centre is formed of nurses; every patient has his/her dedicated nurse.

3.5 Initial trial results

3.5.1 Use of equipment

Challenges, DK Pilot site	Solutions
HIS:	
ECG quality is bad – only 2 out of 10 are OK.	Need to have better contact between skin and electrodes. ECG gel needed.
Lost Bluetooth connection to glucose device (very sensitive)	New device installed. Result of this action is still waiting.
Internet has to be installed in all places	We made contract; during the LAN installation we had to be on site.
In some cases equipment have lost connection after having been used for some time	Re-connection and troubleshooting - we need to go on site.
Weak batteries in the glucose devices	Right now no solution
Ello!:	
We found ello remote control conflict with satellite receiver and in one place with TV.	Solution is up to TMR
Difficult to set up. We experienced that system hangs during the start-up of the system	Need to consult TMR
Some TVs have no SCART inputs, they have RCA, S-Video, etc	In the next version of ello, there should be other outputs as well – HDMI etc.

3.5.2 SF-36 (Health related quality of life) and HADS (Depression) questionnaires

Patients were asked to answer the SF-36 and HADS questionnaires during a domiciliary visit. All patients, who at this point belong in the test group, have completed SF-36 and HADS questionnaires.

Sending SF-36 and HADS questionnaires to the patients belonging in the control group is at this moment an ongoing activity.

3.6 Lessons learned & corrective actions

The patient recruitment was successful; the problem was that due to the delays with technical equipment, some patients dropped out. The feedback from the test group has been positive. We have noticed a tendency that patients prefer to call the nurse, who monitors their data, rather than to a family physician.

The equipment installation process took longer than planned because there were problems with connecting some equipment (e.g. pulse oxymeter and glucometer) to the central unit; also, some defective equipment had to be replaced. After installation, problems occurred that some equipment failed to send data to the central unit. We tried to solve these problems from a distance, but sometimes it was necessary to go to the patient's home in order to solve the technical problem.

The installation of the equipment was also delayed due to the fact that most elderly did not have internet connection. Setting up the internet connections took a lot of time and effort, in order to find a mutual time that suited the elderly, the internet provider and our technical people. Internet has been established at this moment altogether to 19 patients, only one patient had proper internet connection. The process might have been easier if there had been an inclusion criterion from the start, that elderly who participate in the project must have internet connection. On the other hand, this criterion would have further reduced the potential number of patients to include in the project.

4. GERMANY-BERLIN

4.1 Clinical protocol and preparation for trials

4.1.1 Recruitment of the users and random allocation to the test or control group

Participants were recruited from Pflegewerk's 1400 patients who are cared for in different types of accommodation: in ambulant home care, in care homes, in clinics. Besides Berlin, we considered recruiting participants also in other Pflegewerk locations in Hamburg and Leipzig. We decided against this due to data privacy concerns, and the significant technical equipment which are enough of a task to arrange in Berlin alone. Following the pre-selection of 150 persons, 60 participants were recruited to the project.

Categories for the inscription were used as described in the trial protocol. Despite in-depth consultations and high interest on the part of the participants, some legal attendants were hesitant due to the requirement to give their approval.

Pflegewerk put together a team of experienced staff (medical doctor, director of nursing services, social worker and if applicable local caregivers) to arrange consultations at participating premises. Dates were arranged together with relatives, caregivers and local GPs individually or sometimes in small groups. The consultations always took place in the homes of the participants. Everyone involved received detailed information about background, goals, advantages, requirements and organisational questions of Dreaming.

The project trial design was approved by the German ethic commission at the Charité Berlin in January 2009.

4.1.2 Informed consent form signature

Getting the signatures for the declarations of participation proved to be rather time-consuming; most persons first wanted to speak with their relatives or medical doctors. For 8 participants, advisers had to be informed and asked for agreement. When all 60 signatures were gathered the randomisation had to be redone because sadly two persons had died in the meantime. This took four weeks. Then two participants quit at short notice and the procedure had to be done all over again.

In April 2009 all participants were gathered and randomised. The entire process of recruiting and randomisation took about 3 months and was very personnel-intensive.

4.1.3 Description of the resulting trial population

4.1.3.1 Demographic profile

The participant's entry submitted for randomisation according to the clinical protocol has resulted in the treatment group shown in Table 10.

The mean age of all participants in the treatment group, both male and female, stands at 81,77. In total 8 men and 22 women will participate in the treatment group.

Table 10: Germany: Demographic profile – treatment group

IN	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
A.G	F	89	N	N	N	N	N	Y	N	Y	Y	X	A
A.Hu.	F	87	N	N	N	N	N	Y	N	Y	Y	X	A
T.M.	F	86	Y	N	N	N	N	N	N	Y	X	X	C
D.Ch.	M	83	N	Y	N	N	N	N	N	Y	X	X	C
R.B.	F	73	Y	N	N	N	N	N	N	Y	X	X	C
S.A.	F	89	N	Y	N	N	N	N	N	Y	X	X	G
J.W.	M	66	Y	N	N	N	N	N	N	Y	X	X	C
M.M.	F	89	N	Y	N	N	N	N	N	Y	X	X	C
L.H.	F	78	N	Y	N	N	N	N	N	Y	X	X	C
M.R.	F	69	Y	N	N	N	N	N	N	Y	X	X	G
K.H.	M	65	N	N	Y	N	N	N	N	Y	X	X	G
P.L.	F	83	N	Y	N	N	N	N	N	Y	X	X	C
S.W.	F	82	N	Y	N	N	N	N	N	Y	X	X	G
G.C.	F	88	Y	N	N	N	N	N	N	Y	X	X	C
S.K.	F	86	N	Y	N	N	N	N	N	Y	X	X	G
K.E.	F	88	N	Y	N	N	N	N	N	Y	X	X	C
A.H.	M	67	Y	N	N	N	N	N	N	Y	X	X	G
Th.G.	M	81	N	Y	N	N	N	N	N	Y	X	X	G
C.B.	M	65	N	N	Y	N	N	N	N	Y	X	X	G
Th.R.	F	81	Y	Y	N	N	N	N	N	Y	X	X	C
G.H.	M	80	N	N	Y	N	N	N	N	Y	X	X	G
B.M.	F	91	N	Y	N	N	N	N	N	Y	X	X	C
H.I.	F	90	Y	N	N	N	N	N	N	Y	X	X	C
G.J.	M	75	Y	N	N	N	N	N	N	Y	X	X	C
J.L.	F	77	Y	N	N	N	N	N	N	Y	X	X	C
F.D.	F	92	N	Y	N	N	N	N	N	Y	X	X	G
D.A.	F	96	N	Y	N	N	N	N	N	Y	X	X	C
S.E.	F	72	N	Y	N	N	N	N	N	Y	X	X	C
K.E.	F	96	N	Y	N	N	N	N	N	Y	X	X	G
K.G.	F	89	N	Y	N	N	N	N	N	Y	X	X	G
	22F 8M	**81,77**	**10**	**16**	**3**	**0**	**0**	**2**	**0**	**30**			**16C 12G 2A**

The bar diagram (see Figure 7) shows the age range of the population, which for both men and women is 61-96.

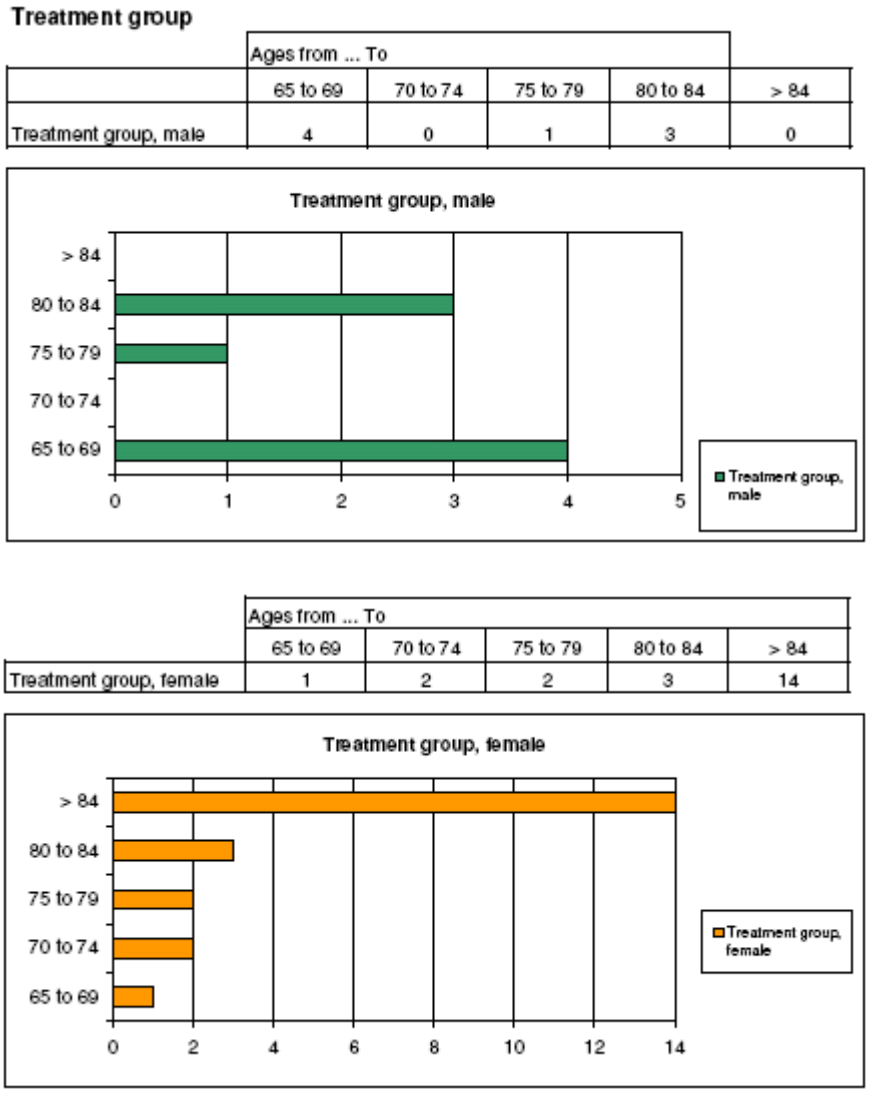


Figure 7: Germany: Distribution by age & gender – treatment group

With regards to the control group, the randomised list shows that the mean age of all participants stands at 79,8 (see Table 11).

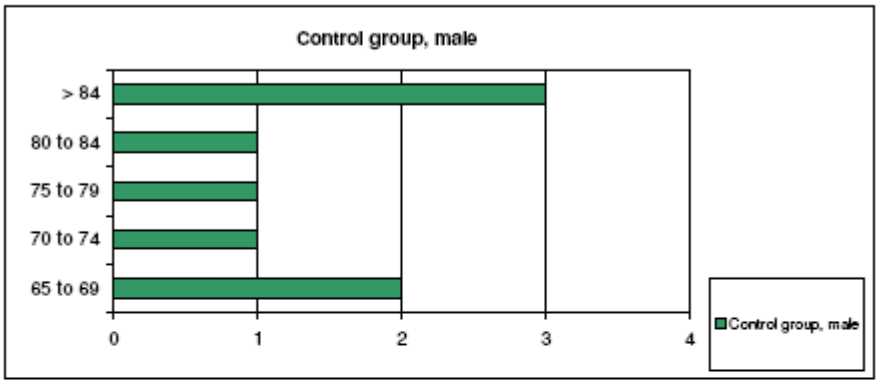
Here the population is structured again as in the treatment group, 8 men and 22 women taking part in this group. The population pyramid (see Figure 8) shows the age range, which for both men and women is 67-94.

Table 11: Germany: Demographic profile – Control group

IN	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
B.H.	F	91	N	Y	N	N	N	N		Y	X	X	G
Th.H.	F	80	N	Y	N	N	N	N		Y	X	X	G
K.J	F	83	N	N	Y	N	N	N		Y	X	X	G
G.G.	F	88	Y	N	N	N	N	N		Y	X	X	C
K:H.	M	94	N	Y	N	N	N	N		Y	X	X	C
M.H.	M	76	N	Y	N	N	N	N		Y	X	X	G
M.G.	M	72	N	N	Y	N	N	N		Y	X	X	G
G.S.	M	67	N	Y	N	N	N	N		Y	X	X	C
P.W.	M	80	N	Y	N	N	N	N		Y	X	X	C
R.H.	F	91	N	Y	N	N	N	N		Y	X	X	G
K.R.	M	93	Y	N	N	N	N	N		Y	X	X	C
N.R.	F	71	N	N	Y	N	N	N		Y	X	X	C
G.M.	F	88	N	Y	N	N	N	N		Y	X	X	C
R.H.	M	67	N	Y	N	N	N	N		Y	X	X	C
W.G.	F	80	N	Y	N	N	N	N		Y	X	X	C
Th.L.	F	87	N	Y	N	N	N	N		Y	X	X	C
L.G.	F	88	Y	N	N	N	N	N		Y	X	X	G
M.B.	F	69	N	Y	N	N	N	N		Y	X	X	G
S.M.	F	81	Y	N	N	N	N	N		Y	X	X	C
K.E.	F	84	N	N	Y	N	N	N		Y	X	X	C
S.L.	F	84	N	Y	N	N	N	N		Y	X	X	G
B.E.	F	77	N	Y	N	N	N	N		Y	X	X	C
R.L.	F	89	Y	N	N	N	N	N		Y	X	X	C
SÖ.M	F	86	N	Y	N	N	N	N		Y	X	X	C
SC.M.	F	89	N	Y	N	N	N	N		Y	X	X	G
W.G.	M	88	Y	N	N	N	N	N		Y	X	X	C
F.E	F	88	Y	N	N	N	N	N		Y	X	X	C
K.H.	F	80	Y	N	N	N	N	N		Y	X	X	G
H.R.	F	83	Y	N	N	N	N	N		Y	X	X	G
V.E.	F	82	N	Y	N	N	N	N		Y	X	X	A
	22F 8M	**79,80**	**9**	**17**	**4**	**0**	**0**	**0**		**30**			**17C 12 G 1A**

Control group

	Ages from ... To				
	65 to 69	70 to 74	75 to 79	80 to 84	> 84
Control group, male	2	1	1	1	3



	Ages from ... To				
	65 to 69	70 to 74	75 to 79	80 to 84	> 84
Control group, female	1	1	1	9	10

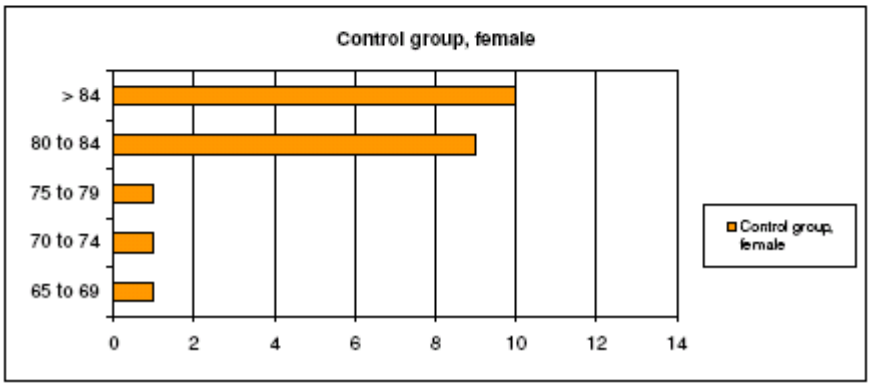


Figure 8: Germany: Distribution by age & gender – control group

4.1.3.2 Profile by pathology

The lists of both groups (treatment and control), as showed in Figure 9, have revealed a homogenous distribution for some diseases, such as chronic heart failure, COPD or history of myocardial infarction. In the case of COPD, the total number of patients suffering from this disease is seven, half of them belonging to the treatment group and the remaining half to the control group.

There is a large number of elderly (33) suffering from chronic heart failure and also the number of elderly (19) suffering from Diabetes Mellitus as it is considered a transversal disease.

Patients	Pathologisches Profil DM	CHF	COPD	HMF	HST	HF	
CG		9	17	4	0	0	(
TG		10	16	3	0	0	2

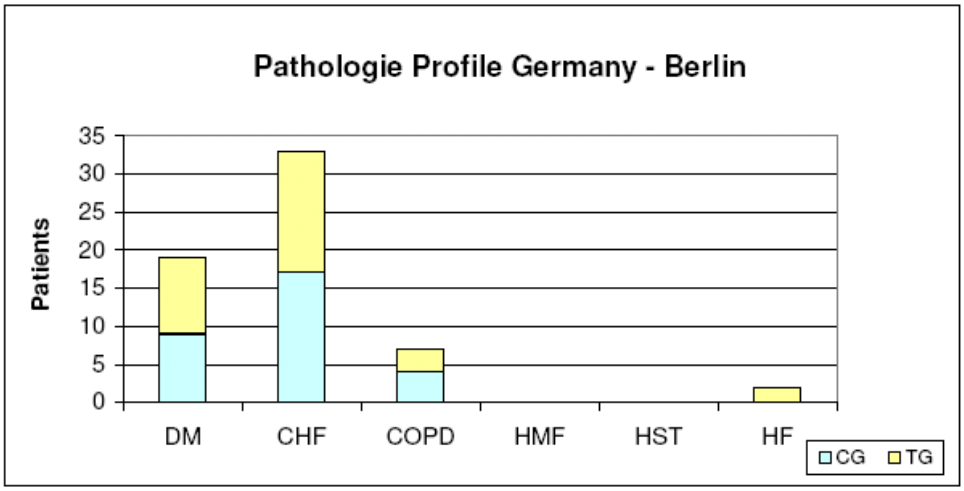


Figure 9: Germany: Profile by pathology

4.1.4 Interventions in test group

Training of patients has been done in their own homes by the healthcare team during one session by a single interlocutor.

4.1.5 Interventions in control group

Check-ups and controls to this group will be carried by the GPs, nurses or the medical centre. For any emergency case, the elderly belonging to this group will go to the Emergency Service of the hospital as they have usually been doing. They will keep the classical healthcare system. The information collection during follow-up will be passive by means of extracting data periodically from the healthcare and social information systems. An interview by the healthcare team with these patients during the midterm and final evaluation will complete existing data with possible requests to the private healthcare.

4.2 Personnel involved in trials

4.2.1 Authority staff: planners, financial and management

The authority staffs involved in the Dreaming project are:

- As a representative of the Senate Administration for Health, the ethics commission based at the Charité Berlin, which is at regional level the healthcare authority.

- Mediplus as the medical services provider.
- The University in Bamberg and the University in Ulm for the accompanying research.
- The management team of Pflegewerk for approving and providing the pilot site, design new processes, etc.

4.2.2 Health & social care staff

The first aim for carrying out the Dreaming project in the German pilot site was to identify the health & social care staff. For this, there has been created a Dreaming team led by a physician, with two or three nurses and social workers. So far, they have been responsible for the recruitment of participants and have managed all communication with patients. They belong to the Medical Centres of Mediplus and the home care provider, having been recruited from this service based on their patient care experience as well as their knowledge of the organisation. They know the competences of the different care levels and can thus optimise the healthcare workflow of the patients, placing each patient at the corresponding level.

They were trained by the staff from HIS in 2-3 days intensive session about configuration and alarms set-up related to the vital and environmental monitors (Pulse oxymeter, 1-12 lead ECG, asthma monitor, glucometer, weight scales). The total number of hours for the training for one team was 5.

Training was done by gathering both healthcare professionals and the technicians from Pflegewerk; one person of the latter was appointed as “tutor” in order to have one unique person at the professionals’ disposal for any technical problems in Pflegewerk or Mediplus.

To train professionals responsible for the Contact Centre takes a lot of time, nearly 20 hours.

4.2.3 Technical staff

The technical staff involved in the project from Mediplus and Pflegewerk are composed of two computing technicians and one innovation technician. There is also an intensive collaboration with HIS in the course of the installation of the system in the patients’ homes. Therefore, all the computing technicians of Pflegewerk took part in the Dreaming training.

In total, three technicians were trained during this 3-day intensive session on service implementation.

The total training hours were 30 hours, distributed over 3 days.

4.3 Equipment

The medical and environmental sensors, the latter only the movement detectors substituted for the other three installed environmental sensors, have been distributed as follows (Table 12):

Table 12: Germany: Distribution of sensors

IN	Gluco meter	ECG	Movement Detector	Pulse oxymeter	Weight scales	Blood pressure meter	Asthma Monitor
A.G		X	X	X	X	X	
A.Hu.		X	X	X	X	X	
T.M.	X		X		X	X	
D.Ch.		X	X	X	X	X	
R.B.	X		X		X	X	
S.A.			X		X	X	
J.W.	X		X		X	X	
M.M.		X	X	X	X	X	
L.H.		X	X	X	X	X	
M.R.	X		X		X	X	
K.H.			X		X	X	X
P.L.		X	X	X	X	X	
S.W.			X		X	X	
G.C.			X		X	X	X
S.K.		X	X	X	X	X	
K.E.		X	X	X	X	X	
A.H.	X		X		X	X	
Th.G.		X	X	X	X	X	
C.B.			X		X	X	X
Th.R.	X		X		X	X	
G.H.			X		X	X	X
B.M.		X	X	X	X	X	
H.I.			X		X	X	X
G.J.	X		X		X	X	
J.L.	X		X		X	X	
F.D.		X	X	X	X	X	
D.A.		X	X	X	X	X	
S.E.		X	X	X	X	X	
K.E.		X	X	X	X	X	
K.G.		X	X	X	X	X	
	8	**15**	**30**	**15**	**30**	**30**	**5**

To summarise:

- All patients belonging to the treatment group have been given the blood pressure and the weight scales.
- Pulse rate meter 'Stabil-O-Graph'.
- 8 diabetics received the glucometer, 15 patients the ECG, all 30 the movement detector and the other 3 environmental sensors, 15 the pulse oxymeter.
- The patients have received on average 2-3 vital sensors and 3-4 environmental sensors.

Dreaming sensors

Patients	Glucometer	ECG	Asthma Monitor	Pulse oxymeter	Weight scales	Blood pressure meter
TG	8	15	5	15	30	30

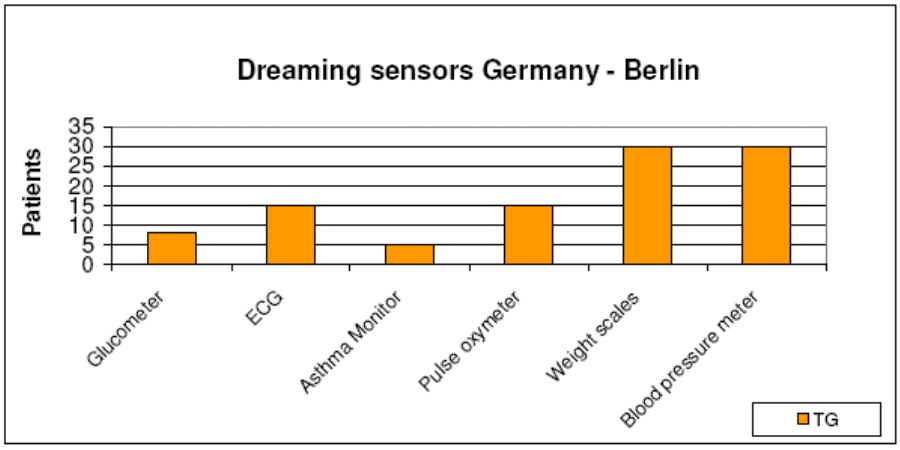


Figure 10: Germany: Distribution of sensors

4.4 Installation issues

4.4.1 Sensor fitted homes

To prepare the installation, it was necessary for the technicians to organise a preliminary visit to the elderly's home to check up where the devices must be connected and what is needed (cables, power strips, additional sockets, etc.).

To optimise the whole procedure and to minimise the time spent at patients' homes on the day of installation, a check list was developed and a description prepared for the technicians.

Before starting the installation procedure, it was important to involve the relatives, the care taker or other responsible persons.

Immediately before the installation day, the participant was once again informed in detailed about the procedure, the qualification and the further support. This is very important, because between the date of first registration of the participant and the installation date, much tine can pass, in some cases several months. So it was necessary to repeat the consultation.

The voice communications and ADSL are centrally paid by Pflegewerk; the ADSL line is directly installed in the telephone line of user's homes.

The installation of all the devices was finished in October 2009. Since this date all the measurements were carried out.

4.4.2 Help desk

In our pilot site the local first level support is managed directly through the technical support of Pflegewerk and the responsible IT team. The second level receives the support of the technological partner HIS, and additionally through a supporting partner of the University of Technology.

The help desk software will be developed till June 2010.

4.4.3 Contact Centre

In our pilot site we have established a specific contact centre called “Koordinierungsstelle”, centralised in one of the stations of the six home care providers of Pflegewerk.

4.5 Initial trial results

4.5.1 Use of Equipment

At the end of October 2009, all the 30 participants use the vital sensors and the environmental sensors at their home. In our pilot site, we are already collecting all incidents, wrong transmission cases and troubles with the performance, and analyse them on the basis of statistic indicators.

So far, the following problems and disorders by using the medical sensors and the videoconference system have been identified:

a) Wrong transmission of measurements from the device to the box or from the box to the HIS Portal: Recently the frequency of these incidents has been reduced to one a week since March 2010. For this we had come to realise that in most cases there were mistakes by the users, the nurses or technical problems.

b) Standard leads ECG cannot be read due to artefacts: This problem could be solved now.

c) Problems with the webcam, the sound and the quality of the video: for several months we have been in an intensive communication process with the Italian partners to solve the problems. At the moment we have installed two units in two apartments to test the usability and handling.

d) Weight scale: the frequently measurements are for some of our participants very difficult - for some of them the scales are too small and uncomfortable to step on. This concerns mostly immobile persons or persons with vestibular disorder.

4.5.2 SF-36 (Health related quality of life) and HADS (Depression) questionnaires

After the installation and the start of the project, patients were asked to answer the SF-36 and HADS questionnaires during a domiciliary visit. Each day three patients were interviewed using around two hours each per interview.

Once again, the same GP and the nurse who had the first visit with participants were responsible for interviewing them.

The initial evaluation was carried out through the double-blind methodology, i.e. none of the agents involved, patients and professionals, knew about who was going to be allocated to each group (control and test).

4.6 Lessons learned & corrective actions

Depending on the technical standards, low-threshold information for the participants proved to be useful. The practical value of the vital sensors and the mobile SOS system “Mambo” was easier to explain than that of the environmental sensors and especially the videoconferencing.

We found that the involvement of the GP in consultation and information conversations was a big advantage. Close integration of relatives was very important. Most concerns of participants addressed possible radiation problems or data security. Here, personnel-intensive and sensitive conversations were necessary.

The long waiting period from the first contact between the Dreaming team and participants until the actual start of the trial could only be successfully bridged with continued close contact and letting the participants get to know the use of the technical devices. This reduced insecurities and mistrust. Here the cooperation between the technology providers and the assistance team has to be optimised.

Most participants were interested in a continued use of the devices after the trial and wanted to learn about the results of the study (individually and made anonymous respectively).

Important for the persons’ estimation of their own participation in the project was the reliable and professional appearance of the project team. If we were not able to give

detailed answers, or responded with commonplace statements, participants got easily suspicious.

A crucial factor for the project is that new staff especially are supportive content-wise and organisationally, and so able to foster sustainability.

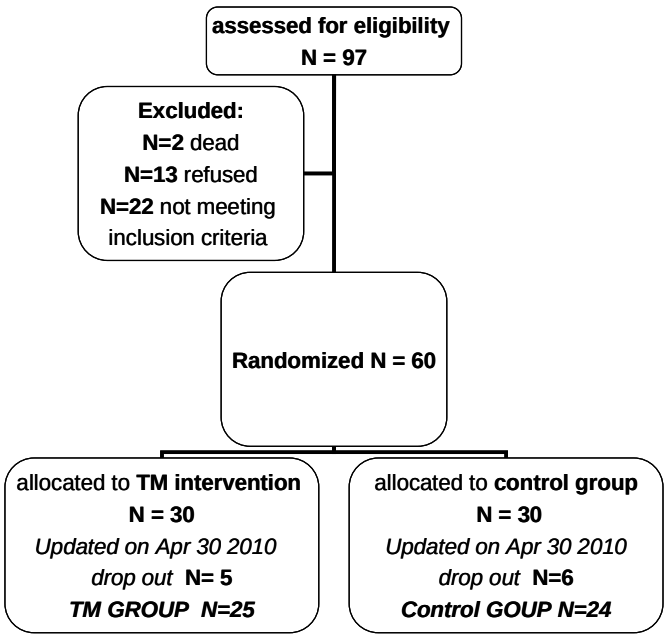
5. ITALY - FRIULI VENEZIA GIULIA

5.1 Clinical protocol and preparation for trials

5.1.1 Recruitment of the users and random allocation to the test or control group

Having completed all the administrative procedures and having presented and explained the Dreaming project to ASS1 staff from January to April 2009, 97 subjects followed up by the health care services of the four Health Districts were selected as eligible as trial participants. 60 meet the inclusion criteria and were randomly assigned to the two groups. The CONSORT flow chart below illustrates the causes of exclusion of the other 37.

Consort flow chart in Trieste



On 5th May 2009 we received the randomisation list. 30 subjects are included in the test group and 30 in the control group.

After completing some internal procedures and acquiring the electronic equipment, time 0 (baseline) of the trial was fixed at 1st July 2009.

Since that date, the participants have been monitored by the professionals (doctors, nurses, etc). The Dreaming ASS1project manager, Dr. Paolo Da Col, personally

contacted each GP of each enrolled participant in order to explain the programme to him/her, and to motivate his/her involvement in the follow-up.

After randomisation, baseline questionnaires (SF-36 and HADS) were completed by all 60 subjects.

At the end of April 2010, 11 people dropped-out from the trial:

- **5 in treatment group**:
  - One because he reported "to be afraid" of radiation.
  - One moved to another city.
  - One left for personal reasons.
  - One died.
  - One permanently transferred to an elderly home.
- **6 in control group**:
  - Three people died.
  - Three left for personal reasons.

5.1.2 Informed consent form signature

As previously reported, we emphasise that the consent form (in Italian) was prepared and approved by the local Ethical Committee in June 2008, and then translated into English and sent to the other all trial partners.

Every local participant received explanations from the doctor and signed the informed consent form during the recruitment phase (first trimester 2009).

5.1.3 Description of the resulting trial population

5.1.3.1 Demographic profile

The allocation of participants to test and control groups is shown in Table 13 (test group) and Table 14 (control group) below.

Table 13: Italy: Demographic / health profile – Treatment group

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
B.C	M	67	N	N	N	N	N	N	Y	Y	X	X	A
B.E.	F	77	Y	Y	N	N	N	N	Y	Y	X	X	A
C.A.2	M	74	N	Y	N	Y	N	N	Y	N	X	X	C
C.E.2	M	71	N	Y	N	Y	Y	N	Y	N	X	X	C
C.I.	F	78	Y	Y	N	Y	N	N	Y	Y	X	X	A
C.L.	F	80	N	N	N	N	N	N	Y	N	X	X	C
C.M.	F	69	N	N	N	Y	Y	N	Y	N	X	X	A
C.M.2	M	66	N	N	Y	N	N	N	Y	N	X	X	A
C.M.4	F	80	Y	N	N	N	N	N	Y	N	X	X	A
C.ML.	F	72	Y	N	N	N	N	N	Y	N	X	X	A
DG.G	M	79	Y	Y	N	N	N	N	Y	N	X	X	C

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
F.L.	F	84	N	Y	N	N	N	N	Y	Y	X	X	A
F.M.	M	80	Y	Y	N	N	Y	N	Y	N	X	X	C
F.R.	F	80	Y	Y	N	N	N	N	Y	N	X	X	A
G.A.	F	70	Y	N	N	N	N	N	Y	N	X	X	C
G.G.	F	73	N	N	N	N	N	Y	Y	Y	X	X	A
L.S.	M	81	N	Y	N	N	N	N	Y	N	X	X	A
M.E.	F	72	N	Y	Y	Y	Y	N	Y	Y	X	X	A
M.G.	F	78	Y	N	N	N	N	N	Y	Y	X	X	C
M.G.2	F	67	Y	Y	N	N	N	N	N	N	X	X	A
M.P.	M	79	Y	Y	N	N	N	N	N	N	X	X	C
P.A.	F	66	Y	N	N	N	N	N	N	N	X	X	A
P.L.	M	71	Y	Y	Y	N	N	N	Y	N	X	X	A
R.G.	F	84	N	N	N	N	N	N	Y	N	X	X	C
S.F.	M	85	Y	Y	N	N	N	N	Y	Y	X	X	A
V.E.	F	67	Y	N	N	N	N	N	Y	N	X	X	A
V.F.	M	82	N	Y	Y	N	N	N	Y	N	X	X	C
V.G.	M	71	Y	N	N	Y	N	N	Y	Y	X	X	C
Z.F.	F	84	N	N	Y	N	N	N	Y	N	X	X	C
Z.G.	F	89	Y	Y	N	N	Y	N	Y	N	X	X	C
	12M 18F		**17**	**16**	**5**	**6**	**5**	**1**	**27**	**9**			

Table 14: Italy: Demographic / health profile – Control group

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
B.A.	M	65	N	Y	N	Y	N	N	Y	N	X	X	C
B.G.	M	65	Y	Y	N	N	N	N	N	N	X	X	C
B.L.	F	82	N	N	N	N	N	N	Y	Y	X	X	A
B.ML	F	72	N	N	Y	N	N	N	Y	N	X	X	A
C.A.	M	76	N	Y	N	N	N	N	Y	N	X	X	C
C.E.	F	69	Y	Y	N	Y	N	N	N	N	X	X	A
C.G.	F	75	Y	N	N	N	N	N	Y	N	X	X	A
C.M.3	M	70	Y	N	N	N	N	N	Y	N	X	X	A
C.M.3	F	81	N	N	N	N	N	N	Y	N	X	X	A
F.G.	F	81	N	N	N	N	Y	N	Y	N	X	X	C
F.L.2	F	87	N	Y	N	N	N	N	Y	N	X	X	A
G.F.	M	94	N	Y	Y	N	N	N	Y	N	X	X	C
H.G.	M	79	N	Y	N	N	N	N	Y	N	X	X	C
I.A.	F	80	Y	Y	N	Y	Y	N	Y	N	X	X	A
M.A.	M	78	Y	N	N	Y	N	N	Y	N	X	X	C
M.L.	F	85	Y	Y	N	N	N	N	Y	N	X	X	A
M.L.2	F	84	Y	Y	N	N	N	Y	Y	N	X	X	C
P.B.	M	66	Y	Y	N	N	N	N	N	N	X	X	A

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
P.C.	F	78	Y	Y	N	Y	N	N	Y	N	X	X	C
P.M.	M	74	Y	Y	N	N	N	N	Y	N	X	X	A
P.M.2	F	69	N	N	Y	N	N	N	N	N	X	X	C
P.N.	F	71	N	Y	N	N	N	N	N	N	X	X	C
P.P.	M	70	Y	N	N	N	Y	Y	Y	Y	X	X	C
Q.U.	M	70	Y	N	N	N	N	N	Y	Y	X	X	A
R.D.L	F	76	N	Y	N	N	N	N	Y	Y	X	X	A
R.U.	M	81	Y	Y	N	Y	N	N	Y	N	X	X	C
S.G.	M	74	N	Y	N	N	N	N	N	N	X	X	C
S.M.	M	75	Y	Y	N	Y	N	Y	Y	N	X	X	C
V.J.	F	80	Y	N	N	N	N	N	Y	N	X	X	C
V.N.	M	71	N	N	Y	N	N	N	Y	Y	X	X	C
	15M 15F		**16**	**18**	**4**	**7**	**3**	**3**	**24**	**5**			

In our sample mean age is 75.9 years; the sample comprises 33 females and 27 males, of which:

- 30 live alone (50%),
- 16 live with husband or wife (27%) and
- 14 with a care giver (23%).

Looking at the test group and control group separately:

- In the test group, the mean age is 75.9 years. There are 12 males, mean age 75.5, and 18 females, mean age 76.1.
- In the control group, the mean age is 76 years. There are 15 males, mean age 73.9, and 15 females, mean age 78.1.

Living situation in the test group:

- 50% (67% F v. 33% M) - the majority- live alone.
- 30% (44% F v. 56% M) live with husband or wife.
- 27% (25% F v. 75% M) live with a care giver.

Living situation in the control group:

- 43% (69% F v. 31% M) subjects live alone,
- 30% (44% F v. 56% M) live with husband or wife
- 27% (25% F v. 75% M) live with a care giver

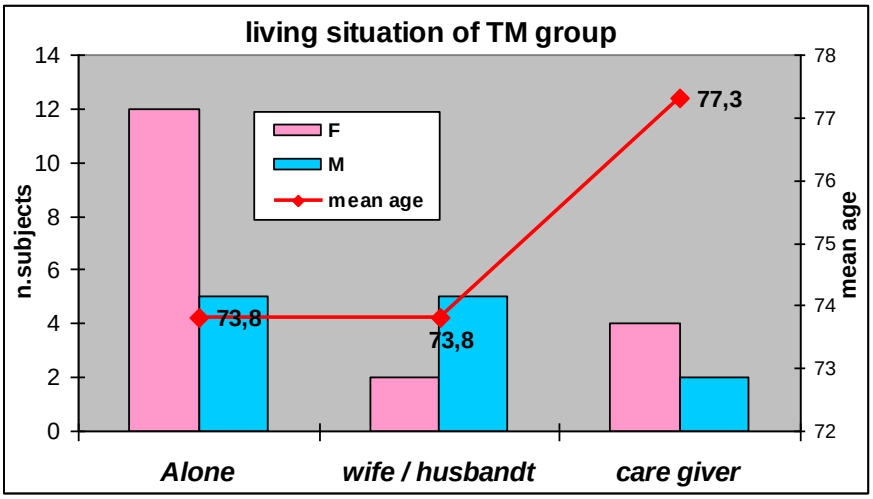


Figure 11: Italy: living situation – treatment group

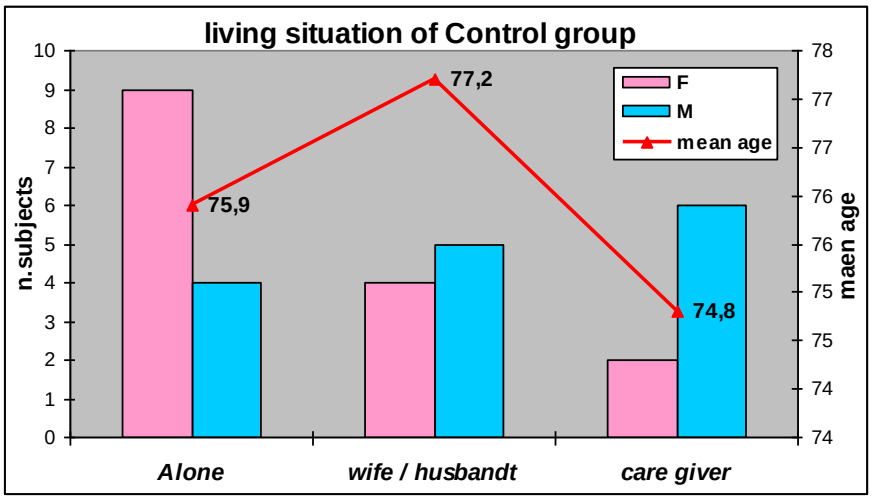


Figure 12: Italy: living situation – control group

5.1.3.2 Profile by pathology

The participants were selected mainly for the first choice given by the trial protocol: Diabetes mellitus (DM), Chronic heart failure (CHF) and Chronic obstructive pulmonary disease (COPD).

One participant (test group) suffers from all three principal pathologies; 11 (6 F and 5 M) in test group and 11 (5 F and 6 M) in control group suffer from two pathologies; 13 participants (8 F and 5 M) in test group and 17 (8 F and 9 M) in control group suffer from one pathology; 5 participants in test group and 2 in control group were selected for other reasons: a history of stroke and myocardial infarction within the last two years (1 of test group), hospitalisation during the last two years (all participants), or age >= 80 years (2 test group and 2 control group).

In summary, people suffering of DM:

- 17/30 (57%: 65%F v. 35%M) in test group.
- 16/30 (53%: 44%F v. 56%M) in control group.

People suffering of CHF:

- 16/30 (53%: 44%F v. 56%M) in test group.
- 18/30 (60%: 44%F v. 56%M) in control group.

People suffering of COPD:

- 5/30 (17%: 40%F v. 60%M) in test group.
- 5/30 (17%: 60%F v. 40%M) in control group.

About second and third choice:

- History of previous myocardial infarction in 6/30 subjects in test group v. 7/30 in control group.
- History of stroke in 5/30 test cases v. 3/30 control group.
- History of falls in 1/30 test cases v. 3/30 control group.
- Hospitalised within the last two years: 27/30 of test group and 24/30 of control group.
- Age >= 80 years: 11/30 in test group and 10/30 in control group.

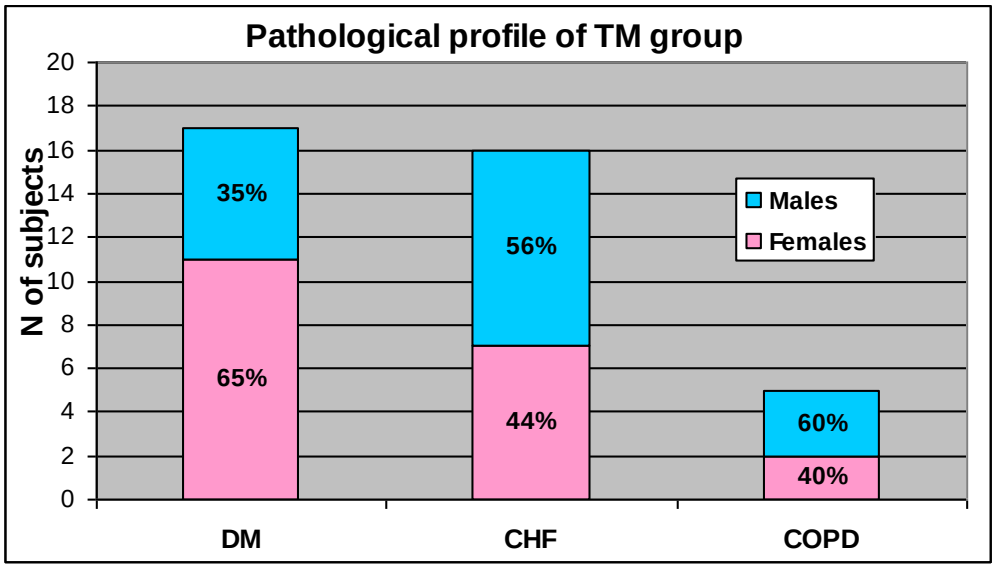


Figure 13: Italy: Profile by pathology – treatment group

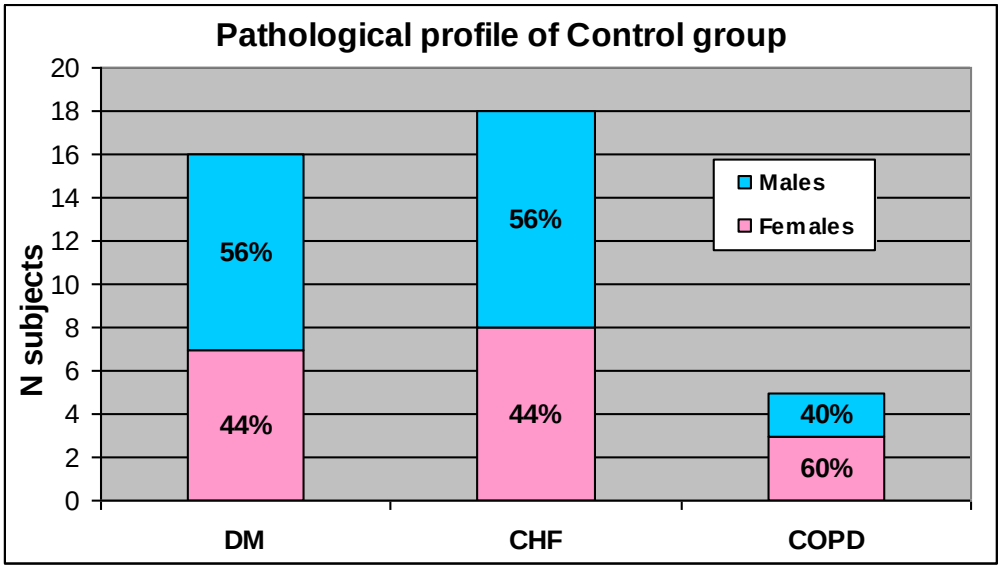


Figure 14: Italy: Profile by pathology – control group

Participant enrolled in home care programme

15 participants (9 TM, 6 C) were previously enrolled in home care programmes of our Public Health Care System.

5.1.4 Interventions in test group

For every participant, a detailed personalised care programme is defined by the team; a "case manager" (generally a nurse) is assigned in order to guarantee an optimal coordination of interventions, an appropriate management of alarms, and an easy point of contact and connection for the participant, his/her care givers and other professionals. Participants who received the technical equipment were trained at home in the use of the devices by technicians of TBS Group SpA. After that, if needed, there was a call by Help Desk and Contact Centre operators of Tesan-Televita Srl to continue the training.

In July 2009 it was decided that all 30 users of test group were included in 24/7 Tele-assistance and Tele-control system with "key service", a home care service usually offered to frail people by ASS1 (Tesan-Televita Srl service).

The protocol (flow chart) for handling type 1 and 2 Alarms was presented in May 2009, then discussed, modified, completed and finally accepted in October 2009 by all the professionals involved. The last version approved by the staff is dated December 2009 and the document delivered to all operators.

During November 2009, the clinical staff delivered to each participant a "travel book" in which he/she was invited to report every significant occurrence (i.e. alarms, visits, admission to the hospital, etc., or other events included in the Dreaming protocol as secondary outcomes). These events were also counted and verified by a weekly call of Tesan-Televita operators until April 2010. In May 2010 the procedure was

updated in order to simplify the check. Now the calls also have the aim to reinforce the participants to fill in the diaries.

In addition, it was established that every case manager of every subject belonging to the four Health Districts of ASS 1 must fill a register (paper and electronic form) to collect the data of secondary outcomes.

The trial monitor (S.K.) collects and transfers these data into the electronic database. According to the scheduled rules, these are sent to the Medical Coordinator of the trial (R.P.). If necessary, the data from users' diaries are integrated with other information derived from health system databases.

5.1.5 Interventions in control group

After enrolment, all participants have been followed up and monitored with the usual care, according to personal needs.

In November 2009, the clinical staff delivered to each participant a "travel book" in which he/she was invited to report every significant occurrence (i.e. alarms, visits, admission to the hospital, etc.) included in the Dreaming protocol as secondary outcomes. These events were also counted and verified by a weekly call of Tesan-Televita operators until April 2010. In May 2010 the procedure was updated in order to simplify the check. Now the calls also have the aim to reinforce the participants to fill in the diaries.

In addition, it was established that every case manager of every subject belonging to the four Health Districts of ASS 1 must fill a register (paper and electronic form) to collect the data of secondary outcomes.

The trial monitor (S.K.) collects and transfers these data into the electronic database. According to the scheduled rules, these are sent to the Medical Coordinator of the trial (R.P.). If necessary, the data from users' diaries (test and control) are integrated with other information derived from health system databases.

5.2 Personnel involved in trials

5.2.1 Authority staff: planners, financial and management

The authority staff involved in the Dreaming project belong to our Supply (procurement) Department and the Finance Department. Both have helped in the preparation of the documents and the positive conclusion of each administrative step. An accountancy official of ASS1 responsible for, in particular, VAT issues, was also involved (i.e. the question was whether VAT should be paid by ASS1). Two internal experts are available to consult on technical and other ICT matters. In 2010 the Director of the Forensic Medicine Service of ASS 1 was also involved in order to define the procedures for the respect of privacy law. With regard to this important issue, it must be underlined that at the beginning of the trial every subject signed a consent form which allows to share information between operators, to use the videoconference, to handle database containing personal information. From the

start, Dr. Paolo Da Col, Head of the Health District N. 1 of ASS 1, was appointed as Dreaming Project coordinator. He is assisted by a professional who acts as secretary and trial monitor.

5.2.2 Health & social care staff

In general, approximately 12 medical doctors and 12 nurses belonging to the four Districts were especially devoted to the preliminary phases of the trial, in order to select eligible subjects and to obtain their voluntary informed consent. Afterwards, the clinical staff of the four Districts started to follow up each case, following the usual care protocol for control group members, and adding the appropriate extra protocols for the test group. Each of the four Health Districts of ASS1 is composed of approximately 20 home care nurses and one doctor. In addition, every participant has their own GP, who is also involved in the trial.

A monthly coordinating meeting held in ASS 1 between all professionals was carried out to create good cooperation between Health Districts' staff, Tesan-Televita Contact Centre operators and the "118 Emergency System".

It was decided to give a list of the test group names and their available medical records to 118 Emergency System, in case an emergency occurs.

Three courses, about the devices and HIS portal, were given in ASS 1 headquarters (20th July, 23rd & 30th October 2009) by Tesan-Televita (TTL) staff to train the operators engaged in the trial. TTL and TBS Group at the time were informed by the suppliers Health Insight Solution (HIS) and by Telemedicina Rizzoli (TMR) which maintain positive relations and upgrades. In February 2010 another two individual courses were given in TTL Contact Centre to train new case managers from ASS 1.

At the moment, the case managers of all enrolled subjects who use the web portal are:

- 15 Nurses.
- 5 GPs.
- 4 Physicians/Specialists of the Districts.

During the monthly meeting held in January 2010 in ASS 1, the case managers agreed to use the ello! video communication system in each of the four Health Districts. They agree to contact the subjects by means of this new system (which allows to listen and view and to be listened and to be viewed).

TTL is responsible for the Help Desk, and as a result is responsible for technical problems directly detected or reported by users. The company interfaces with HIS (HIS web portal – devices) or with TMR (ello! Video system) to solve them. TTL contacts also TBS Group technicians for first assistance at users' home (repairs, removal, replacement, and also shipping to provider for repair or replacement).

TTL is also responsible of operational aspects, as well as the handling of alarms by means of its 24/7 Contact Centre. The company has identified for this Project one operator specifically dedicated to Dreaming. Also selected were a project coordinator, a computer technician and an administrative officer, and other

employees who devote time to Dreaming Project. A business consultant for data processing has also been involved for aspects of privacy law.

5.2.3 Technical staff

Technical support (installation and technical assistance at home) is offered from July 2009 by technicians of TBS Group SpA. The company already provides to ASS1 a service for administration and assistance of medical devices and aids for elderly and disabled.

The technical staff comprises three technicians for installation, configuration and technical assistance. There are also three Teasan-Televita (TTL) operators for the first level of Help Desk. Moreover for each DSL connection at users' homes there are three technicians of the external provider (Fastweb).

Technicians of TBS Group Spa, Help Desk personnel and Contact Centres operators of TTL were previously trained directly by providers (HIS Gmbh and TMR SpA) on 20th January 2009 in an intensive course of 8 hours. With an another intensive course of 8 hours on 13th July 2009 they were re-trained in particular in the installation and assistance (to solve any technical problems through Help Desk or at home). TTL Contact Centre operators have carried out further internal training courses in September and October 2009. In April 2010 two new operators were trained and in May all staff have been updated following the release of a new internal protocol. The need for continuous training will be assessed, especially in case of changes of procedures.

5.3 Equipment

ASS1 ordered, received and paid for the following equipment:

Products	N.	N. global installed 30/04/2010
HIS Central Unit (incl. 36 month HIS Portal licence)	30/(30)	18
Movement Detector - Environmental Monitor	30/(60)	18
Smoke Detector - Environmental Monitor	30/(30)	18
Water Leak Detector - Environmental Monitor	30/(30)	18
Room Temperature/Humidity - Environmental Monitor	30/(30)	18
Mambo 2 - senior mobile	30/(30)	-
Ello! Videoconferencing Software	30/(30)	18
Ello! Set-Top Box	30/(30)	18
Blood Pressure Monitor - I.E.M. Stabilograph	30/(30)	18
Asthma Monitor - Viasys Asthma Monitor AM1+BT	7/(10)	2

Products	N.	N. global installed 30/04/2010
Weight Monitor - I.E.M Weigth Scale	5/(20)	4
Weight, body-fat, body water – Vitaphone 200 BT	5/(10)	3
ECG 1-Lead ECG Monitor	5/(10)	3
ECG 12-Lead ECG Monitor	3/(5)	3
Pulse/Oxymeter Monitors - Nonin Onyx II 9550	10/(15)	6
Glucometer SmartLAB global – Smart Lab Genie	14/(10)	11
SmartLABpro test stripes (50 stripes)	100	
SmartLAB Glucose Control solution (4 ml)	8	

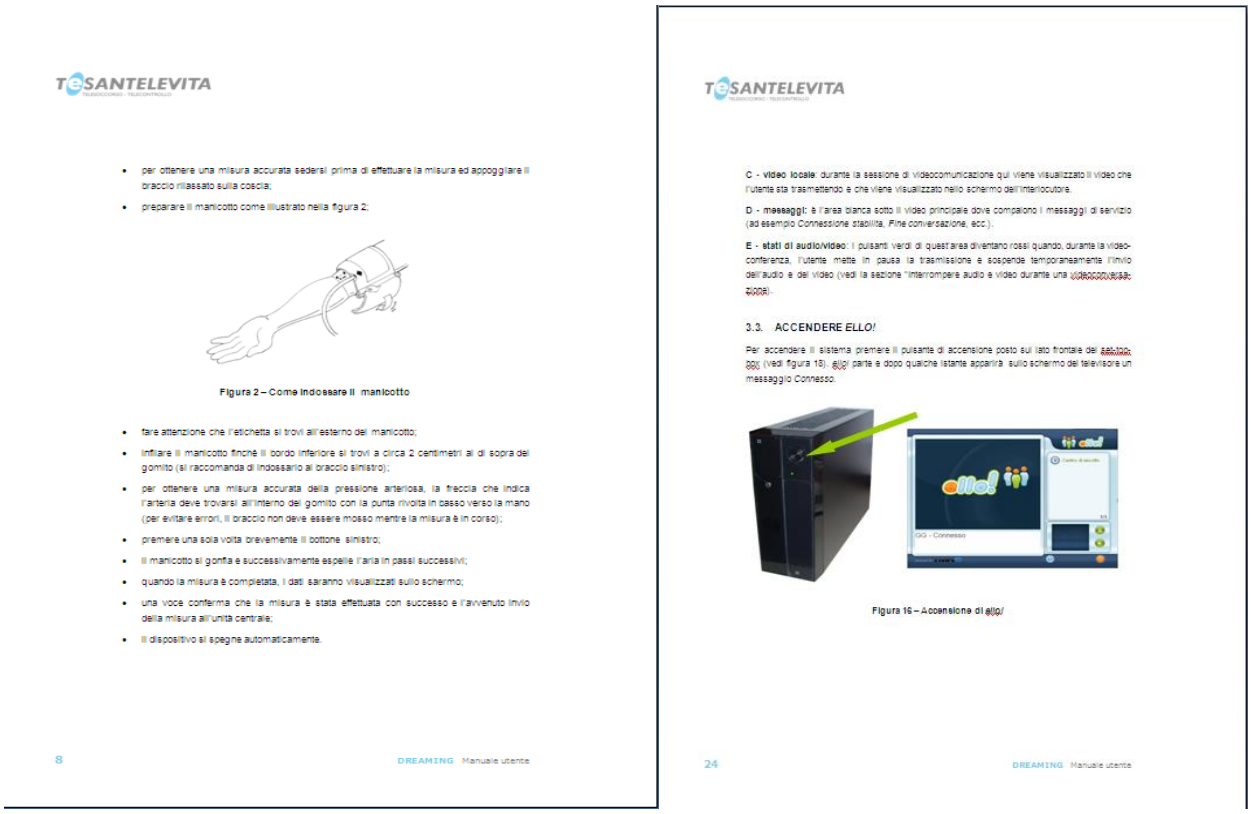
Table 15: Italian: Dreaming sensors

User Init	Gluco meter	ECG	Pulse Oxyme.	Weight Scales	Blood Press.	Asthma monitor	Video ello!	Environ. monitors
B.C	yes				yes		yes	yes
B.E.	yes		yes		yes		yes	yes
C.A.2		yes	yes	yes	yes		yes	yes
C.E.2					yes		yes	yes
C.I.	yes	yes	yes		yes		yes	yes
C.L.					yes		yes	yes
C.M.		yes		yes	yes		yes	yes
C.M.2					yes		yes	yes
C.M.4	yes				yes		yes	yes
C.ML.								
DG.G								
F.L.								
F.M.								
F.R.	yes				yes		yes	yes
G.A.	yes				yes		yes	yes
G.G.								
L.S.								
M.E.			yes	yes	yes		yes	yes
M.G.	yes				yes		yes	yes
M.G.2								
M.P.	yes				yes		yes	yes
P.A.								
P.L.	yes	yes	yes	yes	yes	yes	yes	yes
R.G.								
S.F.	yes			yes	yes		yes	yes
V.E.	yes	yes		yes	yes		yes	yes
V.F.		yes	yes	yes	yes	yes	yes	yes

5.4 Installation issues

5.4.1 Installation process

Every user is issued with a short “illustrated manual” of different devices to complement the installation and training support given to users by the staff of TBS and TTL. This manual is very simple, and contains the phone numbers of Contact Centre and Help Desk in the first page (extract below).



TESANTELEVITA

- per ottenere una misura accurata sedersi prima di effettuare la misura ed appoggiare il braccio rilassato sulla coscia;
- preparare il manicotto come illustrato nella figura 2;

Figura 2 – Come indossare il manicotto

- fare attenzione che l'etichetta si trovi all'esterno del manicotto;
- infilare il manicotto finché il bordo inferiore si trovi a circa 2 centimetri al di sopra del gomito (si raccomanda di indossarlo al braccio sinistro);
- per ottenere una misura accurata della pressione arteriosa, la freccia che indica l'arteria deve trovarsi all'interno del gomito con la punta rivolta in basso verso la mano (per evitare errori, il braccio non deve essere mosso mentre la misura è in corso);
- premere una sola volta brevemente il bottone sinistro;
- il manicotto si gonfia e successivamente espelle l'aria in passi successivi;
- quando la misura è completata, i dati saranno visualizzati sullo schermo;
- una voce conferma che la misura è stata effettuata con successo e l'avvenuto invio della misura all'unità centrale;
- il dispositivo si spegne automaticamente.

8 DREAMING Manuale utente

TESANTELEVITA

C - **video locale**: durante la sessione di videocomunicazione qui viene visualizzato il video che l'utente sta trasmettendo e che viene visualizzato nello schermo dell'interlocutore.

D - **messaggi**: è l'area bianca sotto il video principale dove compaiono i messaggi di servizio (ad esempio *Connessione stabilita, Fine conversazione*, ecc.).

E - **stati di audio/video**: i pulsanti verdi di quest'area diventano rossi quando, durante la video-conferenza, l'utente mette in pausa la trasmissione e sospende temporaneamente l'invio dell'audio e del video (vedi la sezione "Interrompere audio e video durante una videoconversazione").

3.3. ACCENDERE ELLO!

Per accendere il sistema premere il pulsante di accensione posto sul lato frontale del set-top-box (vedi figura 18). ello parte e dopo qualche istante apparirà sullo schermo del televisore un messaggio *Connesso*.

Figura 16 – Accensione di ello!

24 DREAMING Manuale utente

After installation, enrolled subjects sign a “delivery document” (developed by TBS Group) already in use for other services of medical devices on behalf of ASS 1.

SERVIZIO SANITARIO REGIONALE
AZIENDA PER I SERVIZI SANITARI
N°1 - TRIESTINA

VIA G. SAI, N°1-3 - 34127 TRIESTE

Azienda Servizi Sanitari N°1

DISTRETTO 4

Prot. n. 9999331552

CONTRATTO DI COMODATO

Tra _l_ Sig.__ _____, nato/a il _____
residente a _____ in v. _____ n. ___
codice fiscale _____ tel. _____

comodatario

e l'Azienda per i Servizi Sanitari n. 1 " Triestina", via G. Sai n. 1-3, Trieste, codice fiscale 00052420320,

comodante

si conviene, mediante la stipula del presente contratto, la cessione da parte del comodante in uso gratuito

a favore del Sig./ra _____ nato/a il _____
domiciliato/a a TRIESTE in _____
codice fiscale _____ tel. _____

del bene identificato come:

1. Centrale ADSL di cui all'ordine n° ___ inventariato al n° 11238
2. Sfigmomanometro di cui all'ordine n° ___ inventariato al n° 11062
3. Pulsiossimetro di cui all'ordine n° ___ inventariato al n° 11078
4. Glucometro di cui all'ordine n° ___ inventariato al n° _____
5. Video Box di cui all'ordine n° ___ inventariato al n° 11567

dal valore commerciale di Euro _____, per il periodo di _____, ovvero fino alla cessazione dello stato di bisogno dell'assegnatario e nell'osservanza delle seguenti clausole:

fino alla cessazione naturale del progetto Dreaming o dell'eventuale rinuncia ad essere utente del progetto e nell'osservanza delle seguenti clausole:

1. il comodatario è tenuto a custodire e a conservare il bene con diligenza e servirsene solo per l'uso determinato dal progetto Dreaming e dalla natura propria del bene e non può concedere a terzi il godimento del bene;
2. il comodatario che impiega il bene per uso diverso è responsabile di eventuali danneggiamenti del bene, anche se lo stesso risultasse danneggiato o distrutto per causa a lui non imputabile;
3. in caso di constatata inadempienza agli obblighi di cui ai punti 1 e 2, il comodante può richiedere l'immediata restituzione del bene;
4. il comodatario è tenuto a restituire quanto consegnatogli al termine del progetto Dreaming fatta salva l'opzione che, se i dispositivi consegnati si rivelassero efficaci, saranno lasciati in uso al termine del Progetto come indicato nel "consenso informato";
5. l'Azienda si riserva la facoltà di effettuare, in ogni momento, qualsiasi verifica sull'installazione, manutenzione, utilizzazione e conservazione del bene;
6. il comodatario è tenuto a restituire il bene in buono stato di conservazione e manutenzione, salvo il deterioramento derivante dal normale uso, allo scadere del progetto Dreaming o, grazie all'opzione di continuità d'uso oltre alla scadenza del Progetto di cui al punto 3, al venire meno della necessità sanitaria;
7. la stipula del presente contratto non comporta alcun onere di spesa e si provvederà alla sua registrazione solo in caso d'uso, con onere a carico di chi ne richiede la registrazione;
8. il Comodatario dichiara di aver ricevuto in consegna il manuale d'uso, che sarà sua cura conservare, e di aver preso visione della funzionalità dell'ausilio.

Per quanto non espressamente indicato nelle condizioni su esposte e per quanto compatibile varranno i principi contenuti negli art. da 1803 a 1812 del Codice Civile.

In ogni caso nessuna spesa aggiuntiva deriverà al comodatario/utente dalla partecipazione al progetto Dreaming.

Il Comodatario è consapevole che la partecipazione al Progetto Dreaming è volontaria e che ha la facoltà di ritirare il consenso alla partecipazione in qualsiasi momento, con la conseguente restituzione dei beni oggetto di comodato d'uso in buono stato come sopra descritto.

Letto, confermato e sottoscritto
IL COMODATARIO

Ai sensi degli artt. 1341 e 1342 del Codice Civile, si approvano specificamente per iscritto le clausole n. 1, 2, 3, 4, 5 e 7.

IL COMODANTE
(su mandato con rappresentanza conferito dall'Azienda per i Servizi Sanitari n. 1 "Triestina")
Il Legale Rappresentante della Ditta ITAL TBS S.p.A.
Ing. Diego Bravar

Letto, confermato e sottoscritto
IL COMODATARIO

Sottoscritto a TRIESTE il 30/09/09

-1-

EBM

NUMERO DI BOLLA 1050563

AZIENDA	CLASSE APPARECCHIATURA	COD. CIVAB	NUMERO INVENTARIO AZIENDA
ASS1			
PRESIDIO / UBICAZIONE	PRODUTTORE / MODELLO	COD. CIVAB	NUMERO ETICHETTA / NUMERO MATRICOLA APPARECCHIATURA
DS / —			

☐ MANUTENZIONE CORRETTIVA ☐ MANUTENZIONE PROGRAMMATA ☐ SICUREZZA ELETTRICA ☐ COLLAUDO DI ACCETTAZIONE ☐ CONTROLLO QUALITÀ / PRESTAZIONI ☐ CONSULENZE ☐ ADDESTRAMENTO ☐ SERVIZI INFORMATICI ☐ VARIE

DESCRIZIONE DEL GUASTO: Consegna

CODICE RICHIESTA

DESCRIZIONE DELL'INTERVENTO

RICEVENTE

RICHIEDENTE (PERSONA O STRUTTURA SANITARIA)

RIFERIMENTO RICHIEDENTE (TELEFONO, MAIL, ALTRO)

DATA E ORA DI RICEZIONE: 30 09 09 (G M A H M)

Centrale ADSL 11238
Sfigmo 11062
Pulsossimetro 11078
Glucometro
Videobox 11567
Palmare 11293
Bic 633 11480
Sens. H2O 11466
Sens. Fumo 11702
Sens. Movim 11497 Sens. C 11154

STATO APPARECCHIATURA — INIZIALE: ○ NULLO ○ LIEVE ○ MEDIO ○ GRAVE ○ TOTALE — FINALE: ○ NULLO ○ PARZIALE ○ TOTALE

ATTIVITÀ	TIPO ATTIVITÀ	TECNICO / FORNITORE	DATA APERTURA ATTIVITÀ / ORA APERTURA ATTIVITÀ	DATA CHIUSURA ATTIVITÀ / ORA CHIUSURA ATTIVITÀ	ORE VIAGGIO	ORE LAVORO
○I ○E	○CT ○EL ○ET ○ID ○SV — ○NC ○MC ○NR ○VA ○PR		/ / :	/ / :		
○I ○E	○CT ○EL ○ET ○ID ○SV — ○NC ○MC ○NR ○VA ○PR		/ / :	/ / :		
○I ○E	○CT ○EL ○ET ○ID ○SV — ○NC ○MC ○NR ○VA ○PR		/ / :	/ / :		
○I ○E	○CT ○EL ○ET ○ID ○SV — ○NC ○MC ○NR ○VA ○PR		/ / :	/ / :		

PARTI DI RICAMBIO

COD. EBM / CLIENTE	COD. RICAMBIO	DESCRIZIONE	Q.TÀ

FIRMA DEL TECNICO

Si prega di controllare attentamente quanto riportato. Eventuali contestazioni successive non avranno valore alcuno.

FIRMA DEL CLIENTE

5.4.2 Sensor fitted homes

Installation and training of one patient takes a day of work by an expert technician. The training continues with assistance by phone or video by the Contact Centre.

The ADSL and voice communications have been negotiated by ASS 1 with an Italian telephone provider (Fastweb) and centrally paid by Heath Department. Before installation in each elderly's home, at the request of ASS 1, Tesan-Televita (TTL) fixed a preliminary visit together with the technicians of ADSL provider to understand better what was needed for the connection (cables, power strips, additional sockets, etc.) and to explain the installation to users and their family/relatives. The first aim is to minimise the time spent at patients' homes on the day of installation, and to start the explanation of Dreaming Project to users.

5.4.3 Help desk

In the Italian pilot site, the first level support is managed by TTL Help Desk / Contact Centre, which at second level receives the support of the technological company TBS Group SpA.

To provide this service TTL has written internal protocols and procedures according to its Quality System (certified UNI EN ISO 9001:2008).

The help desk software to handle the trouble tickets is supported by TTL system.

During the first period of 7 months (from 01/10/2009 to 30/04/2010), the help desk received 36 calls:

- 24 technical interventions on site (second level).
- 13 solved by phone assistance (most of these solved by turning off the power supply).

Problems:

- 9 Central Units.
- 6 Glucometers.
- 5 Video system ello!
- 4 Weight scales.
- 4 Blood Pressure Monitor.
- 8 Others.
- All the mobile phones with panic button and detecting falls (Mambo 2 from Falcom) collected from the users by technicians and returned to provider.

Protocols to handle the ECG (1 or 12 lead) together with the cardiologist of Cardiovascular Department of ASS 1 are not still defined at the moment, but are under construction.

5.4.4 Contact Centre

In the Italian site, the solution designed for managing events and alarms coming from Dreaming project, is based on the existing Tele-assistance Contact Centres provided by TTL with experience from 1994 in Regione Friuli Venezia Giulia and, from 1997, especially together with ASS 1.

The Contact Centres are equipped with personal computer, telephones, acoustical alert, headset microphone connected to the PC, mobile phone, internet connections and anything else necessary to operators. Premises comply in addition to national security to workers and the legislation on privacy.

To provide the Contact Centres services for Dreaming Project, TTL has written internal protocols and procedures according to its Quality System (certified UNI EN ISO 9001:2008)

5.5 Initial trial results

5.5.1 Use of equipment

26 test users are connected at the end of April 2010, as follows:

- 19 subjects received and use the Dreaming equipments at home (one of them died).
- One subject is scheduled for Dreaming installation, test and explanation.
- Two subjects have at home a DSL line connected by external phone technicians (provider is Fastweb Company) but without router installation.
- In four cases we are waiting the external technical DSL installation (Fastweb).

In some cases the DSL line was necessarily installed directly in the telephone line of user's homes, since it was impossible to install a new dedicated DSL line.

In seven months our pilot site has collected some performance / statistic indicators, documented during the last meeting in Zaragoza (from 22nd – 24th March 2010), as detailed in section 5.4.3 above. Other Dreaming partners identified similar issues, so it was decided to hold a monthly videoconference between the various teams and providers of technology to solve technical problems, resolve doubts and exchange experiences, ideas and suggestions.

The technology providers are scheduling new releases between May and June 2010, in order to improve the performance of their products and systems. At the same time, the new Mambo 2 (emergency phone, with traceability and fall sensor, by Falcom) with technical problems fixed will be delivered to all partners by May 2010.

For these reasons in March the Dreaming partners established a new time-0 for the trial on 1st June 2010 to enable all partners to complete the installations at users' home and refine internal protocols and procedures.

5.5.2 SF-36 (Health related quality of life) and HADS (Depression) questionnaires

For baseline evaluation, after randomisation, questionnaires SF-36 and HADS were completed, by participants in both test and control groups. Questionnaires were delivered to the Dreaming Medical Coordinator at the meeting in Zaragoza (23rd March 2010) by Tesan-Televita coordinator on behalf of ASS 1.

5.6 Lessons learned & corrective actions

Recruitment was much more difficult than expected. It seems that local people are not particularly prone to accept technology and/or able to handle technical equipment to monitor their health condition. There are many different devices (also video and mobile phone in addition to health and environmental devices) that sometimes confuse users. It was necessary to devote attention in order to select eligible candidates to the trial.

The installation of DSL lines by the local provider (Fastweb) is extremely time consuming; it requires an excessive time to obtain them. In addition, a long time is necessary for training both participants and professionals on the different devices. Both are afraid of the alarms; it is mandatory to carefully plan and monitor their use.

The cooperation of the local 118 Emergency System (112), and sharing Dreaming procedures in case of emergency, is necessary for handling the Alarms (in particular Type 2).

Agreement among the organisations, healthcare authorities, managers and healthcare staff has proven to be useful in order to validate properly the new provision in our public health care service. In order to obtain an optimal “climate” and adequate motivation for “Dreaming working”, several meetings between professionals are crucial, looking forward for an accurate internal communication and comprehension programme. Thanks to regular meetings between Tesan-Televita and ASS 1, we are able to detect and share operations of devices and web portal from different expectations and share the management of problems found.

Strategically, with regards to the elderly involved in the Project, both in the test and control groups, every effort was made to involve GPs and to include them in the home care network.

From the beginning it was necessary to fix the time-0 of the trial. We have decided that this should be placed after randomisation and the completion of the preparation phase. After the meeting in Zaragoza, the Dreaming partners decided to fix a new time-0 of the trial on 1st June 2010, in order to enable all partners to align installations and refine internal protocols and procedures.

Concerning professionals, it is important to motivate them in order to follow up the participants, especially those belonging to the test group. This is especially true when there is a long time between the signature of informed consent form and the start of activities.

Concerning the users, as they are elderly people, careful attention should be paid in order to be sure that they are always able to understand the programme and to keep to the recommendations and requirements of the programme. For this reason, periodic contact is necessary. Therefore we have decided to involve both the

professionals of the four Districts and those of Tesan-Televita - making a bi-weekly call - according to personal needs and after every alarm. In particular, after the meeting in Zaragoza it was also established that the Contact Centre will call users for the weekly check via video ello! to stimulate the trial group to use video system.

It is also important that in these sessions elderly people (both test and control group) should be encouraged and sustained to actively participate in this trial. We are aware that that their contribution is crucial for testing new tools and procedures for innovative forms of home care and social inclusion.

Positive points:

The local project staff (ASS n. 1 + TTL) holds a monthly meeting to take stock of the situation and solve problems.

All the case managers of people in the test group get their own account for HIS portal.

Health Districts of ASS n. 1 have recently agreed to acquire the Dreaming video system for calling users.

Users appreciate the attention given to them by the Project (despite some problems of use).

Problems:

The DSL lines connections require an excessive time to resolve problems, and need continuous pressure on the provider.

The thresholds of type 1 alarms are too low and are not very significant clinically for a real life trial – i.e. with a real clinical impact and relevant for a clinical decision.

The management of the technical equipment and connections is much more difficult than expected both for project staff and participants (too many different devices).

6. SPAIN - SALUD

6.1 Clinical protocol and preparation for trials

6.1.1 Recruitment of the users and random allocation to the test or control group

Users were selected from 960 clinical shared records of the Barbastro Hospital. The criteria for selection were to recruit elderly people aged more than 65, belonging to two urban areas, Barbastro and Monzón, and who had been registered at the Emergency Department of the hospital from January to August 2009.

From these records, 160 patients were pre-selected and fulfilled the inclusion criteria (such as age, diseases, grade of dependency, etc.) as described in the trial protocol. The GP and the nurse involved in the Dreaming team arranged medical appointments with 95 patients in their own health care centres to explain the Dreaming project to them in detail.

Professionals of both primary health care centres, Monzón and Barbastro, were informed about Dreaming as well, and were asked for their collaboration. They were consulted about the grade of dependency of the elderly, and the feasibility of deploying the Dreaming service to these patients.

Each day, 14 patients were visited in groups of three persons. After these visits, 12 patients decided not to participate, stating that they were already controlled by their GPs, and that they did not need any additional controls.

They were then double blind interviewed in a domiciliary visit and the initial evaluation was carried out through the SF-36 and HADS questionnaires.

It is important to highlight that the whole evaluation process by means of the SF-36 and HADS questionnaires has been carried out by the same interviewers, and generally they and the Dreaming project have been favourably received by patients.

6.1.2 Informed consent form signature

All participants willing to participate and who were finally assigned to the control or treatment (test) group signed the informed consent form.

During the first visit to patients, after explaining to them all the details about Dreaming, patients were asked to sign the informed consent form. Almost all patients signed it at this time, though four decided to discuss it first with their relatives, and signed it later.

6.1.3 Description of the resulting trial population

6.1.3.1 Demographic profile

The participants enrolled in the trials were submitted for randomisation according to the clinical protocol. The demographic / health profile for the treatment group is shown in Table 16 below. The profile shows the following aspects:

- The mean age of all participants, both of male and female, stands at 75,77.
- In total, 25 men and 15 women will participate in the treatment group.

Figure 15 shows the population frequency by age range.

Table 16: Spain: Demographic / health profile – Treatment group

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
ABLL	F	78	Y	Y	N	N	N	N	Y	N	X	X	C
ACV	F	81	N	Y	N	N	N	N	Y	N	X	X	C
APEP	F	83	N	Y	N	N	N	Y	Y	N	X	X	C
ASB	M	85	N	N	Y	N	N	N	N	N	X	X	C
COP	F	71	N	N	N	Y	N	N	Y	N	X	X	C
CPC	F	78	Y	N	N	N	N	N	N	N	X	X	C
CPF	F	78	N	N	Y	Y	N	N	Y	N	X	X	C
CVH	M	68	Y	N	N	Y	N	N	Y	N	X	X	C
ELF	M	84	N	N	Y	Y	N	N	Y	N	X	X	C
FJT	M	80	N	N	Y	N	N	N	Y	N	X	X	C
GAD	F	77	N	Y	Y	N	N	N	Y	N	X	X	C
JBV	M	76	N	Y	N	N	Y	Y	Y	N	X	X	A
JCA	M	87	N	N	N	Y	N	N	Y	N	X	X	C
JCLL	M	77	N	Y	N	Y	N	N	Y	N	X	X	C
JCN	M	84	Y	N	N	N	N	N	Y	N	X	X	C
JEZ	F	72	Y	N	N	N	N	N	Y	N	X	X	C
JJC	M	77	N	N	N	N	Y	Y	Y	N	X	X	C
JLM	M	78	Y	N	N	N	N	N	Y	N	X	X	C
JMN	F	79	Y	N	N	Y	N	N	Y	N	X	X	A
JMS	M	76	N	N	N	N	Y	Y	Y	N	X	X	C
JPT	M	68	Y	N	N	N	N	N	Y	N	X	X	C
JSM	F	68	Y	Y	N	N	N	N	Y	N	X	X	C
JSS	M	67	N	Y	N	N	N	N	N	N	X	X	C
JVS	M	68	N	N	Y	N	N	N	Y	N	X	X	C
LER	F	68	N	N	N	N	Y	N	Y	N	X	X	C
MBD	M	66	Y	Y	N	N	N	N	Y	N	X	X	C
MBL	M	67	N	N	N	Y	N	N	Y	N	X	X	C
MGP	M	71	N	N	N	Y	N	N	Y	N	X	X	C
MLL	F	68	Y	Y	N	N	N	N	N	N	X	X	C
MMR	M	71	N	N	N	Y	N	N	Y	N	X	X	C

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
MOC	M	79	Y	N	N	N	N	N	N	N	X	X	C
MPM	F	80	N	Y	N	Y	N	N	Y	N	X	X	A
REA	M	76	Y	N	Y	N	N	N	Y	N	X	X	C
RGR	M	78	Y	N	Y	Y	N	N	Y	N	X	X	C
RJM	F	79	N	N	N	N	Y	Y	N	N	X	X	C
RLV	F	82	Y	N	N	N	N	N	N	N	X	X	C
RPP	M	73	N	N	Y	Y	N	N	Y	N	X	X	A
SGC	M	84	N	N	Y	N	N	N	Y	N	X	X	C
SLR	M	71	N	N	Y	N	N	N	Y	N	X	X	C
VGP	M	78	Y	N	N	Y	N	N	Y	N	X	X	C
	25M 15F	**75.77**	**16**	**11**	**11**	**14**	**5**	**5**	**33**				**4A**

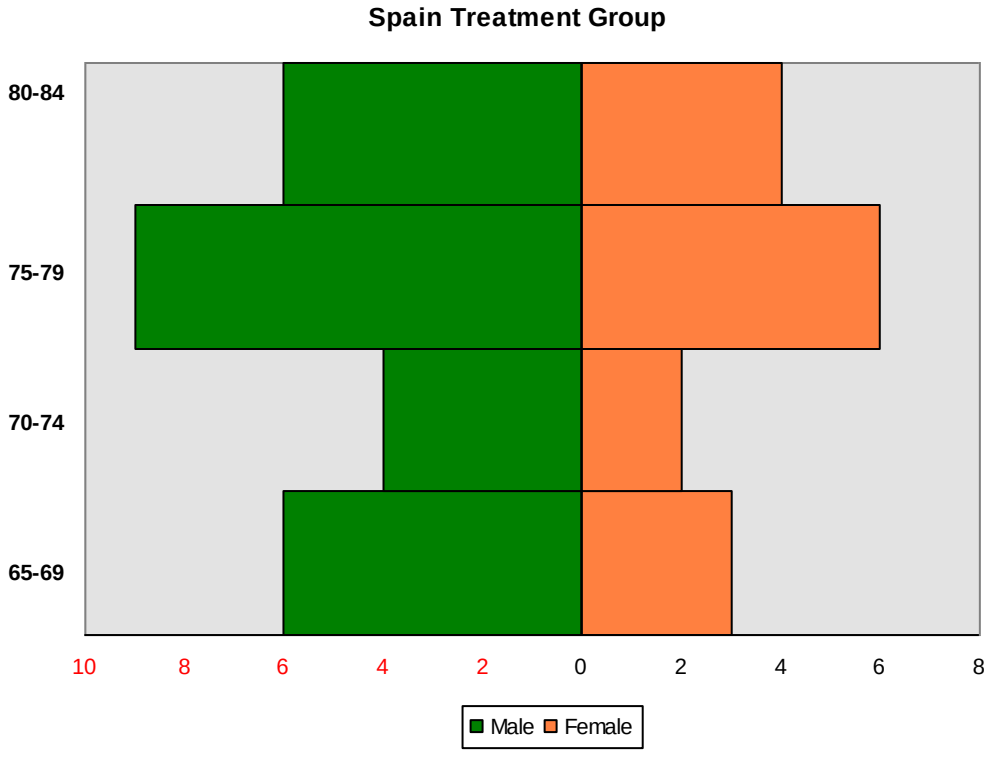


Figure 15: Spain: Profile by age & gender – treatment group

With regards to the control group, the list shows that the mean age of all participants stands at 75,6 (see Table 17).

Here the profile of those taking part in the control group (Figure 16) is structured into 24 men and 16 women. There are two prevalent age groups from 65-69 and from 75-79 in the male population with six participants in each age group; meanwhile the female population shows a majority of six belonging to the age group 75-79.

Table 17: Spain: Demographic /health profile – control group

Init	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	IC	NE	L
JML	F	66	N	N	N	Y	N	N	Y	N	X	X	C
JMD	M	65	Y	N	N	N	N	N	Y	N	X	X	A
FOL	M	66	N	N	Y	N	N	N	Y	N	X	X	C
GPF	M	66	N	N	N	Y	N	N	Y	N	X	X	C
JNA	M	67	N	N	Y	N	N	N	Y	N	X	X	C
TPF	F	66	Y	Y	N	Y	N	N	Y	N	X	X	A
CDD	F	68	Y	N	N	N	N	N	N	N	X	X	C
ISS	F	70	Y	N	Y	N	N	N	Y	N	X	X	C
PPP	F	71	Y	N	N	N	N	N	Y	N	X	X	A
JLB	M	68	Y	N	N	N	N	Y	Y	N	X	X	C
RCB	M	69	Y	Y	N	N	N	N	Y	N	X	X	C
LZG	M	70	N	N	Y	N	Y	N	Y	N	X	X	C
AII	F	73	N	N	N	N	Y	Y	Y	N	X	X	C
JPA	M	72	N	Y	N	N	N	N	Y	N	X	X	C
CPS	F	75	Y	N	N	N	N	N	Y	N	X	X	C
ROE	M	72	N	N	N	Y	N	N	Y	N	X	X	C
CCO	M	73	Y	N	N	N	N	N	Y	N	X	X	C
ERM	M	74	Y	N	N	N	N	N	Y	N	X	X	C
LCS	M	75	N	N	Y	N	N	N	Y	N	X	X	C
ASC	M	77	N	N	N	Y	N	N	Y	N	X	X	C
MMS	F	75	N	N	N	N	Y	Y	Y	N	X	X	C
MPV	M	77	N	N	N	Y	N	N	Y	N	X	X	C
JLS	M	78	Y	N	N	N	Y	N	Y	N	X	X	C
ANG	M	79	N	Y	N	N	N	N	Y	N	X	X	C
MMU	M	79	N	Y	Y	N	N	N	Y	N	X	X	C
JCB	M	82	N	N	Y	N	N	N	Y	N	X	X	C
PSB	F	75	N	N	N	Y	N	N	Y	N	X	X	C
APP	M	83	N	N	Y	Y	N	N	Y	N	X	X	C
CLT	F	78	Y	Y	N	N	N	N	Y	N	X	X	A
FMM	M	84	Y	Y	N	N	N	N	Y	N	X	X	C
GCG	F	79	Y	N	N	N	N	N	N	N	X	X	A
VCG	F	79	N	Y	N	N	N	N	Y	N	X	X	A
EAB	F	80	N	Y	N	N	N	N	Y	N	X	X	C
SCC	M	84	N	N	Y	N	N	N	Y	N	X	X	C
JGL	M	86	N	N	Y	N	N	N	Y	N	X	X	C
TBB	M	86	N	N	N	Y	N	N	Y	N	X	X	C
JSB	M	90	N	Y	Y	N	N	N	Y	N	X	X	C
PMP	F	81	Y	Y	N	Y	N	N	Y	N	X	X	C
MPC	F	83	N	N	N	Y	N	N	Y	N	X	X	C
VNP	F	83	Y	Y	N	N	N	N	Y	N	X	X	A
	24M 16F	**75.6**	**16**	**12**	**11**	**11**	**4**	**3**	**38**				**7A**

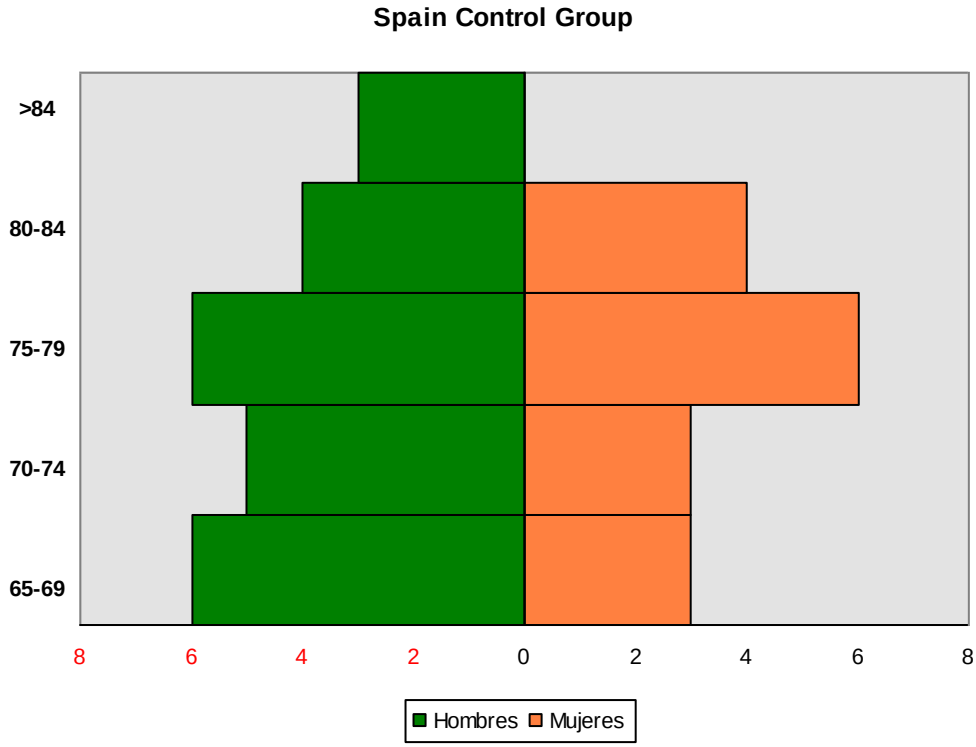


Figure 16: Spain: Profile by age & gender – control group

6.1.3.2 Profile by Pathology

Following randomisation, both treatment and control groups reveal a homogenous distribution (as showed in Figure 17) for some diseases, such as chronic heart failure, COPD, or history of myocardial infarction. In the case of COPD, the total number of patients suffering from this disease is 22, half of them belonging to the treatment group and the remaining half to the control group.

There are a large number of elderly persons suffering from Diabetes Mellitus, as it is considered a transversal disease. Heart stroke is suffered by nine elderly, five of them belonging to the treatment group.

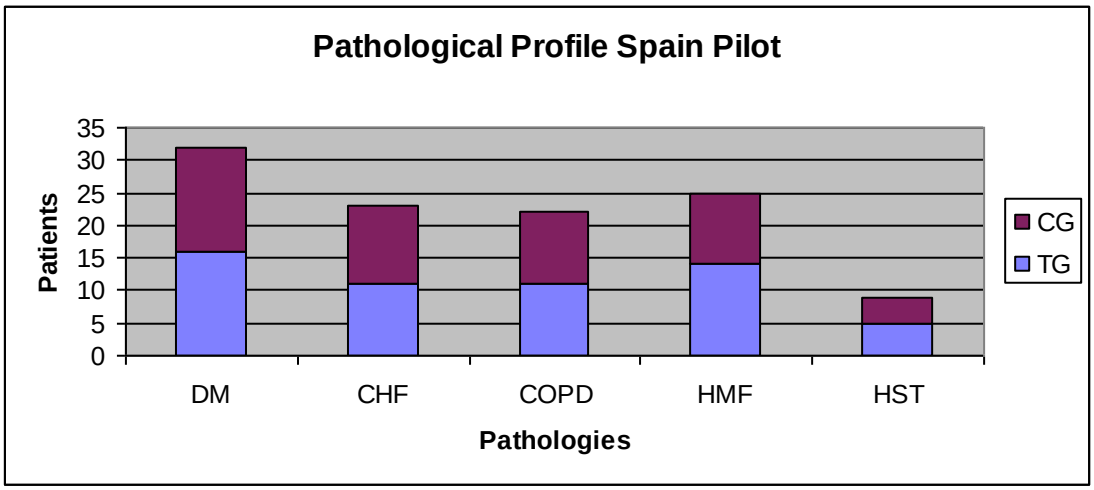


Figure 17: Spain: Profile by pathology

6.1.4 Interventions in test group

Training of patients has been done in their own homes by the healthcare team during one session by a single interlocutor.

6.1.5 Interventions in control group

Check-ups and controls to this group will be carried out in their own healthcare centres; for any emergency case, the elderly belonging to this group will go to the Emergency Service of the hospital as they have usually been doing. They will keep the classical healthcare system. The information collection during follow-up will be passive by means of extracting data periodically from the healthcare and social information systems. An interview by the healthcare team with these patients during the midterm and final evaluation will complete existing data with possible requests to the private healthcare.

6.2 Personnel involved in trials

6.2.1 Authority staff: planners, financial and management

The authority staffs involved in the Dreaming project are:

- To some extent, the Department of Health and Consumption, which is the healthcare authority at regional level.
- The Salud (Servico Aragonés de la Salud) as the public healthcare services provider.
- The I+CS (Aragon Institute for Health Sciences) as an innovation partner.
- The management team of the Barbastro Healthcare Area, for approving and providing the pilot site, design new processes, etc.

6.2.2 Health & social care staff

The first task to carry out the Dreaming project in the Spanish pilot site was to identify the clinical staff. For this, a Dreaming team has been created, led by a GP and a nurse. So far, they have been responsible for the recruitment of participants and have managed all communication with them. They belong to the emergency department of the Barbastro Hospital, and were recruited for the project based on their patient care experience as well as their knowledge of the organisation; they know the competences of the different care levels and can thus optimise the healthcare workflow of the elderly, placing each one at the correct level.

They were trained at a one day intensive session about configuration and alarms set-up related to the vital and environmental monitors (pulse oxymeter, 1-12 lead ECG, asthma monitor, glucometer, weight scales). The total number of hours for training was six (from 9 am to 5 pm) with a lunch break.

Training was done by gathering both healthcare professionals and technicians; one person of the latter was appointed as “tutor” in order to have one unique person available to the professionals for any technical problems in our organisation.

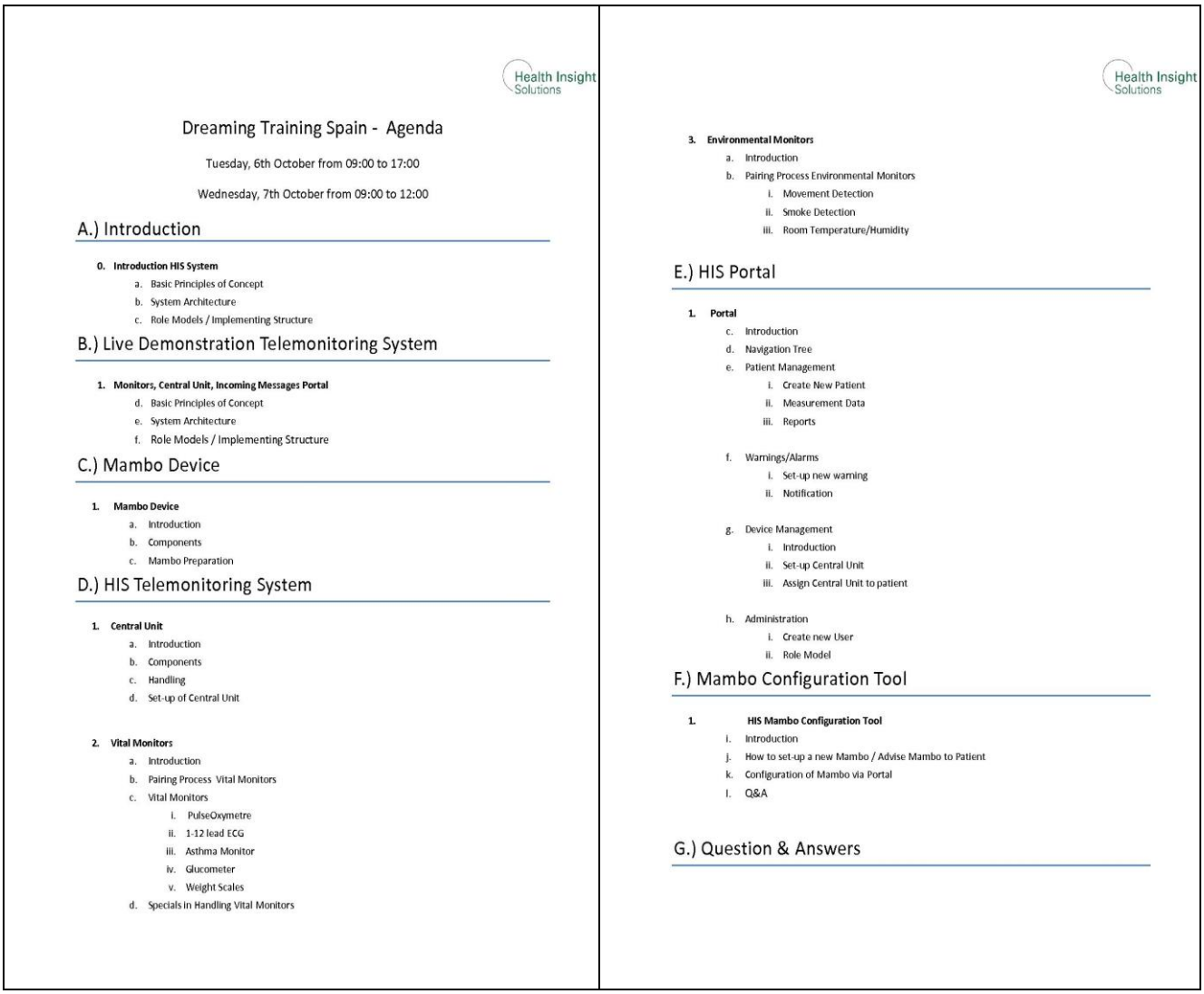
It is envisaged that one hour will be necessary to train in groups those professionals responsible for the Contact Centre.

6.2.3 Technical staff

The technical staff involved in the project at Barbastro Hospital is composed of computing technicians and an innovation technician. As a partner of Dreaming, TB-Solutions also collaborates with the installation of the system in the patients’ homes. Therefore, some computing technicians of TB-Solutions took part in the Dreaming training.

In total, six technicians were trained during this 1 ½ day intensive session about service implementation.

The total training hours was 10 hours, distributed over two days. The agenda is shown below.



Health Insight Solutions

Dreaming Training Spain - Agenda

Tuesday, 6th October from 09:00 to 17:00

Wednesday, 7th October from 09:00 to 12:00

A.) Introduction

0. **Introduction HIS System**
   - a. Basic Principles of Concept
   - b. System Architecture
   - c. Role Models / Implementing Structure

B.) Live Demonstration Telemonitoring System

1. **Monitors, Central Unit, Incoming Messages Portal**
   - d. Basic Principles of Concept
   - e. System Architecture
   - f. Role Models / Implementing Structure

C.) Mambo Device

1. **Mambo Device**
   - a. Introduction
   - b. Components
   - c. Mambo Preparation

D.) HIS Telemonitoring System

1. **Central Unit**
   - a. Introduction
   - b. Components
   - c. Handling
   - d. Set-up of Central Unit

2. **Vital Monitors**
   - a. Introduction
   - b. Pairing Process Vital Monitors
   - c. Vital Monitors
     - i. PulseOxymetre
     - ii. 1-12 lead ECG
     - iii. Asthma Monitor
     - iv. Glucometer
     - v. Weight Scales
   - d. Specials in Handling Vital Monitors

Health Insight Solutions

3. **Environmental Monitors**
   - a. Introduction
   - b. Pairing Process Environmental Monitors
     - i. Movement Detection
     - ii. Smoke Detection
     - iii. Room Temperature/Humidity

E.) HIS Portal

1. **Portal**
   - c. Introduction
   - d. Navigation Tree
   - e. Patient Management
     - i. Create New Patient
     - ii. Measurement Data
     - iii. Reports
   - f. Warnings/Alarms
     - i. Set-up new warning
     - ii. Notification
   - g. Device Management
     - i. Introduction
     - ii. Set-up Central Unit
     - iii. Assign Central Unit to patient
   - h. Administration
     - i. Create new User
     - ii. Role Model

F.) Mambo Configuration Tool

1. **HIS Mambo Configuration Tool**
   - i. Introduction
   - j. How to set-up a new Mambo / Advise Mambo to Patient
   - k. Configuration of Mambo via Portal
   - l. Q&A

G.) Question & Answers

Figure 18: Spain: Training agenda

6.3 Equipment

The medical and environmental sensors (movement detectors) have been distributed as shown in Table 18 below.

Table 18: Spain: Dreaming sensors

	Gluco meter	ECG	Movement detector	Pulse oxymeter	Weight scales	Blood pressure meter
P01	X					X
P02	X					X
P03	X					X
P04	X					X
P05	X					X
P06	X					X
P07	X	X				X
P08	X	X				X
P09		X				X
P10		X				X
P11		X				X
P12		X				X
P13		X				X
P14		X				X
P15			X			X
P16			X			X
P17			X			X
P18	X			X		X
P19				X	X	X
P20	X			X		X
P21			X	X	X	X
P22				X		X
P23			X	X	X	X
P24				X		X
P25				X	X	X
P26				X		X
P27	X			X		X
P28		X		X		X
P29	X			X	X	X
P30				X	X	X
P31				X		X
P32	X			X		X
P33	X	X		X		X
P34		X		X		X
P35		X		X	X	X
P36	X	X		X		X
P37	X	X		X	X	X
P38		X		X	X	X
P39	X	X	X	X		X
P40		X		X	X	X
	17	**17**	**6**	**23**	**10**	**40**

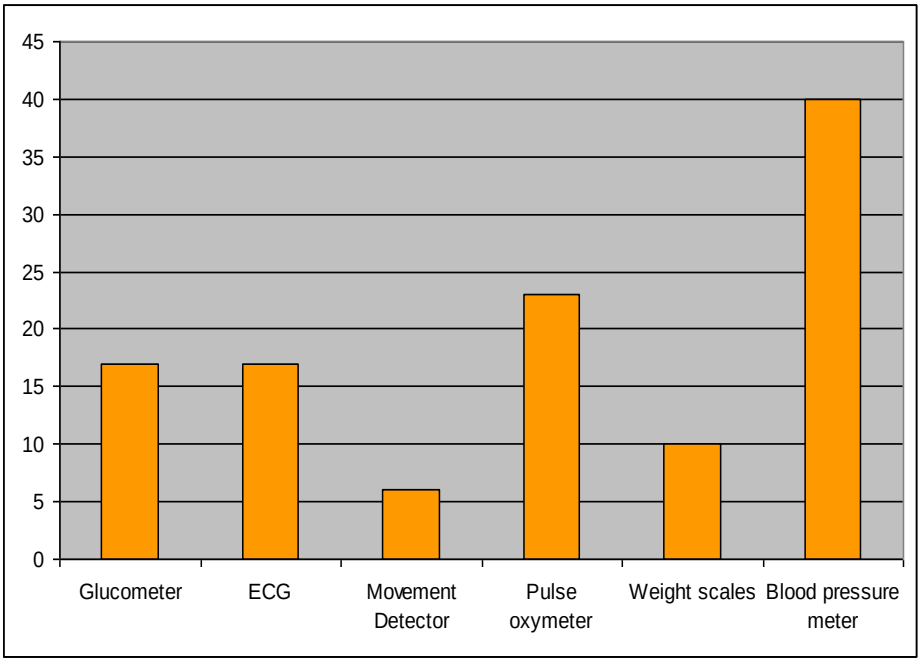


Figure 19: Spain: Dreaming sensors

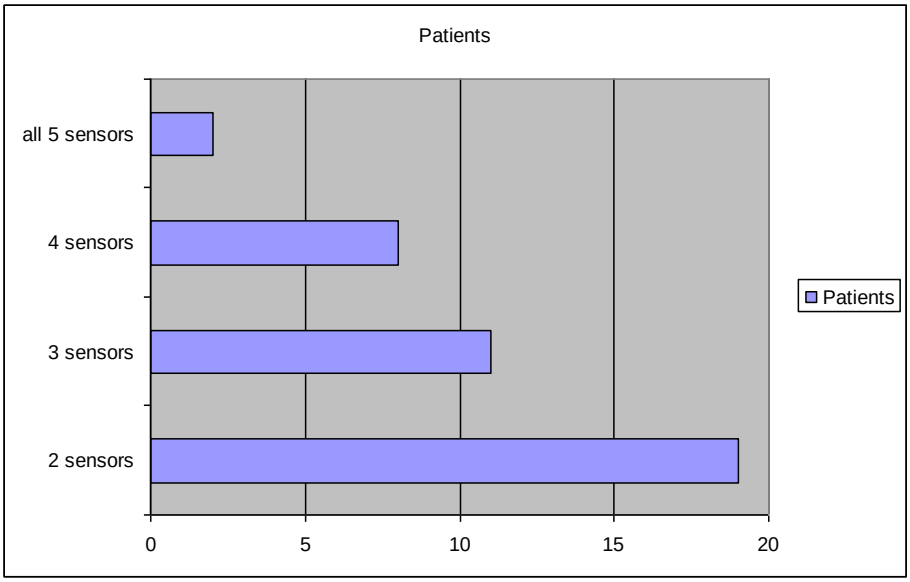


Figure 20: Spain: Dreaming sensors distribution per patient

All patients belonging to the treatment group have been given the blood pressure and pulse rate meter 'Stabil-O-Graph'.

17 diabetics received the glucometer, 17 patients the ECG, 6 the movement detector, 23 the pulse oxymeter and 10 the weight scales.

The different sensors have been distributed to patients in the following manner:

- No patients have just one sensor.

- From all patients, 19 patients have received 2 sensors, 11 got 3, meanwhile 8 patients received 4 sensors and only 2 patients received all 5 sensors.

The Spanish technology partner TB-Solutions has been responsible along with the hospital for the installation of the equipment in the elderly's homes.

An asset list has been created to be completed by TB-Solutions and Barbastro Hospital for each installation, in order to register all equipment installed. It also records any problems that have arisen in each installation; this is especially useful for proactive learning and in order to save time during the next installations. (See Appendix A)

A document called "Dreaming support" has been also created which describes how installation will be carried out at first and second level and/or use of the system. (Appendix B).

In order to have a better control of all equipment installed in each house, an inventory document with a table with the product numbers has to be signed by each patient stating that he/she has received the Dreaming sensors. (Figure 21).

DREAMING Installation

Mr. /Ms. : _____
(Name and surname)

residing in : _____ Street _____Phone nr. _____

with ID.: _____

declares

to have received for participating in the DREAMING Project by way of deposit the following devices in order to monitor all my vital parameters:

Equipmento	Nº serie
☐ Ello!	
☐ Router ADSL	
☐ Central Unit HIS	
☐ Mambo	
☐ Blood pressure	
☐ Glucometer	
☐ ECG	
☐ Pulse oxymeter	
☐ Weight scale	
☐ Movement detector	

Signature _____

Date_____/_____/_____

Figure 21: Spain: Dreaming installation document signed by patients

6.4 Installation issues

6.4.1 Sensor fitted homes

In Spain, the occupational safety and health legislation has meant the need to issue a certificate stating that the patient does not suffer from infectious-contagious disease prior to installation.

The ADSL and voice communications have been negotiated with the Spanish telephone provider and are centrally paid by our organisation.

Before installation, it is important to do a preliminary visit to the elderly's home, as technicians must know how devices must be connected and what is needed (cables, power strips, additional sockets, etc.). The first aim is to minimise the time spent at patients' homes on the day of installation.

6.4.2 Help desk

In our pilot site, the local first level support is managed by the Barbastro Health Care sector IT team, which at second level receives the support from the technology partner TB-Solutions and HIS. A contact person responsible for it has been identified.

The help desk software is supported by Barbastro Healthcare Area Intranet.

6.4.3 Contact Centre

In our public healthcare pilot site, we have established a specific contact centre centralised in the emergency unit of the Barbastro Hospital.

6.5 Initial trial results

6.5.1 Use of Equipment

So far, the following incidences by using the medical sensors and the videoconference system have been identified:

- Standard leads ECG cannot be read due to many artefacts.
- Frequent disconnections of Ello!
- Wrong transmission of measurements.
- Blood pressure sensors give 10 mmdeHg above measurements
- Bad image quality in the videoconference system.
- Frequent batteries replacement of the glucometers.

6.5.2 SF-36 (Health related quality of life) and HADS (Depression) questionnaires

Patients were asked to complete the SF-36 and HADS questionnaires during a domiciliary visit between July and August 2009. Each day five patients were interviewed taking around 1 ½ hours for each interview. The same GP and nurse who had the first visit with participants were responsible for interviewing them.

The initial evaluation was carried out through the double-blind methodology, i.e. none of the agents involved, patients and professionals knew who was going to be allocated to each group (control and test).

In the case of our pilot site, it has been decided to add the Philadelphia indicator to measure lifestyle satisfaction, the Pfeiffer questionnaire in order to measure the degree of cognitive impairment, the Lawton-Brody scale and Barthel index to measure the degree of dependence.

6.6 Lessons learned & corrective actions

The agreement between organisation, healthcare authorities, managers and healthcare staff has proven to be useful in order to validate properly the new provision in our public health care service.

Strategically, with regards to patients involved in the Project, both in the test and control groups, it is very important that the GPs of each patient have joint responsibility with the Dreaming team when presenting the project. This creates confidence and enables a positive attitude towards collaboration.

From the moment patients decide to participate in the study to the moment the pilot site begins, it seems important to establish a permanent communication channel between the Dreaming team and the patients in order to solve any issues related to formality and transparency.

Concerning professionals, it is important that they can identify in their nearest environment a technical “guardian” or interlocutor, following idea of a “single point of contact”. This enables communication by means of accessibility and provides security to the healthcare team. It also minimises the response time as calls enter the technological helpdesk in a specific way.

7. SWEDEN - HEBY

7.1 Clinical protocol and preparation for trials

7.1.1 Recruitment of the users and random allocation to the test or control group

The Swedish trial site requires 40 study participants.

1. Initially a total of 59 people equipped with home alarm and matching the trial inclusion criteria was asked for informed consent to participate. 25 accepted, one was excluded due to diagnosis of dementia. As the turnout in this group was too sparse, we went outside the population equipped with home alarm as follows.
2. All patients having visited or having had telephone contact with the Heby GP or asthma/KOL nurse between 1st October 2008 and 7th April 2009, or with the Heby GP diabetes nurse between 12th March 2009 and 7th April 2009, matching criteria (32) were asked for informed consent to participate.
3. All patients visiting the Östervåla diabetes nurse during the spring of 2009, matching criteria (15) were asked for informed consent to participate.

The collection of informed consent was achieved by providing written information by mail, one week prior to a visit by the home care staff that could provide oral information and answers to any questions. The subjects were then given 24 hours to deliberate.

This resulted in a total of 37 study subjects who, after anonymisation, were randomised to either control (18) or test (19) group.

7.1.2 Informed consent form signature

As a preparation for the visits to the elderly people, the project management group had an afternoon with role play. An external person who did not have any previous information about the project was asked to help out. That gave an opportunity to go through the information and informed consent forms and prepare for questions that could be asked by the elderly.

We started by sending out the “Information sheet and informed consent form”, see deliverable D6.1. After about a week, the person from home care contacted them and asked if they could pay them a visit in their homes. Most of them had already made up their mind at that point if they want to join the project or not. If they were positive they received a visit and they signed the informed consent forms.

7.1.3 Description of the resulting trial population

7.1.3.1 Demographic profile

The statistics shows that in the year 2008 the Heby municipality had just over 2800 people aged 65 years and older (21% of the total population in the municipality) and that there were 416 people aged 85 and older (3% of the total population in Heby).

The participating elderly are between 65 and 93 years of age, with a mean age of 78 years and a median age of 76 years. 14 of them are male.

Table 19: Sweden: Demographic profile – treatment group

Initials	Sex	Age	DM	CHF	COPD	HC	IC	NE
S.A2	F	81			1	yes	x	x
O.A	M	70			1	yes	x	x
G.Z	F	69	1			yes	x	x
N.P	M	70	1			yes	x	x
K.F	F	65	1			no	x	x
R.F	M	86	1			no	x	x
B.J	M	76	1			no	x	x
K.E	F	89		1		yes	x	x
A-L.E	F	90		1		yes	x	x
I.F	F	69	1			no	x	x
A.G	F	65	1			no	x	x
B.L	M	82		1		yes	x	x
A.H2	F	82		1	1	yes	x	x
A.H	F	80	1			yes	x	x
A-B.A	F	81	1	1		yes	x	x
K.D	M	69	1			no	x	x
R.A	F	83	1	1		yes	x	x
M.P	F	90		1		yes	x	x
B.C	M	70	1			no	x	x
	7M 12F	**77,21**	**12**	**7**	**3**	**12y**		

Figure 22: Sweden: Distribution by age & gender – treatment group

Table 20: Sweden: Demographic profile – control group

Initials	Sex	Age	DM	CHF	COPD	HC	IC	NE
B.A	M	74	1			no	x	x
J-E.S	M	68	1			no	x	x
S.P	M	76	1		1	yes	x	x
S.A	F	84	1	1		yes	x	x
M.H	F	72	1			no	x	x
G.B2	F	72	1			yes	x	x
E.B	F	73	1			no	x	x
A.S	M	68	1			no	x	x
G.E	F	88			1	yes	x	x
S.H	M	85	1	1		yes	x	x
F.L	F	92			1	yes	x	x
G.B	F	72	1	1		yes	x	x
M.J	F	80	1			yes	x	x
K.S	F	88		1		yes	x	x
A.W	M	71	1			no	x	x
A.E	F	87		1		yes	x	x
A.L	F	75	1	1		yes	x	x
N.O	M	93	1			yes	x	x
	7M 11F	**78,78**	**14**	**6**	**3**	**12y**		

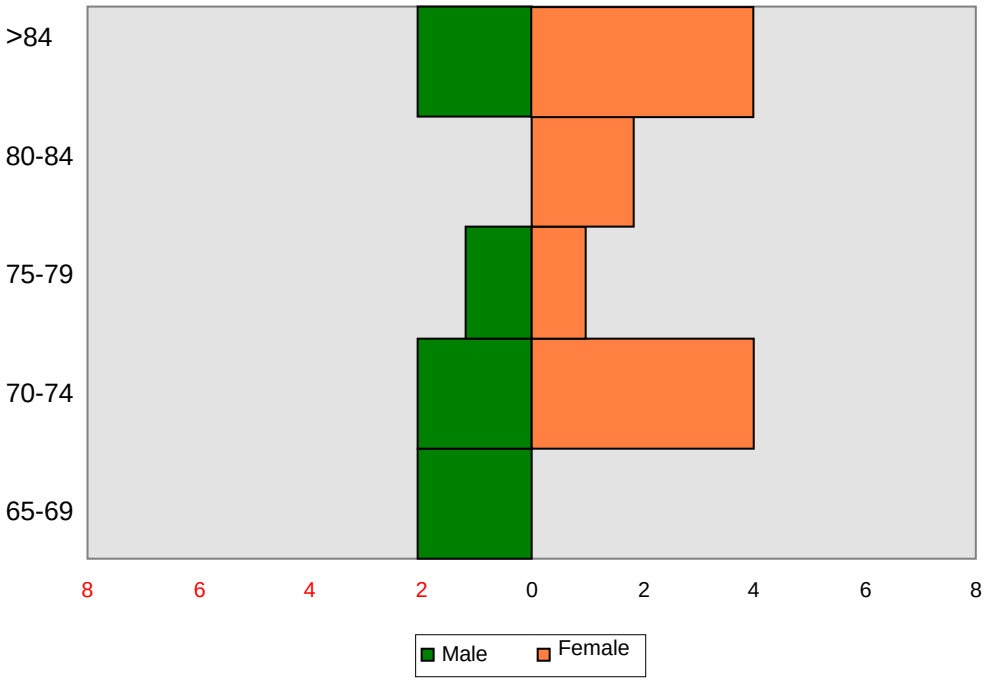


Figure 23: Sweden: Distribution by age & gender – control group

7.1.3.2 Profile by pathology

The study population includes 12 diabetes diagnoses, 7 chronic heart failure and 3 COPD. Eight patients have more than one diagnosis.

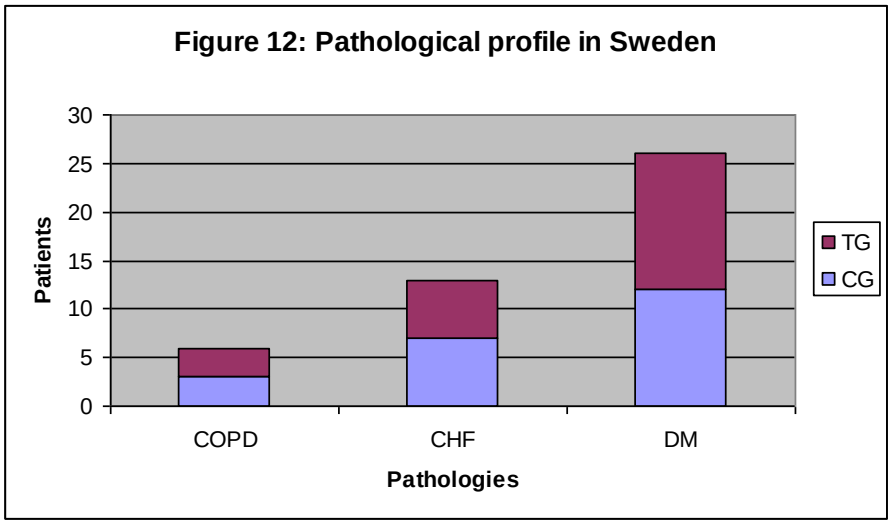


Figure 24: Sweden: profile by pathology

7.1.4 Interventions in test group

Training of patients has been done in their own homes by the healthcare team during one session by a single interlocutor.

7.1.5 Interventions in control group

Check-ups and controls to this group will be carried out in their own GP surgery; for any emergency case, the elderly belonging to this group will go to the Emergency Intake of the University Hospital of Uppsala. The information collection during follow-up will be passive by means of extracting data periodically from the Electronic Health Care Record. An interview of these patients during the midterm and final evaluation will complete existing data with possible requests to the private healthcare.

7.2 Personnel involved in trials

7.2.1 Authority staff: planners, financial and management

In Heby municipality, there is one project coordinator who works with planning, doing the reports etc. There is also an economist attached to the Dreaming project. One person is available to consult on technical and other matters that concern ICT.

7.2.2 Health & social care staff

In Heby municipality there are six persons from the local home care that work with installing the devices and support the elderly in using the devices. All the staff among the local home care are responsible for answering the (not medical) alarms from the elderly, for example when they fall or if they push the button themselves. They get the information about the alarms from SOS-alarm in Västerås as they do with the existing alarms.

The health service is provided for this population mainly by primary care in one of two GP surgeries, Heby and Ostervala. Every patient receiving prescription medications will visit their GP at least once yearly, for check up and evaluation in relation to diagnoses, renewal of prescriptions, dose adjustments etc. Additional visits or contact by telephone are initiated by the patient, a nurse or a relative, according to need. In addition, the three diagnosis groups received the following attention:

- Patients with diabetes have at least one additional visit with a specialised diabetes nurse yearly, but may have up to weekly contact if needed. The nurse monitors effects of changes in treatment as well as disease progress. She assesses secondary symptoms due to diabetes and informs and supports the patient with regard to diet and exercise. If the need arises, a dietician can see the patient.
- COPD patients are offered assessment of lung capacity and function by spirometry yearly or every other year. This is performed by a trained asthma /

COPD nurse. Patients are offered professional support to end habitual smoking.

- Patients with chronic heart failure are offered close monitoring during dose adjustments. If needed in case of acute respiratory distress, intramuscular diuretics are offered.

7.2.3 Technical staff

MIT at CCU did the matching of the equipment, and the staff in Heby installed it in the participants' homes. The staff at MIT support the staff in Heby if they have any questions; if they do not know the answers, they get in touch with HIS.

7.2.4 Dreaming Training Sweden

7.2.4.1 Dates

Tuesday the 29th September 2009 9:00 – 17:00

Wednesday the 30th September 2009 9:00 – 17:00

7.2.4.2 Agenda

Introduction (45min)

Introduction HIS System
a. Basic Principles of Concept
b. System Architecture
c. Role Models / Implementing Structure
d. Experiences with the Users of the System

HIS Telemonitoring System (90min)

1. Central Unit
a. Introduction
b. Components
c. Handling
d. Set-up of Central Unit

2. Vital Monitors
a. Introduction
b. Pairing Process Vital Monitors
c. Vital Monitors
   i. PulseOxymetre
   ii. 1-12 lead ECG
   iii. Asthma Monitor
   iv. Glucometer
   v. Weight Scales
d. Specials in Handling Vital Monitors

3. Environmental Monitors
a. Introduction

b. Pairing Process Environmental Monitors
   i. Movement Detection
   ii. Smoke Detection
   iii. Room Temperature/Humidity

HIS Portal (90 min)

4. Portal
a. Introduction
b. Navigation Tree
c. Patient Management
   i. Create New Patient
   ii. Measurement Data
   iii. Reports
d. Warnings/Alarms
   i. Set-up new warning
   ii. Notification
e. Device Management
   i. Introduction
   ii. Set-up Central Unit
   iii. Assign Central Unit to patient
f. Administration
   i. Create new User
   ii. Role Model

Live Demonstration Telemonitoring System (45min)

Mambo (90min)

5. Mambo Device
a. Introduction
b. Components
c. Mambo Preparation

6. HIS Mambo Configuration Tool
a. Introduction
b. How to set-up a new Mambo / Advise Mambo to Patient
c. Configuration of Mambo via Portal
d. Q&A

Ello! System (60min)

Live Practice & Repetition (120min)
7. Technical Set-up/Installation
8. Set-up Patients/Users/Alarms
9. Set-up Mambo / Configuration Mambo

Question & Answers (60min)

7.3 Equipment

Table 21: Sweden: Dreaming sensors

Initials	Test	COPD	HF	DM	IEM Stabil-O-Graph	IEM weight scale	HMM Glab	Viasys	Nonin Avant 400
					BP	Weight	Glucose	PEF	PO2
A.H	1			x	1		1		
S.A			x	x					
N.P	1			x	1	1	1		
G.Z	1			x	1		1		
N.O				x					
R.A	1		x	x	1	1	1		1
M.J				x					
M.P	1		x		1	1			1
R.F	1			x	1		1		
K.F	1			x	1		1		
I.F	1			x	1		1		
K.D	1			x	1		1		
J-E.S				x					
B.C	1			x	1		1		
A.W				x					
F.L		x							
A.H2	1	x	x		1	1			1
B.L	1		x		1	1			1
O.A	1	x			1	1			1
A-B.A	1		x	x	1	1	1		1
A-L.E	1		x		1	1			1
K.E	1		x		1	1			1
K.S			x						
G.E		x							
A.E			x						
S.H			x	x					
S.A2	1	x			1	1			1
S.P		x		x					
A.L			x	x					
G.B			x	x					
G.B2				x					
M.H				x					
A.S				x					
A.G	1			x	1		1		
B.A				x					
B.J	1			x	1		1		1
E.B				x					
					19	**10**	**12**		**10**

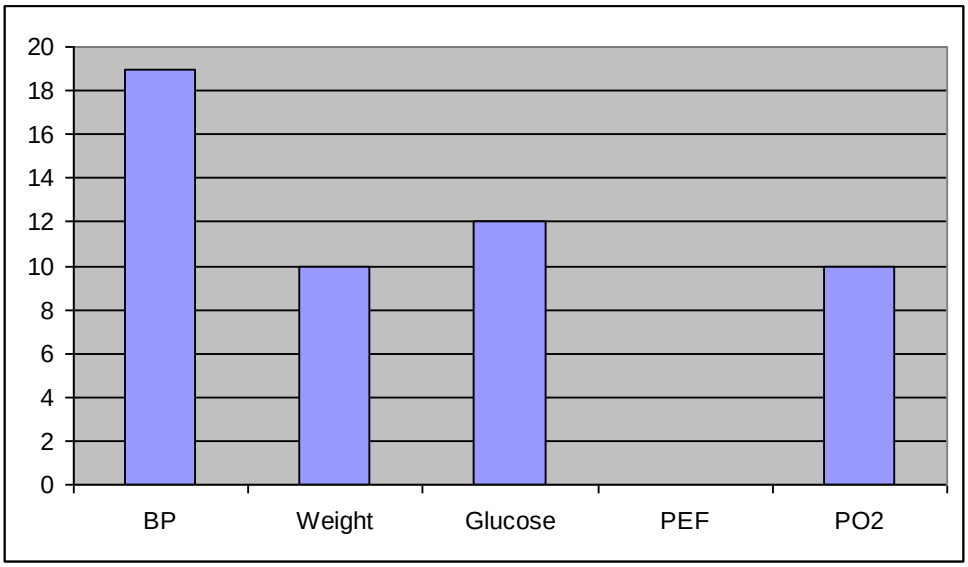


Figure 25: Sweden: Dreaming sensors

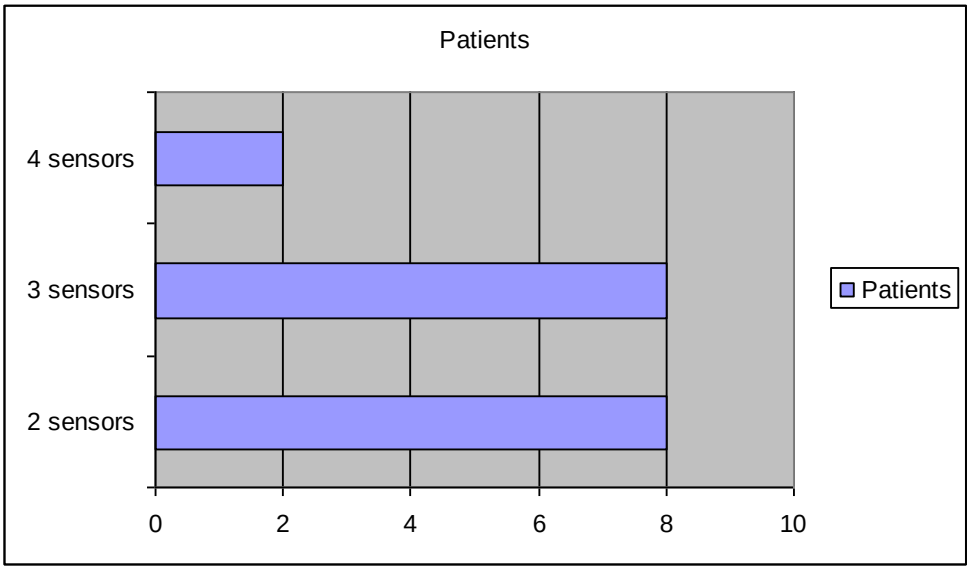


Figure 26: Sweden: Dreaming sensors - distribution by patients

All patients belonging to the treatment group have been given the blood pressure and pulse rate meter 'Stabil-O-Graph'.

All 12 diabetics received the glucometer, 10 the pulse oxymeter and 10 the weight scales.

The different sensors have been distributed to patients in the following manner:

- No patients have just one sensor.
- From all patients, 8 patients have received 2 sensors, 8 got 3, meanwhile 2 patients received 4 sensors.

7.4 Installation issues

7.4.1 Sensor fitted homes

The present status in Sweden is that a total of 14 installations have been done and one is still missing due to lack of time and stable function. (March 2010).

7.4.1.1 Equipment installed

Central units (14 units installed)

Medical equipment

- Blood Pressure Meters: 14 devices installed.
- Gloucometer: 9 devices installed.
- Oxymeter: 5 devices installed.
- Weight Scale: 14 devices installed.

Environmental equipment

- Movement detector: 14 devices installed.
- Smoke detector: 14 devices installed.
- ello! Systems: 5 units installed. Two systems in use (three idle).
- Mambo: 12 devices introduced, two more planned. All of the Mambos are presently recalled due to unreliable function (12 devices).
- Key-fobs have not been delivered from the supplier. Note: In Sweden we decided earlier that the “old” current indoor alarms (8 installed previously) should be kept and not replaced by the key-fobs. Delivery status is planned to April 2010.

7.4.1.2 Experiences

Internet Connection

ADSL has been installed to all in treatment group. There has been no problem with time to delivery. Five (of 19) already had Internet connection. There were practical problem only at two installations.

Central Unit

Randomly a “hanging problem” happens now and then (more documentation available). One problem is that there is no active alert when this happens – more of “no activity”. Persons are instructed to switch OFF and ON when this happens.

Blood Pressure Meters

Generally, blood pressure monitoring is an unreliable and frustrating area which has been a key focus for both our Medical Engineering as well for the medical profession. This question has been discussed during the last PSC meeting.

There have been a number of alarms (values out-of-range). A small number was too low BP but most of the alarms have shown too high BP.

Technical check out showed problem in most cases. One example 151/72 on patient was 128/54 measures by district nurses. (More documentation available). A new device gave no change.

There have also been frequent errors (Error 1 and 2 – misplacement and movement).

After discussion at the PSC 5 in Zaragoza a decision was made to carry out a test with the IEM Stabil-O-Graph blood pressure meter. The blood pressure was simulated in a blood pressure generator and reference values were measured by a Dräger Delta patient monitor. The results recorded by Medical Engineering in Uppsala are showed below:

Table 22: Denmark: Medical Engineering results

Blood pressure	IEM Stabil-O-Graph	Dräger Delta
60/30	Error 1	59/32
80/50	80/54	79/51
100/65	97/65	99/67
120/80	114/82	119/81
150/100	143/103	144/102
200/150	194/152	198/151
255/195	Error 1	253/199

The test certifications which we received from the manufacturer also show that the IEM Stabil-O-Graph device meets the strict requirements of the British Hypertension Society (BHS) concerning accuracy.

Another question is how to act with persons suffering from arrhythmia? Device seems to detect wrong values. This question has to be further discussed by the medical professionals in the project.

Gloucometer

The gloucometers frequently sends value “zero” wrongly. The results is that the Contact Centre has to check by telephone every time it occurs; this worries the elderly.

New pairing is needed in the case when the Central Unit “hangs”. This has been the cause in 2 of 25 cases. The reason in the rest of the cases is unknown. After pairing again it works OK.

This has happened most frequent at 2 (of 9) installations, but a few from the others.

Because of the uncertainness this has requires home visit of staff every time. With this background the GP has made decision to take all units out of service.

Oxymeter

No problem to use. We have though noticed that we have to replace the batteries more often than expected. After five months we had to put new batteries in to the oxymeter, but earlier in the project we got the information that the batteries should not have to be replaced more than maybe one time for each device during the whole project.

Weight Scale

No problem to use.

Movement detector

No problems.

Smoke detector

No problems.

One correct alarm has occurred due to dry cooking!

Ello!

We are not satisfied with the overall quality

We have installed five systems but only two of them are in use.

Mambo

No system is in use for the moment. Earlier we had 12 systems introduced into the treatment group, but they were recalled by HIS. This procedure caused a number of visits to the elderly of the staff from the municipality.

Key-fobs

Eight of the persons in the study group have an emergency alarm since before the start of the project. It was decided that these persons should keep the old alarms with a Mambo added, but the others should be equipped with key-fobs and a Mambo as well.

However the suppliers experience of the key-fob quality is too poor. As a result the whole batch was withdrawn.

No key-fob system introduced so far.

7.4.1.3 Lessons learnt

Enthusiastic Treatment and Control Group.

Vacancies of GP is a problem.

Technical problems have led to less creditability for the project.

Refill strategy in both Treatment and Control Group must be solved.

7.4.2 Help desk

In Sweden the first level support is carried out by the staff of municipality of Heby.

The second level support is carried out by Medical Engineering of University Hospital of Uppsala.

7.4.3 Contact Centre

In Sweden, the contact centre is SOS Alarm centre for alarms of type level 2. The SOS Alarm centres are accessible 24 hours every day and co-ordinate the dispatching of the emergency services. The Centre will in principle send an ambulance if the alarm is serious after telephone check with the person.

The alarms of type level 1 are transferred to the GP surgeries in Heby or Östervåla. The cases are followed up by the staff at the GP surgeries.

7.5 Initial trial results

7.5.1 Use of equipment

So far there are no indicators or statistics (June 2009).

7.5.2 SF-36 (Health related quality of life) and HADS (Hospital Anxiety And Depression Scale) questionnaires

The questionnaires are sent out about two weeks after the equipment has been installed in the homes.

In the Control group, 15 questionnaires have been sent out and 13 have been received. Two reminders have been sent out.

For the study group, we send out the questionnaires two weeks after installation. Until today we have sent out eight questionnaires and received eight replies. Seven pending, due to late installations.

7.6 Lessons learned & corrective actions

The initial plan was to recruit study participants out of a population of about 300 people equipped with home security alarms. The idea was that they were already used to technical equipment in the home environment, and also that all contact information for an alarm situation was already gathered. However, out of the 59 who matched the study inclusion criteria, only 27 were willing to sign informed consent, after written and verbal information and a time period for consideration of approximately one week. During the course of participant selection it also became clear that the existing safety alarm could not be replaced by the study equipment (Mambo2) as no reliability data is available for this function. Hence, the list of potential study participants was extended.

Now we have realised that we probably would have saved a lot of effort and discussions if we have chosen elderly people who did not already have a safety alarm in their homes. We chose these persons because we believed that they were going to move to an elderly home within the near future. Later on we realised that the age of inclusion was from 65 years and older. That is probably an explanation that the average age is quite high.

We now have decided to make another randomisation during the spring 2010. That is because of a rather lot of drop outs.

8. Global Data

The following tables and figures show the different global data collected from all sections of each pilot site.

Table 23: Global data: Description of the resulting population

Partners	Randomized Participants	Group	Drop-outs		Mean age	Male ♂	Female ♀
Denmark	22	TG	10	45%	77,68	11	11
	22	CG	7	32%	79,44	10	12
Estonia	30	TG	9	30%	74,80	12	18
	30	CG	0		75,04	12	18
Germany	30	TG	0		81,77	8	22
	30	CG	0		79,80	8	22
Italy	30	TG	5	17%	75,90	12	18
	30	CG	6	20%	76,00	15	15
Spain	40	TG	6	15%	75,77	25	15
	40	CG	2	5%	75,60	24	16
Sweden	19	TG	4	21%	77,21	7	12
	18	CG	3	17%	78,78	7	11
TOTAL	341		52		77,2	151	190

Table 24: Global data: Pathologies

	CHF	DM	COPD	HMG	HS
Denmark	15	18	10		
Estonia	31	14	20		
Germany	33	19	7		
Italy	34	33	10		
Spain	23	32	22	25	9
Sweden	13	24	6		
Total	**149**	**140**	**75**	**25**	**9**

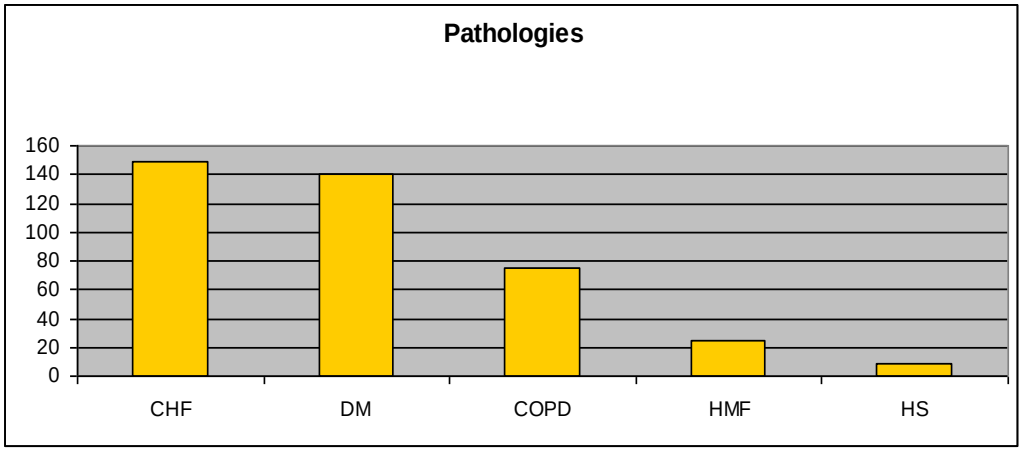


Figure 27: Global data: Pathologies

Table 25: Global data: Equipment

Blood Press.	Weight Scales	Move ment	Pulse Oxy-meter	ECG	Gluco meter	Smoke	Water Leak	Room Temp./ Humidity	Asthma monitor
140	74	66	65	61	51	30	30	30	12

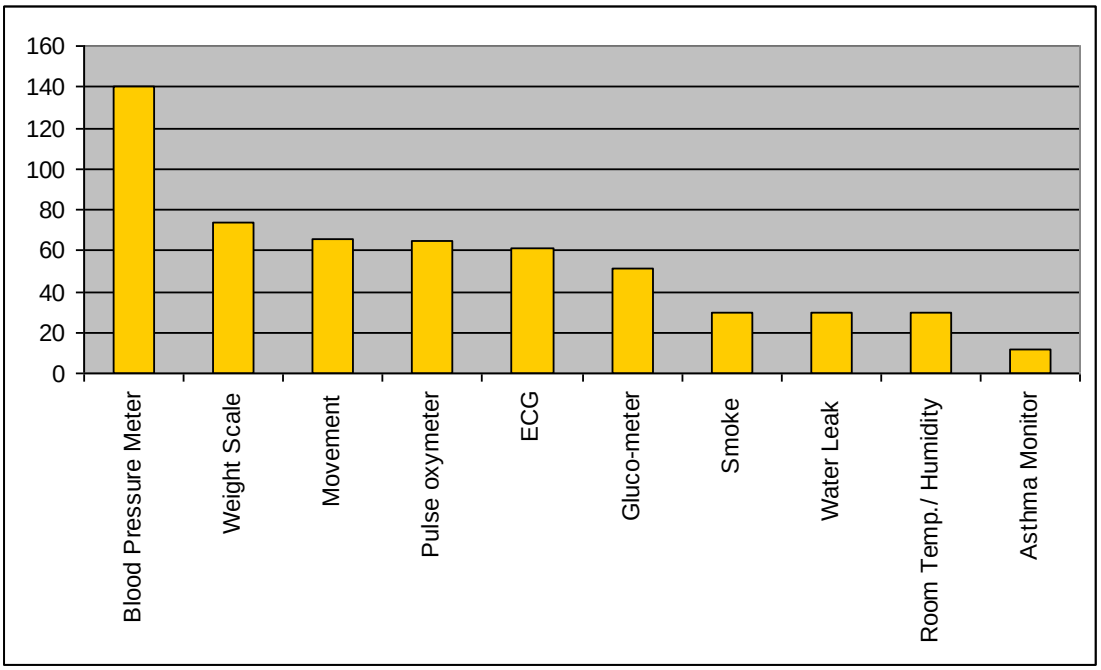


Figure 28: Global data: Equipment

9. Service implementation conclusions

The following conclusions have been extracted from global data and from a spreadsheet table (see Annex C) sent to all partners.

9.1 Population involved

From the total 341 patients, 44% are male and 56% female.

Estonia and Spain youngest population vs. Germany and Denmark the oldest.

Drop-outs: high in percentage terms Estonia and Scandinavian Countries, low in Germany and Mediterranean countries.

Chronic Heart Failure is the most frequent disease, followed by Diabetes Mellitus (54%).

9.2 Equipment

The most frequent medical sensors deployed are the blood pressure meter (25.04%), the weight scale (13.24%) and the pulse oxymeter (11.81%), which all together make more than 50% of all sensors. Meanwhile the less frequent sensor is the asthma monitor (2.15%).

By the use of the equipment, some general technical problems have been identified highlighting the following weaknesses:

- Set-up box and Central Unit:
  - Frequent disconnections.
  - Power plug very sensitive to disconnection.
  - Nightly beeps.
  - TV unwanted connections.
  - Set up box and Central Unit heating.
  - Null and erroneous measures. It is not the same.
  - Commented Central Unit measure does not correspond with portal sent one (Glycaemia).
- Ello Video-conference system:
  - Very poor video quality.
  - Sound lag.
  - Minimum bandwidth.
  - Webcam image/video resolution.
  - For elderly is a common problem to use TV channel for calling (answering and making). This is a bigger problem in TV installations with only a euroconector (scart).

- Devices
  - Generally it has been identified to establish best practices stating When? Where? and How? to use the medical sensors.
  - Blood pressure meter: It needs calibration as there is a tendency to slightly higher values. In a case it showed 20 mmHg above the normal value which lead to mistrust. It seems important to establish best practices deciding when, where and how to take the measurement.
  - ECG: We have not received any quality set until now. Here again, it seems important to establish best practices deciding when, where and how to take the measurement.
  - Glucometer: Downward trend in the measurements.
  - Oximeter / Pulsioximeter: batteries need to be frequently removed.
  - Weight scale: problems of stability.
  - Asthma monitor: no incidents.
  - Domotic sensors: no incidences.

9.3 Contact Centre

Half of the partners have chosen a private management model where there has been chosen a shared centre. In the public environment, it has been more common to establish a specific centre to deal with Dreaming.

The centres are mainly managed by mixed organisations of social and healthcare nature; only in two cases they are controlled by pure healthcare organisations.

With the exception of the Swedish patient's recruitment, the responsibility relies on healthcare organisations.

All operate 24 x 7, 365 days a year, except in Estonia which has a more restrictive schedule limited to working days.

The solutions of the healthcare organisations tend to the centralisation in emergency units, while the mixed have multicentric models.

9.4 Helpdesk

All have local first level support, which at second level depends on at least one external technology enterprise.

The help-desk software mainly used is that of their own organisations.

All have identified a contact person responsible for the help desk.

9.5 Sensor fitted homes

Patient's Safety: All partners have considered the legislation which protects patient's data. Some partners are considering clinical safety as a result of the reliability of the measurements obtained, calibration and sensitivity of devices and good practices by taking measurements.

Professionals' safety: In the case of Spain, the occupational safety and health legislation has meant the need to issue a certificate stating that the patient does not suffer from infectious-contagious disease prior to installation of the devices at home.

The ADSL and voice communications have been mainly negotiated and centrally paid by the organisation of each pilot site.

The electric consumption of devices has worried patients in Spain (10-15 € monthly where there is a universal public healthcare system without consumption limits). A flat rate telephone compensation for domestic calls has been negotiated.

With regards to the deployment organisation and training there has been an unintentionally agreement among several partners. It has been decided to deploy in 3 stages. Italy has been the only one who has made training in a different way.

9.6 Set-up

There is a high degree of consensus on minimising the time spent to install equipment in the patient's home. Seeking for this goal, it seems necessary to do a preliminary visit to plan the installation.

The joint responsibility of family members, if any, and of the elderly in the preliminary visit is important for a successful participation in the project.

In all pilot sites, there have been formed multidisciplinary teams for the set-up. In the Swedish model, technicians work along staff of social services, whereas the rest have been working with healthcare staff.

Installation time is between 1 ½ hours and 3 hours

9.7 Portal

Partners are equally divided on the need to install a local portal and to integrate it with their clinical history information systems.

The portal is accessible for professionals of specialised care, except in the Scandinavian pilot sites.

For professionals of primary care, it is available in all pilot sites except in the Estonian model.

Social services have access to the portal only in German and Swedish pilots.

Thus, there are 4 models:

- Mediterranean (Italy and Spain) where information is accessible to all actors of the two levels of care.
- Germanic, where there is access to healthcare and social professionals.
- Scandinavian, where the available information is for GP and social workers.
- Estonian, the most restrictive with access only to specialised care.

Except in the German and Swedish cases, the nature of the organisation responsible for the project affects the nature of the sensors deployed.

A great majority of the members felt the need to include a guide on good practices for the acquisition of signs and to take measures to raise the calibration - validation of sensors and reliability of acquired data.

Appendix A – Asset List (Spain

This list is completed by TB-Solutions and Barbastro Hospital for each installation, in order to register all equipment installed. It also records any problems that have arisen in each installation.

tb·solutions salud

Lista de Instalación técnica

Datos del técnico (TB-Solutions):	**Datos del paciente:**
Nombre:	Nombre:
Número de Contacto:	Dirección:
Datos del técnico (Salud)	Número de Contacto:
Nombre:	
Número de Contacto:	
Datos personal médico (Salud):	
Nombre:	
Número de Contacto:	

Información sobre la Cita para la instalación:
Fecha:
Hora:

Equipo a instalar:		
Biosensores	Sensores ambientales	Video-Conferencia
☐ Peso	☐ Movimiento	☐ Ello!
☐ Tensiómetro		
☐ Glucómetro		
☐ ECG de una derivación		
☐ Pulsi-oxímetro		

Comentarios

Verificación de Requisitos (Salud)	
El residente ha sido dado de alta en el Portal:	Si / No
Se ha preparado una lista de contactos para ello! Messenger:	Si / No
Todo el equipo para la instalación de la Unidad está disponible:	Si / No
☐ ADSL funcionando en el domicilio ☐ Router multipuerto conectado al ADSL ☐ Teléfono convencional conectado a la línea telefónica ☐ Cable Ethernet para conectar el router y la Unidad Central ☐ Cable Ethernet para conectar el router y la Unidad ello! ☐ Cable Euroconector para conectar la TV y la Unidad ello! ☐ Adaptadores / Regletas / Divisores en caso necesario	
Todos los sensores necesarios están disponibles y con baterías:	Si / No
☐ Peso ☐ Tensiómetro ☐ Glucómetro ☐ ECG de una derivación ☐ Pulsi-oxímetro ☐ Sensor Movimiento ☐ Unidad ello!	

Verificación de Requisitos (TB·Solutions)	
La Unidad se ha conectado con el portal:	Si / No
La Unidad se ha asignado al Paciente en el portal:	Si / No
Todos los sensores necesarios han sido emparejados satisfactoriamente:	Si / No
☐ Peso ☐ Tensiómetro ☐ Glucómetro ☐ ECG de una derivación ☐ Pulsi-oxímetro	
Usuario dado de alta en ello! Messenger:	Si / No
Llave de instalación de ello! preparada:	Si / No
Todos los dispositivos necesarios están disponibles:	Si / No
☐ Teclado USB ☐ Equipo portátil	

Número de MAC de la Unidad Central	

Comprobaciones de la instalación (Unidad Central y Portal HIS)	
Todos los sensores necesarios se han podido conectar:	Si / No
La Unidad sigue en comunicación con el portal:	Si / No
Emparejamiento de Sensores satisfactorio: ☐ Peso ☐ Tensiómetro ☐ Glucómetro ☐ ECG de una derivación ☐ Pulsi-oxímetro	
☐ Movimiento	

Verificación		
Persona de Contacto en el Call Center:		
	Valor en el Sensor	Valor en el Portal
☐ Peso ☐ Tensiómetro ☐ Glucómetro ☐ ECG de una derivación ☐ Pulsi-oxímetro ☐ Movimiento		

Comprobaciones de la instalación (Unidad ello!)	
La Unidad se ha instalado correctamente:	Si / No
La Unidad sigue en contacto con el servicio de mensajería:	Si / No
Funcionamiento correcto del sistema: ☐ Llamada entrante ☐ Llamada saliente	

Mambo		
Número de Serie:		
Número tarjeta SIM:		
Número de Teléfono:		

Comentarios

Validado por (Salud):	Nombre: Firma: Fecha:
Validado por (TB·Solutions):	Nombre: Firma: Fecha:

Appendix B - Dreaming support document (Spain)

This document describes how installation will be carried out at first and second level and/or use of the system.

SOPORTE DREAMING

El presente documento resume los niveles de soporte ofrecidos a los usuarios del proyecto DREAMING del piloto del Sector de Referencia. El soporte se divide en dos niveles:

- Primer nivel: Soporte dado a los usuarios finales en el propio domicilio.
- Segundo nivel: Soporte al personal médico, de administración y gestión del Sector de Referencia.

Soporte de Primer Nivel

Gestión de incidencias y resolución de problemas de los residentes de las casas piloto. El tratamiento de estas incidencias puede requerir personarse físicamente en el domicilio del usuario.

Responsable: Hospital de Barbastro

Personal médico asignado al proyecto	
Incidencias de:	- Residentes de las Casas Piloto
Atribuciones:	- Resolución de problemas derivados del manejo de los biosensores. - Desplazamiento al domicilio del usuario en caso necesario.
Modo contacto:	- Telefónico. - Video-Conferencia utilizando el Set-Top-Box de *ello!*

Personal de servicios asignado al proyecto (Sección Informática)	
Incidencias de:	- Residentes de las Casas Piloto - Personal médico - Usuarios del portal HIS - Usuarios del cliente de mensajería para PC *ello!*
Atribuciones:	- Configuración y mantenimiento local de biosensores: 1. Emparejamiento 2. Configuración 3. Reemplazo de baterías - Desplazamiento al domicilio del usuario en caso necesario. - Incidencias relacionadas con el portal HIS: 1. Edición de usuarios 2. Validación de datos médicos
Modo contacto:	- Telefónico. - Correo electrónico. - Video-Conferencia utilizando el STP de *ello!*

Soporte de Segundo Nivel

Gestión de incidencias y resolución de problemas de los responsables del Soporte de Primer Nivel.

Responsable: TB·Solutions

Personal técnico asignado al proyecto	
Incidencias de:	- Personal del Soporte de Primer Nivel
Atribuciones:	- Resolución de problemas relacionados con el portal HIS (enlace con Health Insight) - Resolución de problemas relacionados con el portal *ello!* (enlace con Tele-Medicina Rizzoli) - Consultoría sobre problemas de configuración de dispositivos
Modo contacto:	- Herramienta de Gestión de Incidencias

Herramienta de Gestión de Incidencias

Temporalmente el acceso al Gestor de Incidencias no está disponible. Las incidencias se darán de alta vía correo electrónico a la lista de soporte de DREAMING y se crearán en el Gestor de Incidencias desde TB·Solutions.

soporte_barbastro@dreaming-project.org

En el contenido del correo deberá indicarse:

- Ámbito de la incidencia:
  - Biosensores (indicar cuál)
  - STB *ello!*
  - Portal HIS
  - *ello!* Messenger para PC
- Descripción detallada del problema
- Datos del residente / miembro del personal al que afecta el problema.

Appendix C – Implementation comparison of all pilot sites

	Issue	Description	Spain	Denmark	Estonia	Germany	Italy	Sweden
Contact Center	Specific/Shared	Do you have created the contact center specifically for the project or do you have integrated a shared contact center to your organization?	Shared	Specific	Specifically	Shared	integrated a shared contact center	Shared
	healthcare/social/mixted	Is it managed by a healthcare or social organization or both?	Public Health	Mixed	Public healthcare	both	private organization: tesanTelevita s.r.l.	Mixed
	Location	Where is it?	Emergency Unit of Barbastro's Hospital	Local emergency units at Langeland (three points corresponding to the specific sharing of responsibility of elderly patients between the three units on the island) One centre in the south, one in the centre and one in the north responding to issues from their specific citizens.	East Tallinn Central Hospital	The own Contact Center of Pflegewerk and Mediplus	TesanTelevita srl (piazza S. Giovanni 6, Trieste – Italy : at least 1 operator during weekdays) + (via S. Francesco 70/A, Trieste – Italy : at least 5 operators 24 hours / day)	Emerency unit of SoS-Alarm (not located in a hospital)
	Availability	How long will it be working?	24 x7, 365 days a year	24 x7, 365 days a year	8-17 working days	24 x7, 365 days a year	24 x7, 365 days a year	24 x7, 365 days a year
	Elderly's recruitment: health care/ social	Who has been responsible for elderly's recruitment: health care staff or social services?	Health care staff has been responsible for the elderly's recruitment	Health care staff has been responsible for the elderly's recruitment	Health care staff has been responsible for the elderly's recruitment	Health care staff has been responsible for the elderly's recruitment	health care staff	Social service staff has been responsible for the elderly's recruitment. Fine tuning of long list in cooperation with Healt Care Centre
	Public / private	Kind/Nature of provider	Public	Public	Public	privat	private	Privat

	Issue	Description	Spain	Denmark	Estonia	Germany	Italy	Sweden
Help Desk	Location	Where is it?	Barbastro's Hospital	Prevention centre at Langeland	East Tallinn Central Hospital	Pflegewerk	TesanTelevita srl	Municipality of Heby - first line and for technical support, 2nd line, Medical Engineers Department at the University Hospital of Uppsala
	Maintenance Fist level	Who is going to give at first support and maintenance to the system?	Barbastro health sector IT team	Social service staff at the prevention centre of Langeland Municipality as well as responsible person from RSD	East Tallinn Central Hospital medical engineering	Pflegewerk health sector IT team	TesanTelevita srl	Social service staff at the Municipality of Heby.
	Maintenance Second level	Who is going to give support and maintenance to the system at second level?	Tb-solutions and HIS	TB solutions and HIS as well as responsible staff from RSD	ETCH medical engineering and HIS	Tb-solutions and HIS	Ital TBS	Medical Engineers Department at the University Hospital of Uppsala
	Specific/Shared Software	Help Desk software	Shared Software with Intranet	Only small scale so far. No need for special software so far because of few patients. Use of internal excel document to track events.	Shared software with internet	in the moment by telefon service and Software (distant support) erfolgen. We plan a special Trouble-Ticket-System	Shared	Only small scale so far. No need for special software. Second line tech support (Medical Engineering Dep) has Case Manager Support system (Medusa).
	Contact Person	Who is going to be responsible for help desk?	A technician of our organization acting as a tutor will be the contact person for all technical issues related to help desk	Municipal staff as well as responsible person from RSD.	Head of medical engineering	In the moment a technician of our organization will be the contact for all technical issues related to help desk	Tesan-Televita	Municipality of Heby, Social staff (Jessica Eriksson)

	Issue	Description	Spain	Denmark	Estonia	Germany	Italy	Sweden
Homes	Safety measures patients	Which safety measures for patients have been consided?	In our case, it is mandatory to follow the national Data Protection Law	Original safety meassures are still present. In DK it is also mandatory to follow the national data protection law. Ethically, it has also been evaluated whether or not the project violates any ethical meassures. It was concluded that it didn't.		Pflegewerk follows the national Data Protection Law and the defaults of the ethic commission		Emergency alarm (indoor) earlier determined is still in use as an safety back up.
	Safety measures professionals	How are professionals protected?	Document stating none infectious disease of elderly	No need for extra safety in Dreaming project		by internal standards	non-sense- non pertinent to a health care service, which must be organized to treat every subject with a constant adequate caution	No need for extra safety in Dreaming project
	ADSL contracting and payment	Negotiations with phone provider. They have been centralized, in the sense of contracting lines for all paritipants or contracting individual lines? How will this be payed?	Centralized lines contracting and centralized payment for the project.	Centralized ADSL provider and centralized payment from the project (Langeland Municipality pays the bills). However, the ADSL provider has not been able to provide ADSL for everyone. We have therefore been forced to use another provider in certain cases (YouSee).	Centralized lines contracting and centralized payment for the project.	Negotiations with phone provider have not been centralized, we have contracted individual lines. This will be payed by Pflegewerk.	Centralized contracts and centralized payments.	Centralized contracting for broadband providers and centralized payment for the project. The municipality of Heby has contratctning network provider Telia.
	Voice lines contracting (Mambo)	Negotiations with phone provider. Has it been centralized, in the sense of contracting phone cards for all paritipants or contracting individual cards?	Centralized.	Individual subscription, but Langeland Municipality pays the bill and manages the ordering.	**Centralized.**	Centralized.	Centralized contracts and centralized payments.	Individual subscription but Heby municipality pay the bill
	Electricity consumption payment	Do patients complain about high electricity consumption? If yes, let us know how will you solve the problem?	Yes. We have reached an agreement with patients. They will pay 10-15€ monthly due to high electricity costs and will be compensated for it with flat rate in national calls to landlines.	No problem so far.	No. We have no such negotiations with patients.	No, there is no problem	no, they do not	No - not a problem in Sweden so far.

	Issue	Description	Spain	Denmark	Estonia	Germany	Italy	Sweden
Set-up	Deployment	Installation has been carried out in one single visit or in several times?	We have divided the installation in 3 steps:1. Medical and environmental devices, 2. videoconferencing solution and 3. Mambo and keyfob	We have divided the installation in 3 steps:1. Medical and environmental devices, 2. videoconferencing solution and 3. Mambo and keyfob (no mambo installed yet)	We have divided the installation in 3 steps:1. Network 2. Devices 3. Mamobs and ellos!	Firts we did it in one step, now like Spain we have divided the installation in 3 steps:1. Medical and environmental devices, 2. videoconferencing solution and 3. Mambo and keyfob	We divided the installation in 3 steps: 1. ADSL connection, 2. ADSL device, 3. DREAMING devices	Two steps earlier. But after problems with Mambo it has been split in three steps.
	Training to elderly's of devices	Training has been done in one single session or in several sessions?	Training to elderly will be done according to a 3 steps procedure (as described above). They have been trained first on how to use equipment, next the Ello! system and finally the Mambo.	Training to elderly will be done according to a 3 steps procedure (as described above). They have been trained first on how to use equipment, next the Ello! system and finally the Mambo.	Training to elderly will be done according to a 3 steps procedure (as described above). They have been trained first on how to use equipment, next the Ello! system and finally the Mambo.	Training to elderly will be done like in Spain according to a 3 steps procedure (as described above). They have been trained first on how to use equipment, next the Ello! system and finally the Mambo.	officially , in one session but the technicians are available each time during weekdays	Three steps. Se above
	Previous visit	Before installation, what have you done to check-up home connections?	We decided to do a previous visit to know how devices must be connected and what is needed (cables, power strips, additional sockets, etc.). It is important to minimize the time spent at patient's homes the day of installation	We have had a stock of different things necessary to the installations (cables, power plugs, sockets, etc.) with us when we go to the elderly. We take a pride in making the installation phase as non-intrusive as possible.	We made home visits to make sur if the network is working properly.	In a previous visit we check to know how devices must be connected and what is needed (cables, power strips, additional sockets, etc.). Through this procedure it is possible to reduce the error sources and the overhead (time)	We made a visit to explain the project and to know how devices must be connected and what is needed.	We checked with network provider who already had connection. For those who didn't had any a order was made.
	Consent with relative/ tutor	Have you contacted with a relative or family member in order to know if they agree with the equipment installation and reassure the project's enrollment?	Yes, it is important to let relative members participate in the whole set-up process in order to obtain	This is done seperately from case to case. Some participants does not have any relatives and others have relatives who would like to use the videoconference solution.	If the relative is present on the installation, it was important for them to participate.	Yes, it is very important to make sure that relative members canparticipate in the whole set-up process in order to obtain. It is important too that the GPs will be integrated in the whole procedure.	yes	We made a request if a supporting relative was wanted to participate'
	Composition of implementation team	Who carries out the implementation?	In our case 1 technician coordinator of our organization + 2 persons of our healthcare team (SALUD) + 2 persons of the technological partner (TB·SOLUTIONS)	Collaboration between two persons from RSD and one person from Langelands healthcare team (project nurse)	We had group of three people - 2 at site and one who was solving techical issues with His and putting devices together.	In the moment a technician of our organization and 1 person of the heathcare team. Our hope is, that some day the installation could be so easy that the user can do it for himself	In our case a person of our healthcare team and two persons of the technological partner.	Social service and Medical Engineering in cooperation.
	Installation time	Time spent during installation	2 installations during 2-3 hours per day	Approx 1.5-2 hours per installation.	2 installations during 2-3 hours per day	The complete installation lasts averagely 3 hours per day	2 hours for ADSL connection, 1 hour for ADSL router installation, 3 hours for DREAMING devices installation.	About 2 hours per installation.
	Calibration	When will you do calibration of equipment and measures?	At this moment, we are studying this.	No decision yet, but this will be a task to be discussed soon.	At this moment, we are studying this.	We wait for the first results of Mambo	We did it.	No plans for the moment but this is a question for regular maintenace plan
								Engineering Dep to determ.

	Issue	Description	Spain	Denmark	Estonia	Germany	Italy	Sweden
Test group	Participants	How many patients participate in the test group?	40	16 (more to be included)	19 at the moment	30	30	18
	drop-outs	How many persons have decided to leave the project and for which reasons?	4: 2 of them didn't meet the inclusion criteria anymore, 2 not interested	6: 2 dead, one entered a nursing home, 3 not interested		1, dead	4: 1afraid of ”radiations” + 1 dead+ 1 moved to another city+ 1 personal reasons	4: 1 dead, 1 have moved to elderly home before installation. 1 drop out because of medical reasons and 1 was not interested any more.
Control group	Participants	How many patients participate in the control group?	40	15 (more to be included)	26 at the moment	30	30	19
	drop-outs	How many persons have decided to leave the project and for which reasons?	1, dead	7: 4 dead, 3 not interested anymore (partly because of medical reasons)	2, dead	1, dead	5 : 2 dead, 3 personal reasons	3: 2 dead, 1 wasn´t interested when she was randomised into the control group.

	Issue	Description	Spain	Denmark	Estonia	Germany	Italy	Sweden
Software	Integrated with IS	Does the Dreaming software (portal) will be integrated with the Information System of your organization?	Yes, but the integration is a pending issue yet	Not during the project phase, but will likely be an issue after the project end. The nurses are using it in their daily routines.	Yes, but the integration is a pending issue yet	Yes, but we wuse a very famous new one, the Vita-X patiant record	No.	Not nessesary for project phase.
	Local portal	Do you envisage to create a local portal in your organization?	Yes. It has been agreed to use during the first 6 months the server located in Germany, but later we will install a local portal in our Information System (at Barbastro).	No	We have installed local portal	Yes. It has been agreed to use during the first 6 months the server located in Germany, but later we will install a local portal in our Information System (at Barbastro).	No.	No
	Access from hospitals (Specialized Care)	Do specialized professionales have access to the portal?	Yes. Until Integration, they have access to the portal with their own password.	If needed, the nurses will commuicate with the hospitals, but noone in the hospitals have access yet (hasen't been necessary).	Yes, they have access to the portal with their own password.	Yes. Until Integration, they have access to the portal with their own password.	Yes, they have access to the portal by their own password.	If, data is needed for transfer we use our EHR system covering whole county.
	Access from GPs and nurses (Primary Care)	Do GP's and nurses have access to the portal?	Yes. Until Integration, they have access to the portal with their own password.	Yes. They have their own password.	They dont have access to the portal	Yes. Until Integration, they have access to the portal with their own password.	Yes, they have access to the portal by their own password.	Yes.
	Access from social services	Do workers of social services have access to the portal?	None social services have been involved yet.	Not so far, but this will most likely happen within the next couple of months.	None social services have been involved yet.	If neccessary, yes	None social services have been involved yet.	Yes.
Sensors	Nature of sensors choosed for the pilot site	Does the nature of your organization has an influece on the use of medical sensors or domotic sensors? Say why	Yes. In our case as we are a healthcare organization, we have decided to use mainly medical sensors because it is important to validate from the clinical point of view.	Yes. In our case as Langeland's prevention centre is a part of the municipal's healthcare organization, they have decided to use mainly medical sensors because it is important to validate from the clinical point of view.	Yes. In our case as we are a healthcare organization, we have decided to use mainly medical sensors because it is important to validate from the clinical point of view.	No, it depends of the individual demands of the participant	certainly yes, since we provide home care in the whole city/community. Our public Health Authority has the specific commitment to organize this service providing facilities that can improve the system and the quality of care (consequently also QOF of subjects)	In our case, both professionals from medical and social sides have had impact in the project.