

# **Deliverable - 3.1**

DATE	29 Mai 2015
VERSION	V1.1
PRODUCTION LEADER	H&S



COLLABORATOR	CST, CYB,WU, UREN, Viveris
--------------	----------------------------

IDENTIFICATION	
PROJECT	PhysioDom-HDIM
PROJECT NNO	620992
CALL IDENTIFIER	CIP ICT PSP-2013-7
WORK PACKAGE	WP3 – Pre-Pilot Execution
DELIVERABLE	D3.1 – End-users needs report
TASKS INVOLVED	T3.2 – Take part in evaluating local needs for the main PhysioDom-HDIM
	services
	T3.8 – design and writing of the outline for the summary report given to the
	Pilot site
	Type of home installation and computing environment
STATUS	OK for dissemination

PARTICIPANT		
ORGANIZATION	H&S – Paul Pilichowski , Marit van Bakel, Gérard Duru,	
ORGANIZATION	CST – Esther Gimenez Perez, Ramon Roca Puig	
ORGANIZATION	CYB – Daniel Heery	
ORGANIZATION	WU – Marije Vanatten, Annemien Haveman	
ORGANIZATION	UREN – Monique Ferry	
ORGANIZATION	Viveris – Patrick Meidenger	

DISSEMINATION	
EC	For EC

SUMMARY	
	End-users needs report – V2
	Complete achievement + Metrics to assess project progress (Indicators) +
	Details of the end-users needs studies

CONTENTS
CONTILITIE



## Table of contents

PHYSIODOM-HDIM - WP 3 - D3.1- END -USERS NEEDS REPORT	5
GENERAL POINTS	5
Tasks involved in writing D3.1	
Plan for the D3.1 report	5
Distribution of tasks among the four WP leaders	5
Introduction	6
I - SCHEDULE OF THE ACTIONS FOR THE NEEDS SEARCH	7
II - SETTING OF THE THREE PILOT SITES —	8
TERRITORY, GENERAL ORGANISATION, PLACE OF THE PILOT IN THE HEALTH ORGANIZATION OF THE COUNTRY	8
II.1 - The Nederlands	8
II.2 - United Kingdom	10
II.3 - Spain	15
III - EXPRESSION OF THE NEEDS REGARDING THE TYPE OF SERVICES TO BE OFFERED PHYSIODOM-HDIM	
III.1 - Issues	22
III.2 – Methodology	23
III.3 - Results	24
III.4 - Discussion	1
IV - DEVICES – THE CHOICES FOR THE PROJECT	2
IV.1 - The end user TV	2
IV.2 - TV-box	2
IV.3 - Devices provided	3
IV.4 - Global structure of PhysioDom service	6
IV.5 - Software provided	6
IV.6 - Back office	11
V - Organisation	12
V.1 - The Organization during the project	12
V.2 - The objectives	13
V.3 - Implementation in four different levels	13
V.4 - The Pilot Site	14
VI - THE REQUIREMENTS IN RELATION WITH THE HOME HEALTH RECORD - HHR	20
VI.1 - The requirements for the shared file - Home Health Record –HHR ®	20
VI.2 - What the current HHR will not be able to do	22
VII - EVALUATION STUDIES	23



VII.1 - The three studies	23
VII.2 - Clinical Impact Study design	24
VII.3 - Acceptability/usability study	28
VII.4 - Cost effectiveness study	28
VII.5 - References	29
VIIII - INDICATORS	30
VIII.1 - Table of the Indicators	30
VIII.2 – Details	32
ANNEXE 1 – DETAILS OF THE END USERS NEEDS STUDIES	37
PhysioDom-HDIM - 2014	38
PhysioDom – Vercors-Santé – 2011	44
PhysioDom – Vercors-Santé – 2005	46



## PhysioDom-HDIM – WP 3 - D3.1- End –Users needs report

## **General points**

In deliverable D3.1 (H&S + Pilot Sites) —Report on the End-users' needs — we will describe the needs in terms of : Services and Devices requested, Organisation on the Pilot Sites, Home Health Record content, Evaluation study design.

### Tasks involved in writing D3.1

- T3.1: Pilot site management
- T3.2: For each Pilot Site Participation in evaluating local needs for the main PhysioDom services calendar management, home services delivery, messaging and HDIM services
- T3.8: To be shared among the Pilot Sites Summary report to assess the type of users, the tools and services to be deployed first appraisal.

## Plan for the D3.1 report

### Introduction

- Schedule of the above mentioned tasks fulfilled since the beginning of the project
- Setting of the three Pilot Sites Territory, General organisation, Place of the Pilot in the Health organisation of the Country
- Main tasks and results concerning
  - The main requested <u>services</u> offered by PhysioDom-HDIM
  - The tools and the <u>devices</u> to be used in the project
  - o The organisation to be deployed first approach
  - o The content of the HHR
  - The study design content

## Distribution of tasks among the four WP leaders

	D3.1						
	I Schedule	II Pilot setting	Expression of needs – main chapters				
			III Services	IV Devices	V Organisation	VI HHR	VII Study design
CST							
СҮВ							
WU							
H&S							

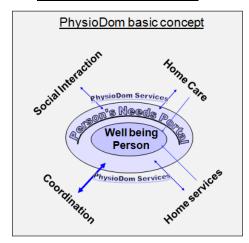
Table 1 - Tasks shared between the four leaders of WP3



### Introduction

The study on needs was conducted in several stages:

- <u>A re-reading of the DOW</u> - Section B1 . Relevance, for memory to recall:



O The EU policies on active and health ageing of older people, well displayed through the work produced by the European Innovation Partnership on Active and Healthy ageing - EIP-AHA - November 11, and which served as a basis of consideration in defining the 2013 CIP ICT PSP Programme and particularly the Theme 3 – ICT for health, ageing well and inclusion.

The requests should be located in this domain

- The basic concept of Physiodom is based on three major convictions:
- the person at home should be able to post all of his/her needs somewhere in order to coordinate and facilitate home services;
- to coordinate home services with efficacy, reliability and relevance implies knowing the current status of local supply and demand around the clock;
- home and remote home services must be organized as a network, set up in a country-wide planning approach.
- A re-reading of the study realized during the 'Réseau Vercors Santé' project
  (Vercors Health Network) ICT platform with the aim to connect home services
  with health and social professionals.

The needs expressed in this project concerned the basic services: sharing data among professionals, personal agenda management, electronic messaging and remote monitoring of the delivery of home services.

- <u>A study carried out in each pilot site</u> on (See Table 1):
  - the type of services to be put in place for the beneficiaries and the professionals;
  - the organisation of the homes with the different devices communicating with the TV;
  - the structuring of the pilot sites in order to organise the PhysioDom-HDIM services on the basis of the ICT use;
  - o the desired configuration of the shared record Home Health Record;
  - the specific needs generated upon the evaluation of the usage, the efficiency and the cost-benefit ratio



## I - Schedule of the actions for the needs search

2014 / 2015	Who	What	Tasks	
		DOW – B1.1, B1.3	Kick-Off	
		RVS study	Consideration of the DSD (French HHR)	
			Kick Off meeting	
		Shared Dietary Book	Basic Dietary and	
			Activity Prescriptions	
			Visit (H&S) of the three	
	Pilot Sites	Discussions on the need	Pilot Sites. Meeting	
	r not sites	for the basic and	with end users to carry	
		specific HDIM services,	out user needs analysis.	
		the design study	Pilot Sites Meeting in	
March / August			Paris	
			Web Presentation of	
			two versions of the HHR	
			Comments from the	
			Pilot Sites	
	Technical Partners		Face to face / Video	
		Discussions on the	meetings	
		needs as regards the home equipment, HHR content,	Presentation of the	
			versions of the HHR-	
			HOME and HHR-PRO	
			Comments from the	
			Partners	
		First synthesis	First release D2.1	
	All Partners	PMB meeting -	Changes on needs as	
September / October		Grenoble	regards the dietary	
September / October		Grenosie	prescriptions	
			Last release of the D2.1	
		Last synthesis	– Functional	
			specifications	
December / January	Pilot Sites + H&S	Writing / Publication of D3.1		

Table 2



## II - Setting of the three Pilot Sites -

# Territory, General organisation, Place of the Pilot in the Health organization of the Country

Each pilot site operates in a complex system of health and social care and this section explains the main actors and their roles. One of PhysioDom's greatest challenges is taking a common system and integrating it in each of the pilot areas.

## **II.1 - The Nederlands**





### II.1.1 - Context PhysioDom project

The pre-pilot will be executed among home care clients of care organization Zorggroep Noordwest-Veluwe (ZNWV), living in the municipality of Nunspeet. The pilot will be executed in a larger area and includes clients from ZNWV living in the municipalities Nunspeet, Harderwijk, Ermelo, and Putten. This region will further be indicated as 'North-West Veluwe'.

## II.I.2 - Local Health System

Until the end of 2014, two policy acts regulated the financing of the chronic care for the Dutch elderly, namely the AWBZ (Algemene Wet Bijzondere Ziektekosten / General Act Special Care Costs) and the Wmo (Wet maatschappelijke ondersteunining / Act Societal Support).

- The AWBZ includes financing nursing care, personal care (e.g. bathing, hygiene) and treatment (e.g. occupational therapist, physiotherapist) and is regulated via the national government.
- The Wmo includes financing domestic care and providing aids (e.g. wheelchair, meals on wheels, transportation). This is regulated via the municipality.

However, from 2015 the government has drastically reformed these laws. Three acts have replaced the AWBZ and the Wmo:

- A new Wmo act has replaced replace the former one. The municipality regulates more types of care than in the past (treatment and daily support).
- The Zorgverzekeringswet (Zwv) / Act health care insurance, which includes nursing care and personal care at home. This is regulated and financed by health care insurance companies. The act also includes financing of the district nurse: from



2015, every Dutch citizen has the right to receive care from a district nurse (financed by the Zorgverzekeringswet), as long as there is a proper indication.

- Wet langdurige zorg / Act chronic care (WIz) has replaced the AWBZ.

The focus of ageing policies is to let elderly citizens age in their own homes, in a responsible way with increased efforts of informal caregivers. The reason for this is to reduce health care costs, as the Netherlands has a relatively large proportion of elderly living in institutions, as compared to other Western countries. Thus, the government currently propagates 'ageing in place', and care for the elderly will predominantly take place in the community.

Along with these new acts and focus on ageing in place, the budget for health care will be cut down. Municipalities and care providers thus face the challenge of organizing health care in a new way with a reduced budget. In this changing context, the Physiodom project will be implemented. On the one hand, this can be an obstacle in implementation as municipalities and care providers face organizational change and instability. On the other hand, the Physiodom project can go along with these changes and prove its value in this changing context. For example, as the health care budget is cut down while the proportion of elderly citizens is growing, new ways should be found in providing cost efficient health care. An E-health application like PhysioDom could possibly contribute to this.

Care organisation of the Dutch Pilot is outlined in § - Organisation



## **II.2 - United Kingdom**





## II.2.1 - Overview of Organisations and their role

- The UK health service was resturctured in April 2013 see Fig 1
- In practical terms (for the PhysioDom project) the local structure is shown in Fig 2
- The social care services are delivered via Cumbria County Council see Fig 3

### The Secretary of State for Health

The Secretary of State for Health has ultimate responsibility for the provision of a comprehensive health service in England and ensuring the whole system works together to respond to the priorities of communities and meet the needs of patients.

## The Department of Health

The Department of Health (DH) is responsible for strategic leadership of both the health and social care systems, but will no longer be the headquarters of the NHS, nor will it directly manage any NHS organisations.

### NHS England

Formerly established as the NHS Commissioning Board in October 2012, NHS England is an independent body, at arm's length to the government. Its main role is to improve health outcomes for people in England. It's activities are:

- provide national leadership for improving outcomes and driving up the quality of care
- oversee the operation of clinical commissioning groups
- allocate resources to clinical commissioning groups
- commission primary care and specialist services

## Clinical commissioning groups (CCGs)

Primary care trusts (PCTs) used to commission most NHS services and controlled 80% of the NHS budget. On April 1 2013, PCTs were abolished and replaced with clinical commissioning groups (CCGs). CCGs have taken on many of the functions of PCTs and in addition some functions previously undertaken by the Department of Health.

All GP practices belong now to a CCG and the groups also include other health professionals, such as nurses. CCGs commission most services, including:

- planned hospital care
- rehabilitative care
- urgent and emergency care (including out-of-hours)
- most community health services



- mental health and learning disability services

CCGs can commission any service provider that meets NHS standards and costs. These can be NHS hospitals, social enterprises, charities, or private sector providers.

However, they must be assured of the quality of services they commission, taking into account both National Institute for Health and Care Excellence (NICE) guidelines and the Care Quality Commission's (CQC) data about service providers.

Both NHS England and CCGs have a duty to involve their patients, carers and the public in decisions about the services they commission.

### Health and wellbeing boards

Every 'upper tier' local authority is establishing a health and wellbeing board to act as a forum for local commissioners across the NHS, social care, public health and other services. The boards are intended to:

- increase democratic input into strategic decisions about health and wellbeing services
- strengthen working relationships between health and social care
- encourage integrated commissioning of health and social care services

Also read the DH's guide on Health and wellbeing boards.

## Public Health England

A new organisation is also being created; Public Health England (PHE) will provide national leadership and expert services to support public health and will also work with local government and the NHS to respond to emergencies. PHE will:

- coordinate a national public health service and deliver some elements of this
- build an evidence base to support local public health services
- support the public to make healthier choices
- provide leadership to the public health delivery system
- support the development of the public health workforce



## II.2.2 - The Health & Care system

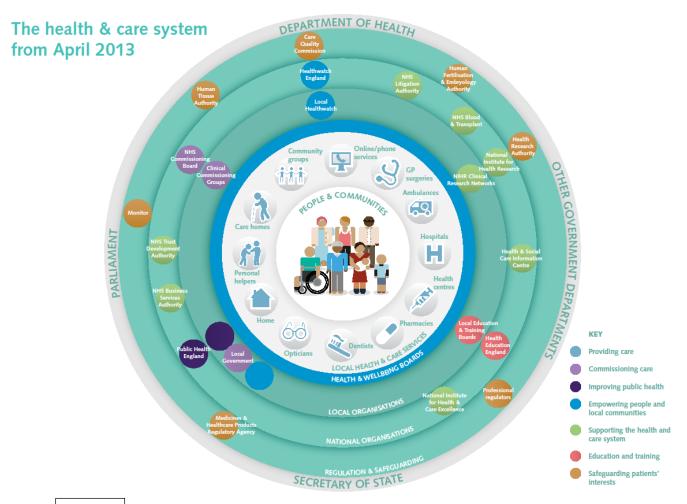


Fig 1



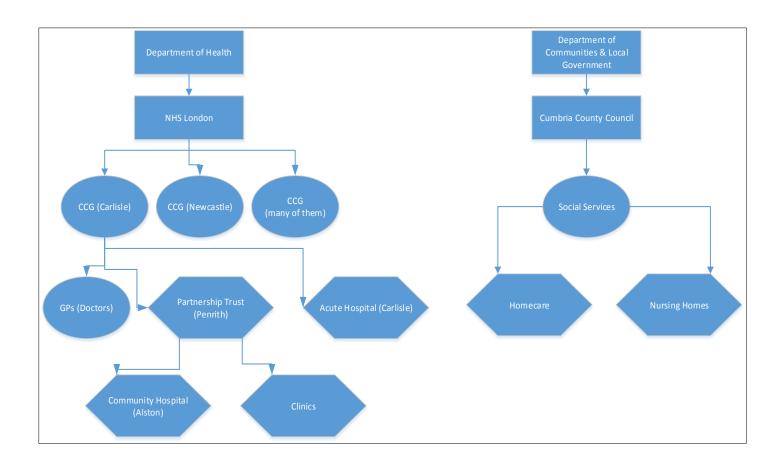


Fig 2



### http://cumbria.gov.uk/healthandsocialcare/adultsocialcare/default.asp

### **Adult Social Care**



## **About Adult Social Care**

What is Adult Social Care, and useful background information



### **Information and Advice**

Cumbria Support Directory, advocacy, publications, easy read information



### Getting Support from Adult Social Care

Eligibility criteria, making a referral, applying for a blue/ car badge, etc.



### **Short Term Support**

Prevention (e.g. community meals, equipment) and short term support (e.g. reablement)



### **Long Term Support**

Support at home, extra care housing, care homes, end of life care, etc.



### Costs of Care and Support

Costs of care and support, including information for self-funders



### **Support for Carers**

Help and support for people who care for others



### **Staying Safe**

Preventing abuse and promoting safety, including how to report adult abuse or harm



## **Health and Wellbeing**

Heath services, continuing healthcare, coming out of hospital, mental health services, etc.

Fig 3

Care organisation of the English Pilot is outlined in § - Organisation



II.3 - Spain



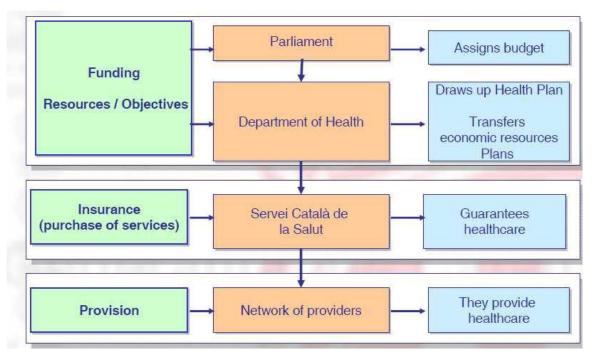


## II.3.1 - Overview of the Catalan health organisations and their role

There was a Social Security reform in 1977 with the separation of economic services from healthcare services. In 1981 there was a process of decentralization and a transfer of responsibility for regional healthcare to the Catalan Autonomous Government "Generalitat"

Catalonia has a public health budget of 7.952 M € for a 7 M population and its own organisational structure. It is decentralized from the central government and funded by taxes. It has universal coverage and free access of a very wide range of publicly covered services. It also has a co-payment system in pharmaceutical products. Services are provided mainly in public facilities.

Funding resources and global scheme of funding, health managers and providers.



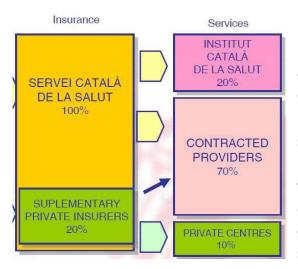
Also an involvement of Interterritorial Boards and Civil society participation.

### II.3.2 - The catalan health care system

Servei Català de Salut is providing the funding to the Service providers. 20% of Service providers belong to the public sector (ICS Institut Català de Salut) and 70% are contracted providers. GENERAL DIAGRAM OF CATALAN HEALTH CARE SYSTE



There are 68 hospitals (public healthcare providers) in Catalonia, 12 are State hospitals



(Catalan institute of health), 18 are private foundations or Council societies, 19 are public consortiums, 11 private companies, 5 Insurance Hospitals and 4 Church Hospitals. Catalan Government is providing the funding to the health Catalan system through the CatSalut Agency to all public providers (state providers such as the Catalan health institute (ICS), and other public providers such as CST or other private services contracted to give service to the public system.



CST is a contracted public provider, it is a public institution but does not belong to the Catalan health institute (ICS)

## III.3.3 - Primary care centers in Catalonia

The teams are formed by a GP (family doctor), a pediatrician, a dentist, a nurse and a social worker. In CST there is also a Nutritionist including 6 CCP and 1 hospital. The



team is lead by a medical doctor coordinator and a nurse coordinator. The team is providing services to 5000 to 25.000 inhabitants.

1GPs / 1 Nurse 1500 inhabitants

1 Pediatricians/1 Nurse1 Dentist1 Social Worker1200 inh11000 inh25000 inh

Depending of the kind of service the teams can vary in composition, Ex: Homecare (Social Worker, GP or Pediatrician, Nurse, Dentist)

Chronic Care (All the Team + Call Center + Nurse Liaison + Coordination ...) Community Care (All the team, community agents community plan)

## Basic Health Area:



- 1 or more teams
- Homogeneous features:
  - Demographic
  - •Geographic
  - -Social
  - Epidemiologic
- Primary Healthcare Centre: Building



- 1 or more teams
- Teams share facilities
- Team: Multidisciplinary Team



- In 1 or more buildings
- Common goals



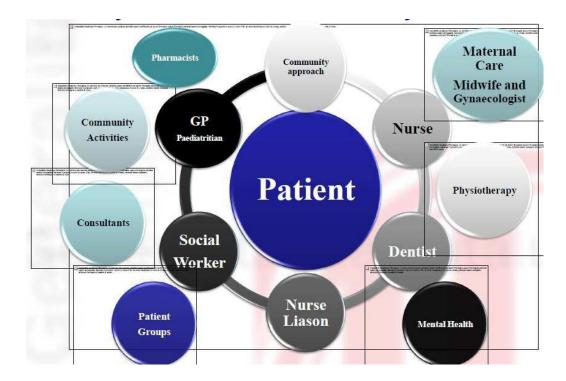
All of the health care system is patient oriented and involves GPs, nurses, social worker, dentist and pharmacist. Also some additional social service requirements are detected by the health system but provided by other

organizations such as Councils or private social services providers.

The health care system has also community liaisons, contact with patient groups and organizes community activities.



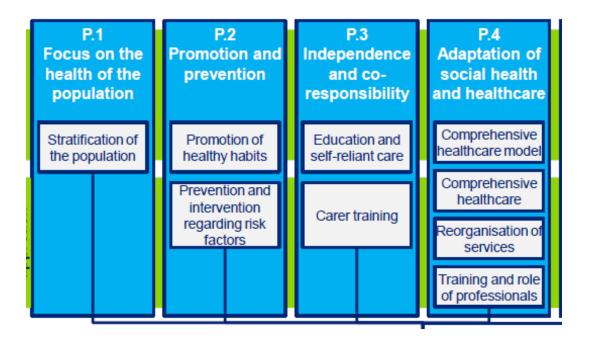
620992 - PHYSIODOM-HDIM D3.1



There are several activity levels of health care coordinated from the Primary health care centers and focused on the patient.

- P.1 There is an IT tool managing all the data of the population, able to stratify the population depending on different degrees of illness or dependency based on CRGs.
- P.2 There is also a level promoting prevention and health habits and which fits very well with PhysioDom.
- P.3 There is a level related to education and self-reliant care, and care training. This part also matches PhysioDom purposes.
- P.4 There is a level of adaption of social care allowing reorganization of the services and training the professionals to adapt the way care is provided in specific areas.





# II.3.4 - Social healthcare and geriatric care <u>in</u> Catalonia Health System

Since the recent reforms in the Spanish public health system came into effect, home care has become the responsibility of primary health care teams. Home care definition is not based on a specific disease but arises instead from bio psychosocial circumstances such as the patient's inability to leave the home. This may be the reason why home care varies depending on the disease, social circumstances or emotional state of both the patient and the care provider. Most centers in Catalonia offered home care and the staff members responsible for the program were

TABLE 1	Protocols used most often in home care			
Protocols		PCTs using the prote		
Pressure :	sores	69.1%		
Terminal i	Iness	43.6%		
Bedridden	l)	41.8%		
Pain		40.9%		
Constipati	on	38.2%		
Feeding		30.9%		
Home axy	gen therapy	29.4%		
Dementia		23.6%		
Catheter		7.2%		
Grieving	II.	2.7%		
Incontiner	IC8	2.7%		
Partial par	alysis	0.9%		

nurses (53.3%), physicians (20%), both (11.1%), or other professionals (15.6%), being nurses the professionals devoting more time, on average, to home care programs (Nurses (5.09 h) physicians (2.85 h) and social workers (2.65 h)). A social worker was included in the team at 70% of the primary care centers (PCC). Half of the centers provided education in home care training (66%), that should form part of periodic training activities at all PCCs.

The main difficulties running the home care from the primary centres were: 65.2% noted burden of care,



51.8% noted insufficient time,

43.8% mentioned inadequate social support,

33% cited lack of coordination with other levels of care.

### Social healthcare and geriatric care in CST PCC

Social healthcare is part of the services offered by the organization, which coordinate or integrate in-house healthcare and social services to assist both health and social need simultaneously as they are generated by specific individuals.

The progressive aging of the population and the combination of multiple chronic pathologies have increased the demand of these types of services in recent years.

The social health services and dependency care services directed to:

- Elderly people with multiple pathologies
- People of all ages with chronic progressive diseases (respiratory, neurodegenerative, etc...)
- along with functional dependency.
- people with dementia (Alzheimer or others)
- People with terminal illness. (Palliative Care).
- Anyone with autonomous limitations that require social healthcare.

### II.3.5 - Social services at Terrassa Council

Social Services in Catalonia are not managed through the Catalan Health Organization and the management is carried out through local private or public entities. In Terrassa most part of such services are provided by Terrassa Council. **The Council of Terrassa** has resources allocated for social services and is in charge to deploy the social services plan to the community including elderly people. Being Terrassa (215.000 h) city has a wider range of social services and a important level of organization. Small towns like Matadepara (8.774 h) has a less sophisticated structure with fewer social services. This plan has several sections, and the most relevant to elderly people are described below.

The Social services <u>in Terrassa</u> are organized by areas and are located at the civic centers of community centers in different districts and the team is composed by: Administrative / Social Educator / Social worker

Initially there is the detection of the Social Service need. The detection can be achieved by direct request, interview request or also can be detected by doctors or nurses at the primary health care center or hospital through the social worker at these centers.

The aim of the Social Services in Terrassa is to ensure equal opportunities and welfare for all people living in the city through universal access to welfare services through



personal and individualized attention. This personalized attention has the goal to optimize resources and to ensure everyone can access the same benefits provided. The aim is to work towards a model of inclusive city where access to welfare for all possible citizenship is guaranteed.

- Detection and prevention of risk or exclusion / Receipt and analysis of social demands / Information, guidance and counseling.
- Processing and monitoring of programs and services that require intervention
- Community social work.

### **Basic Services**

Provide basic social services, primary care to citizens with immediate needs, with generals and basic needs.

### Home help service

This provides an organized and co-ordinated set of actions performed at the user's home, aimed at providing personal care, urgent help in the home and social support to individuals or families in a situation of lack of personal autonomy, difficulties development or family problems including elderly people.

This service is intended for people or families that are, for physical reasons or social situations of lack of to perform routine tasks of daily life after a preliminary assessment of professional or professional basic social services, responsible for monitoring every case.

Services offered: Home telecare / Food at home / Cleaning home / Volunteering / Technical aids for dependent people's autonomy be that either temporary or permanent. The service provides staff.

### **Support services**

Care for groups at risk of exclusion or vulnerability treating each case with the development of a **specific intervention plan**.

**PUMAD** (Disability and handicap services)

Advice, information, counseling services, resources, performance to improve care for the disabled both affected family members or caregivers, etc..

Care organisation of the Spanish Pilot is outlined in § - Organisation



## III - Expression of the needs regarding the type of services to be offered in PhysioDom-HDIM

Assessing the needs in each pilot area was a process which began in Spring 2014, with each pilot site carrying out consultation with potential end users (patients, medical staff and social care staff). The PhysioDom system had already been used extensively in France and this project was not resourced to carry out a full redesign of the system. This was an extension to the existing system to accommodate dietary intake monitoring functionality and so it did not permit a full range of user needs analysis. However, within the scope of the project, consultation took place with a range of stakeholders to understand their requirements.

### III.1 - Issues

## Overview of the System

PhysioDom-HDIM is an innovative ICT solution that aims to enhance living conditions for senior citizens, as well as to improve the efficiency and integration of health and social care systems. The PhysioDom-HDIM system has been developed based on a small French pilot, the Réseau Vercors Santé project (RVS), which successfully trialled the system in 50 homes and engaged 70 health and social care professionals. The pilot was run over a two year period and delivered positive results and acceptance by its users. It now needs to be validated on a larger scale as part of an e-Health approach that involves all of the players - from institutions to end-users at home. The evaluation of the Vercours system and the needs expressed by end users were incorporated into the initial designs for PhysioDom.

The system will use an observational approach and analysis of daily living to monitor weight, lean/fat ratio and physical activity. The study population will be senior citizens (aged >65) who are active, in a state of pre-frailty or frail health, dependent and/or having a chronic illnesses, such as heart failure, diabetes, high blood pressure, or receiving chemotherapy treatment. (See part - VI).

### Research

More and more research confirms the central role of an adequate diet and a reasonable level of physical exercise in (the maintenance of) good health and wellbeing. To address this issue, a new key component has been added to the PhysioDom system - a lifestyle coaching system called Home Dietary Intake Monitoring (HDIM). This system now gives personalised advice on dietary intake and physical exercise levels. This is based on individual needs and it monitors user compliance with these recommendations.



## III.2 – Methodology

### **Qualitative Research**

The methodology to assess user needs was first to hold meetings and understand the needs of the potential beneficiaries in each of the pilot areas, from both professionals and end users. This was a series of conversations that highlighted potential problems in their daily lives that the system could address (see Annex 1) for details of the meetings.

This allowed the teams at the pilot sites to identify potential "champions" (those who are enthusiastic about the idea) and "blockers" (those who will not engage and potentially aim to impede the project). While it was important to engage with the latter group, from experience it is far more productive to engage with the champions who are more co-operative and willing to give feedback.

To meet these requirements, PhysioDom-HDIM must deploy services meeting the local needs expressed by the stakeholders as close as possible. However, from experience with the RVS study we know that it is very difficult for professionals to express their requirements, as they lack the knowledge of potential ICT solutions used for care at home. In the UK pilot, a number of health based ICT projects have struggled to engage staff and have been perceived negatively, so professionals are sceptical of technical solutions which purport to solve problems.

The results of the interviews showed that there was a requirement to carry out more preventative work in weight management and prevention of undernutrition across all of the pilot sites. There was also an appreciation that technology could play a role, particularly in Cumbria, UK, where there are people living in isolated rural areas.

### Quantitative Research

Alongside the qualitative research into user needs, a simple survey to assess views, and comparable results between pilots was carried out:

- Based on the RVS + DOW;
- Six groups of services have been created Public Health, Basic services,
   Symptoms, Dietary monitoring, Dietary coaching, Other services;
- The needs concerning the services of these six groups are appreciated on the territory of each Pilot using a scale from 0 to 5;
- For each of the six groups we will evaluate the relevance between the actual needs requested by the Pilots and the components of Physiodom RVS + DOW;
- This relevance is expressed as a percentage;
- The results will be presented using a "radar" graph.

Home Physical Activity follow up needs

	physiodom®		D3.1  With regard to the PhysioDom-HDIM services, expression of needs  by the Pilot Sites taking into account the Public Health Politics					
For each Sympton we evalu by the P compon	ds are appreciated on the tent of the six groups -Public Hens, Dietary monitoring, Dietar uate the relevance between tillots using a scale from 0 to 5 ents of Physiodom expressed evance is expressed as a percessed as	alth, Basic services, y coaching, Other services, he actual needs appreciated (grey boxes) and the I in the DOW.	score	*	score	Needs on Terrassa	score	
			90%		95%		90%	
P u b	Healthy ageing politics in the (	See the Do <del>v</del>	5	Nutritional Wellbeing of the British population PIPP / Age UK	5	ENIDE / AESAN	5	Social Support Act, Public Health Act, National Program for Elderly Care (NPO). Focus of national healthy ageing policy: Elderl people should live in the community as long as possible, preventing living in an institution (nursing home). The district nurse assists community dwelling older adults in indepent living, health care and social care. It is the aim of the government that ICT applications assist older adults in living independently, enhancing levels of self-management and self-determination.
i c	Healthy ageing politics on the	See the Dow	5	Cumbria County Concil	5	Canal Salut	5	AGORA/GGD Noord-Oost Gelderland
H e a	Undernutrition problems		5	Yes - this is a priority for the project	5	Yes - this is a priority for the project	5	Yes, 11-35% of Dutch community dwelling elderly is undernourished (Schilp, 2012), in institutions even higher prevalences are observed However, in absolute number most of malnutrition exists in the community.
t h	Overweight problems		3	This is a priority in the territory but not for the project	4	This is a priority in the territory and you can see the effects of dietary	3	This is a priority in the territory but not for the project, as moderately overweight older adults do not have higher mortality risk (Hollander, 2012) and weight loss is only recommended in obese elderly suffering from chronic diseases from which symptoms can be diminished by weight loss. Undernutrition is priority; however promoting a healthy diet benefits both underweight and overweight older adults
			59%		44%		46%	
B	Health data sharing needs		1	Not a priority for the project as there are other systems in place to store data	1	Not a priority because we are a system connected  Not a priority because we are a system connected	3	Yes, priority of the government. However, caregives themselves may be less willing to learn to work with new systems to share data. There is a need for a closer connection and more collaboration between social care and health care.
s	Social data sharing needs Home Dietary follow up needs		4	Yes - important to provide data to the residents Yes - important to provide data to the residents	5	connected Yes - important	4	Petween social care and health care. Yes, as compliance to quidelines for a healthy diet is generally
۱ i		·						Yes combined nutrition and everoise intervention are most

Yes-important

4 Yes - important to provide data to the residents

Yes, combined nutrition and exercise intervention are most

promising in achieving beneficial effects



## Table 3

				<u> </u>	-			t
	Agenda	in terms of needs on the Pilot territory	4	Yes - important to provide data to the residents	3	Potentially	3	Yes, might be useful for informal and formal caregivers
5					4		4	Yes, important to provide additional advice and guidance in a
e	Message to Home	in terms of needs on the Pilot territory		Yes - important to provide data to the residents	<u>'</u>	Important		easy, quick way, saving time for professionals
1		in terms of needs on the Pilot territory		No - existing secure messaging already in place	1	We don't need we are conneted		Unknown, depends on needs of professionals
V	Home Physiological Data Mo	in terms of needs on the Pilot territory	3	Yes				yes
i		AP	4	Potentially	4	Potentially	3	Potentially
c		Pulse	4	Potentially	3	Pontentially	3	Potentially
ē		T·	2	Potentially	1	Not a need of care organization	1	Not a need of care organization
-		BG level	4	Potentially	1	Not a need of care organization	1	Not a need of care organization
S		Diuresis	2	Potentially	1	Not a need of care organization	1	Not a need of care organization
		others			1	Not a need of care organization	1	Not a need of care organization
			60%		60%		50%	
YON	Symptoms assessment	in terms of needs on the Pilot territory						
STREET CON.		Physiological	3	Yes-	3	Potentially	2.5	Not a need of care organization
7		Psychological	3	Yes-	3	Potentially	2.5	
			64%		68%		80%	
н	Home dietary monitoring	in terms of needs on the Pilot territory						
•		weight	5	Yes	5	Important	5	ues
		Lean/Fat	3	Potentially	3		2,5	potentially
. i .		ВМІ	3	Potentially	3		5	yes, also for establishing MNA-SF score
		Other clinical parameters	0		1		2,5	potentially
•		Questionnaires - MNA/SNAQ/						<u> </u>
' <b>'</b>		DHD-FFQ	5	Vh	5	l	5	yes, for comprehensive nutritional assessment
, i		DHD-FFQ	52%	Yes - plus potentially local questionnaires	00**	Important	40**	yes, for comprehensive nuclicional assessment
					60%		42%	
	Dietary Coaching - Ad hoc Sei	in terms of needs on the Pilot territory	l		_			
		Needs scoring for:		I'm not sure what this section is about	<b>+</b> -			
o C		Pro frailty	5		5		_	potentially
i °		Undernutrition	5		5		5	yes
e a		Dokydration	5		5		3,5	potentially
t.		Overseight	2		4		3,5	yes, but not the focus of the project
`h r a n		Minur cuquitive impairment	1		1		1	no, only background characteristic for research purposes
		Chronic pathologies	1		2		1	no, only background characteristic for research purposes
		Cardiac inrafficioncy - lovel I-II	4		4		1	no, only background characteristic for research purposes
, ,		Renal insufficiency	1		1		1	no, only background characteristic for research purposes
y		Hyportonrium (first phares)	1	l	2		1	no, only background characteristic for research purposes
y		Hypertenrium (first phares)						
У		After chemotherapy (> 1 month)	1		1		1	no, only background characteristic for research purposes
y 			<u> </u>		0%		1 0%	no, only background characteristic for research purposes



Table 4

physiodom <sup>a</sup>		Needs on Alston Moor	Needs on Terrassa	Needs on North-West Veluwe
Public Health		90%	95% 44%	95% 46% 50% 80% 42%
Basic services		59%		
Symptoms		60%	60%	
Dietary Monitoring		64%	68% 60% 0	
Dietary Coaching		52%		
Others Services		0		
	Others Services Dietary Coaching	50% Basic services  0% Symptoms  Dietary Monitoring	<ul> <li>Needs on Alston Moor</li> <li>Needs on Terrassa</li> <li>Needs on North-West Veluwe</li> </ul>	

### III.4 - Discussion

This study will focus on the planned offer of services in PhysioDom-HDIM, arising from the study carried out in Vercors and described in the DOW. It does not pretend to address all e-Health issues of the territories in the Pilot sites

The methodology may be criticized, as the same tools are used to compare Public health needs, service requirements - basic services, coaching, monitoring tools - Symptoms and Dietary monitoring.

Nevertheless the 'radar' graph explicitly shows the convergence between the theoretical offer of services in PhysioDom and the needs currently expressed by the pilots:

- The needs are comparable from one Pilot to another, the differences are not significant.
- The relevance between the PhysioDom-HDIM and "Public health" goals appear excellent for three Pilot sites.
- With regard to: "Basic Services", "Symptoms", "Dietary monitoring" and "Dietary coaching" the convergence between what can theoretical be offered in PhysioDom-HDIM and the expressed needs is estimated to be around 50%. These results are similar to those found in RVS, reflecting the difficulty for professionals to imagine the type of services that the ICT can offer for home care. If the same study would be repeated at the end of the project, the radar graph would probably have a higher coverage.
- No interest was shown in the category "Other Services". This was due to the pilots aiming to keep the scope of this project tightly focused on weight management.
   At the end of the project and even already at the end of the WP3, the result for this category may change as other services are identified e.g. diabetes management.

The main purpose of the Pre-Pilot study is to converge at best the actual needs of local stakeholders with the offer of tools and services. The next "radar" results - D3.2/D3.3 will allow to evaluate the progress made.



## IV - Devices - The choices for the Project

## The tools and the devices to be used during the project

All participants will receive the PhysioDom devices for the intervention as a part of an integrated care with includes the following components.

### IV.1 - The end user TV

The end user TV won't be provided but it is required and it is a very important asset for the services provided by PhysioDom. The end user TV will became a simple and user friendly Man Machine Interface (MMI) operated through a remote control. This MMI allows access to different PhysioDom services hosted by the TV box "S-Gate":

- Messaging from the remote home services or professionals.
- Personal agenda management.
- Monitoring of home services (Measurements, questionnaires, reports, symptoms)
- Plans (Healthcare, Activity plan, Social plan and Nutritional plan).

Research was carried out on alternative systems such as tablet computers, which could also deliver a service and be connected to a TV by HDMI cable. However, discussions with potential users lead us to feel that this would be less robust and lead to problems such as:

- Handling a tablet may be difficult and unfamiliar to many of the target end users.
- Unplugging the tablet and plugging it in again to the TV may lead to damage and a need to replace equipment.
- The picture may not render well on old TVs without HDMI cables.

### IV.2 - TV-box

The box is located in the end user home named "S-Gate". "S-Gate" can receive the data from wireless devices and transmit the information the data by 3G o ADSL to a "S-Server" where all medical data will be stored. "S-Gate" can also have a connection to the home TV to display specific data stored to the "S-Gate and S-Server"

The TV-box named "S-Gate" can also allow the introduction of manual data by a wireless Infrared remote control. Display will be through the TV.

- Podometer information
- Health status

Research carried out on the tablet computers, showed that they could deliver the same functionalities of TV box and be connected to a TV by HDMI cable. However, it was felt that this solution would be less robust, both physically and technically.



A bespoke TV box is more secure than a tablet and less likely to crash as the environment is fully controlled. It is more likely that a tablet would be handled and dropped or run out of power if unplugged. This would lead to higher support costs and visits to resolve problems with the equipment.

## Technical Features of PhysioDom TV box





- Acrylic casing
- B2120 rev D main board
- B2161 front panel
- Factory-flashed u-boot and BDTSW
- test SW
- Remote controller x1
- CVBS/Audio adapter cable x1
- YPbPr adapter cable x1
- HDMI cable x1
- Power supply x1
- No wireless adapter

Additionally, participants will receive two different dongles intended to provide proper connectivity to the system.

- o wireless USB Dongle Bluetooth 4.0 USB-BT4LE to connect devices
- o wireless USB Dongle 3G Huawei E3131H-2 USB to connect SIM card

### IV.3 - Devices provided

## IV.3.1 - Scale BCMCS -A&D uc-411pbt

The scale equipped with Bluetooth to transmit user's data live through the "S-Gate" to the PhysioDom server "S-Server". BCMCS measures as well the body fat and free fat masses of the user whose profile will have been configured beforehand (age, gender, height).





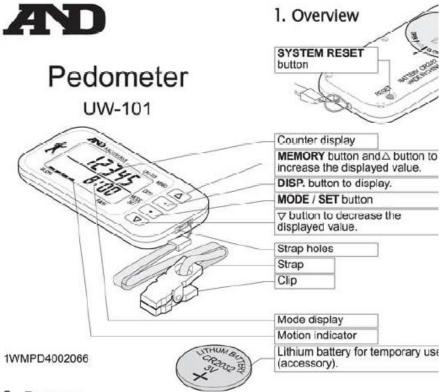
	Specifications				
Model	UC-411PBT-C				
Bodyweight	0-100 kg in				
Body Fat Percentage	5.0 - 50.0% in 0.1% units"				
Body Fat Percentage Judgment	Low / Normal / High / Very	High			
BMI	0.1 unit				
Basal Metabolic Rate	1 kcal/day unit	Target age			
Muscle Mass	0.1kg unit / 0.2 lb unit	18 and over*2			
Body Water	0.1kg unit / 0.2 lb unit	TO GITU OVE			
Communication	Bluetooth Ver.2.1 class 1 SSP HDP compatible				
Transmitted Details	Weight, impedance, body fat percentage, height, basal metabolic rate, muscle mass, body water, individual number, measurement time				
Setting Items	Unit: kg or lb				
	Individual number: 1-5				
	Age: 10-80 years of age				
	Sex: female / male				
	Height: 90-220 cm / 35-90 in in 0.25 in units				
Power Supply	Four type AA alkaline batteries				
Battery Life	Approximately one year (when alkaline batteries are used, assuming 5 measurements per day)				
External Dimensions	350 mm (w) x 350 mm (D) x 39 mm (H)				
Weight	2.3 kg (including batteries)				
Accessories Instruction manual, trial use batteries					

## IV.3. 2 - Pedometer A&D - UW-101b

Pedometer measurements will be taken manually by the beneficiary and entered to the system by a remote control through the TV box "S-Gate" to the PhysioDom "S-Server"







## 2. Features

- Displays daily data for the number of steps, walking distance, and calories burned.
- Equipped with the following functions:
  - A 3-axis accelerometer to detect motion.
  - A motion indicator to display the strength of walking and moderate jogging.
  - A mode to display walking distance in km and calories burned in kcal.
  - A memory function to store and display data for the last 14 days.
- When the pedometer is idle for one minute, the display turns off. If you start walking
  or press a button, the display turns on again.

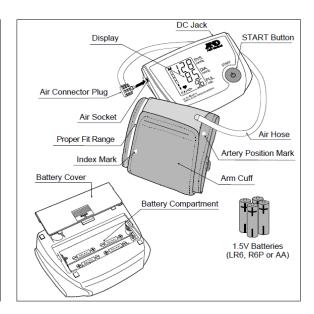
### IV.3.3 - Blood pressure monitor A&D UA-767PBT-CI

The BP monitor will transmit user's data live by Bluetooth through the TV-box "S-Gate" to the PhysioDom server.

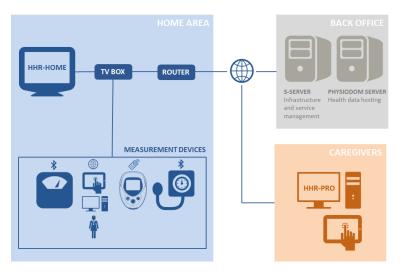




UA-767PBT-Ci Type Measurement method Oscillometric measurement Pressure: 20 - 280 mmHg Measurement range Pulse: 40 - 200 beats / minute Measurement accuracy Pressure: ±3 mmHg ±5% Pulse: Power supply 4 x 1.5V batteries (LR6, R6P or AA) or AC adapter (TB-233) (Not included) Approx. 450 measurements, when AA Alkaline Number of measurements batteries are used, with pressure value of 180 mmHg at room temperature of 23°C Internally powered ME equipment (Supplied by Classification batteries) / Class II (Supplied by adapter) Clinical test According to ANSI / AAMI SP-10 1987 IEC 60601-1-2: 2007 **EMC** Wireless communication WML-40AH (MITSUMI Electronics Co. Ltd.) Bluetooth Ver.2.1 Class 1 HDP SSF Continua certified +10°C to +40°C / 15%RH to 85 %RH/ Operating conditions 800 hPa to1060 hPa -10°C to +60°C / 15%RH to 85 %RH Transport / Storage conditions Approx. 147 [W] x 64 [H] x 110 [D] mm Dimensions Approx. 300 g, excepting batteries
Cuff Type BF ★ Weight Applied part



## IV.4 - Global structure of PhysioDom service



Global structure to be deployed developed and PhysioDom-HDIM during project is described in the picture below and will require also a software able to work with the user TV called HHR Home and a software able to work with professional computers and tablets called HHR Professionals. HHR

### Professionals has access to the

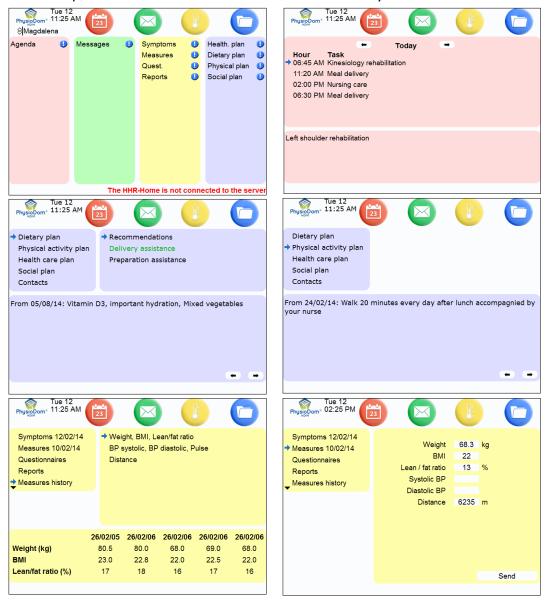
"S-Server" to display the data for professionals and send information to the users, and HHR home has access to limited information of the "S-Server" to be displayed on the user home TV.

# IV.5 - Software provided IV.5.1 - TV - HHR Home.

Participants will receive a TV channel on their television: Home Health Record-Home (HHR-Home) that allows to navigate throughout this TV channel with a remote control. The main functions of HHR Home are:



- Participants can view the results of self-measurements and will become aware of their weight, dietary intake (Dutch Pilot), nutritional status, and other parameters.
- Participants will receive feedback on their dietary intake and physical activity levels with advices how to improve compliance to guidelines for diet and physical activity.
- Care professionals can use HHR Home as a way of communication to the



participants.

- They can send messages to participants as part of regular care, e.g. tips to adhere to a healthy diet, special diet information, etc. Care professionals will be notified if a participant has opened the message.
- Adaptation of the Sirlan framework for HHR home to the load, and to the internationalization and localization imposed by the pilot sites.



### IV.5.2 - HHR-Pro

The first iteration of the HHR Pro was demonstrated to pilot sites in Spring 2014 and feedback was given from stakeholders in each site.

This new presentation was adopted for the next release of the HHR Pro system.

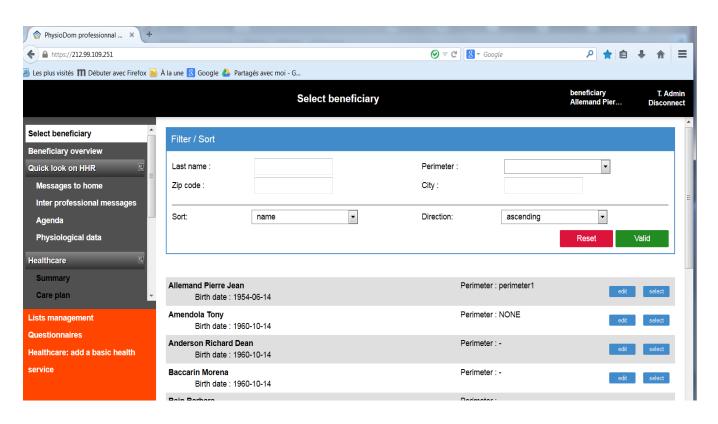
In Grenoble, a workshop was held with the pilot sites to go through each feature of the system to identify which elements could be removed to make it easier and quicker to use for professionals. In the UK social care workers have 15 minutes per user to carry out a range of tasks and so updates need to be fast and intuitive.

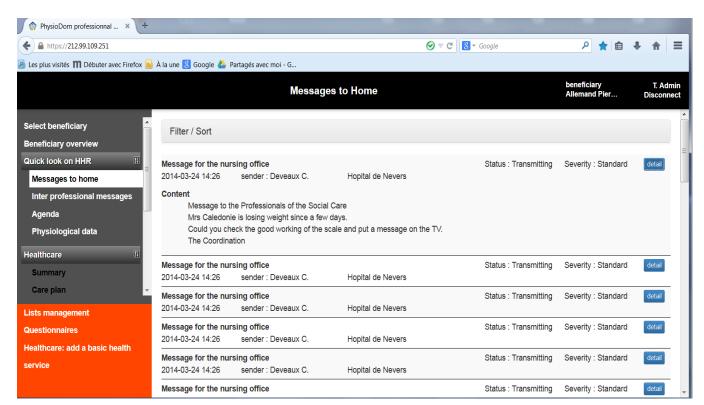
Some of the steps were removed after this workshop, despite a recognition that the data obtained would be valuable.

Authorized professionals of each organization involved in the health care of participants can access the telemonitoring system via software called HHR-Pro, which will be available on the PC or tablet. The main functions of HHR-Pro are:

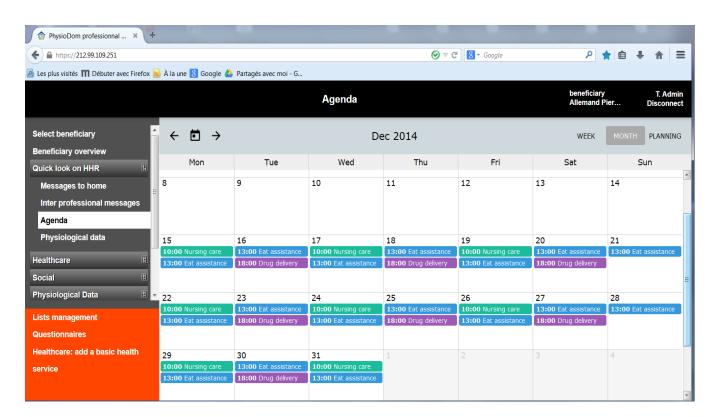
- Authorized professionals can view the participant's plan and results from the telemonitoring system.
- The professionals can define thresholds for each parameter that is monitored. They will do this individually for each client. Defining of threshold is preferably based on scientific literature. Thresholds for scores from questionnaires for appetite and nutritional status can follow the classifications that belong to that questionnaire. When parameters exceed the defined threshold value, the professional will receive an automated alert.
- The professional can define the desired frequency of self-measurements in HHR
  Pro for each client individually. This is based on the participant's health or
  nutritional status. According to that, reminders for self-measurements will be send
  to HHR Home.
- Improvements and changes to address needs detected during the pre-pilot phase.
- Improvements in reliability and security of the data exchanges between the TV box and the server in terms of local regulations.

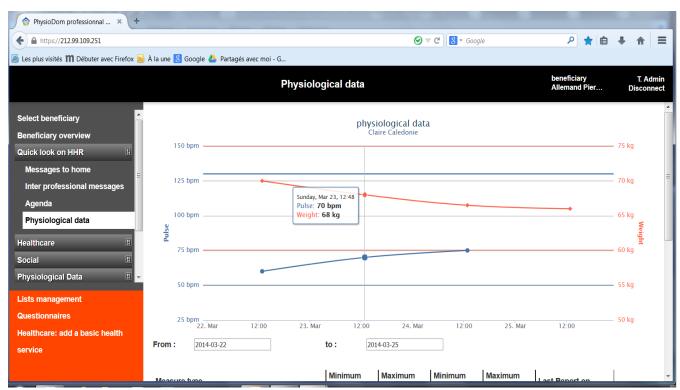














#### IV.6 - Back office.

A back office located on Internet and hosting "S-Gate" server for "S-Gate" device management, and a web portal for health professionals, allowing them to access to end user health data records (HDR). Two servers, the S-server and the PhysioDom server, will function as back office and will be used to securely store data from the telemonitoring system.

The Back office will be provided by an external provider with large experience in medical records storage.

The hosting healthcare applications:

- IDS hosts applications including personal health data.
- Home support dependents or hospitalized at home.
- Administrative delivery systems or training
- R&D

The infrastructure of IDS based on two server rooms, and connected by a dedicated optical fiber 10Gb. Each of the rooms is located in premises secured with RFID badge, alarm and video surveillance. Two rooms are located in the premises of the security company VITARIS with staff present 24h and providing remote monitoring. Both rooms have UPS and generator, with autonomies of 16 and 72 hours respectively.

All servers are dual power, each supply chain with its own inverter. Both rooms have air redundant conditioned. With the inter-fiber, both Internet access are visible from both rooms.

Private DNS servers redundant in both rooms, route the client requests on one or the other service providers using the DNS name resolution hosted domains. Access is provided by a firewall cluster at both sites. These firewalls are a DMZ in which are reverse proxies that help secure application servers and a network of association says which distributes the traffic and validated decrypted by reverse proxies to own networks to each client IDS or those dedicated to the operation of the infrastructure.

Each customer or customer group holds a second firewall cluster in different technologies grip firewalls, which guarantee inter-client sealing. If several customers coexist behind the same firewall, they are partitioned into separate virtual networks.

Applications can use two separate virtual networks. The private network receives the sites subject to constraints of the healthcare data hosting. It is accessible only from the private reverse proxy, which rout all unauthenticated access to authentication servers IDS infrastructure. An independent network allows you to make a backup GFS on a daily cycle day, week and month.



# **V** - Organisation

## V.1 - The Organization during the project

The telemonitoring system will be complementary to usual care and will be embedded within the care procedures of the health organization. It is the responsibility of the professionals of every pilot to employ the telemonitoring system properly (trained and supported by the research team), and to provide health care upon recognition of a deterioration in telemonitored parameters.

The care provided will follow the usual protocols that professionals use to provide at each organization but with the added value of the telemonitoring system provided by PhysioDom. In some organizations, participants might need to be referred to another social care professional within or outside the health care organization. In other words, the scope of this research project is early detection of deterioration of telemonitored parameters; it will not intervene in the usual health or social care provided by care professionals.

Thus, the difference with the control group is the timing of usual treatment or care referral, as it is aimed that deteriorations will be detected earlier through the telemonitoring system.

PhysioDom is a telemonitoring service designed to provide services in different countries, different profiles of organization (public and private bodies, health care and social services providers). Each organization will implement the services provided by PhysioDom taking into account its particular structure.

There will be several common settings for all pilots that already have been described in different PhysioDom Deliverables such as the ethics charter and the study design submission to the ethics committee. Trial design, Inclusion criteria, Exclusion criteria, Informed consent, Sample size and data analysis.

One of the challenges is to manage the deployment of PhysioDom in a "live" health and social care system, where it effectively duplicates existing systems. The real savings to pilot organisations are derived from redesigning services around PhysioDom. However, most organisations are unwilling to take this risk on a new technical solution. Throughout the trial, as PhysioDom proves its value, stakeholders in each of the pilot sites will be better placed to decide how they can adopt the technology.



## V.2 - The objectives

## V.2.1 - General Objectives

- To assess the effects of implementing the telehealth solution PhysioDom–HDIM as a part of integrated care programme for ageing people.
- To demonstrate that telehealth services improve quality of life and enable ageing people to be involved in their self-care and empowerment while optimising the use of resources.
- To assess if PhysioDom can facilitate the coordination of health signals and appropriate follow-up actions in an in-home assisted elderly population.

## V.2.2 - Specific Objectives

- To assess differences between the same group pre and post intervention in terms of services used: Number of visits to Primary healthcare centres, number of hospital admissions.
- To assess differences in terms of life quality perceived.
- To assess if healthcare professionals detect early signs of worsening in the monitoring conditions (nutrition, physical activity and monitoring related to chronic diseases)
- To assess the organizational impact of implementing PhysioDom-HDIM intervention in the existing CST health services. Satisfaction by patients / caregivers / professionals / administration
- To evaluate within the large-scale pilot the effect of nutritional coaching on nutritional status and the Usability and satisfaction with ICT tools

# V.3 - Implementation in four different levels

PhysioDom will be implemented at all pilots at 4 different levels:

- **HDIM service-level 1** The monitoring done on a large population of seniors in a given area.

HDIM service-level 2 Local healthcare and social welfare services - homecare services

- **HDIM service-level 3** New service to be established: dietary coaching and physical exercise.
- HDIM service-level 4 Family physicians and specialists



# Level 1 self management

## Monitoring

Weight, FFM/FM ratio, nutritional status, appetite and wellbeing assessment by

# Follow up

Self reflection on monitored data; automatically generated advices on dietary

# Level 2 district nurse/social service professional

Monitoring

receipt and managing of monitoring signals

Follow up

Further examination, dietary coaching

# Level 3 paramedical

Follow up

Specialized follow up (from speech therapist, dietician, etc.)

# Level 4 medical

Follow up

Specialized follow up (from physician or

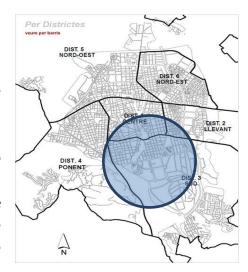
## V.4 - The Pilot Site

## V.4.1 - CST

## Organization Description

CST, as an integrated healthcare provider, has a sizeable population to draw on, and will base the pilot on its own organization. CST belongs to the public health service in Catalonia and is bound to their rules and regulations to provide health in Terrassa's urban area.

Primary health care services in urban areas are designed in order to guarantee the accessibility to the health service from citizens. Primary health centers are located close to patients, not exceeding 15 minutes on





average travel time from their home. They can request an appointment with their referral doctor or nurse when they need it.

## Setting

The pilot will be conducted by professionals working at CST facilities, mainly Primary Healthcare Centers of CST located in Terrassa and Matadepera. The PhysioDom-HDIM system will be deployed to end users at home by CST professionals. All end users will belong to the reference population of CST (approximately 200.000 persons). Given the design of the Catalan health system and the characteristics of CST, it is not foreseen that any other external stakeholder will need to be directly involved in the execution of the pilot, but other public entities which may provide complementary value added services could be invited if convenients such as Terrassa social services.

#### Recruitment

The recruitment of participants will be carried out by the pilot team after identifying patient conditions established as inclusion criteria. Data will be obtained from existing databases. All patients will be screened and consecutively selected with a view to inclusion in the study. An informed consent will be signed for all participants.

## Deployment

CSTs internal support departments (IT, maintenance, etc.) will give the technical support necessary, including assistance in installing the system in the homes of end users and providing a first level technical help desk.

## Care suitable to be provided through PhyisoDom.

Healthcare for any of the chronic diseases of the target population and will include several profiles of professionals such as doctors, nurses, nutritionists and social services professionals.

- Health Service: CST is a integrated health care organization with a Hospital and a number of primary health services. Doctors and nurses can provide any health service and assessment related to any health condition included in the inclusion criteria for elderly people with chronic diseases older than 65, and also to any condition related to undernutrition, dehidratation or obesity.
- Nutrition service: CST has nutritionist able to provide nutrition guidelines, also counts on a highly regarded Nutritional Expert to provide dietary advice in Dr. Simon Schwartz from Meditecnologia (MedTec).
- Physical Exercise Services: CST has a special research focus on Sports Medicine, with various initiatives focused on the use of physical activity to improve health both in terms of prevention, treatment and teaching, makes the physical activity tracking of the PhysioDom-HDIM solution particularly interesting.



Social Services. Depending on their health conditions, CST nurses and doctors can go to homes as many times as necessary to provide health care to patients with (chronic care programs, vaccines, emergencies, clinical analisys, etc). Also if required, Terrassa council provides services of food at home, housekeeping service if required, personal care service if required and also there are several day center service. They can also have tele medicine service if required to monitor some parameters

## V.4.2 - WU

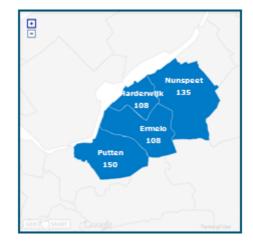
## Organization Description

Wageningen University (WU) is a university and research organization with a highly regarded specialization in nutrition; its Division of Human Nutrition is one of the leading nutrition institutes in Europe. Thus WU has a special interest in the nutritional aspects of the PhysioDom-HDIM solution and will pay special attention to this part. It has a collaboration with a health care organization 'Zorggroep Noordwest-Veluwe' (ZNWV)

## Setting

Care organization plays a big role in recruitment of beneficiaries and implementation

of the PhysioDom telemonitoring intervention. ZNWV provides care to approximately 1.500 mainly elderly persons, who are living independently or living in sheltered housing or a nursing home. The pre-pilot and pilot will be implemented among community living home care clients of this care organization.



#### Recruitment

Recruitment will be done by ZNWV and only the home-living clients of the ZNWV will be included in the PhysioDom project. Potential participants

will be duly informed about the study and will be free to sign or not the informed consent.

#### Deployment

In the pre-pilot, WU has the role to install the telemonitoring devices in the beneficiaries' homes. This will allow the project team to get an elaborate overview of technical issues that may arise during installment and deployment. During the pilot



study, the care organization has the role to install the telemonitoring devices in the beneficiaries' homes, which appears to be very time consuming.

## Care suitable to be provided through PhysioDom

The ZNWV provides the following types of care:

- Psychogeriatric / somatic care
- Care at home: cleaning, help with groceries, meal preparation, personal care (bathi ng, getting dressed) and nursing care
- Care in institutions: residential housing, nursing, medical rehabilitation, palliative care
- Centre for medical advice and treatment (paramedic and medic specializations)
- Case management dementia
- Adult day care (mental / social stimulation, break for caregivers)

Home care clients receiving the following types of care will be invited for participation in the PhysioDom project:

- Domestic care
- Personal care (bathing, clothing)
- Nursing care
- Individual or group support

The following care professionals will be recruited:

- Caregivers ZNWV, especially the district nurse who has been appointed to receive telemonitoring results and to coordinate automatic alarming signals arising from the telemonitoring system.
- The dietician will have an important role in the dietary coaching aspect.



## V.4.3 - CYBERMOOR

## Organization Description

Cybermoor is a social enterprise focused on improving living conditions in the region of Alston Moor, in the Cumbria region of the UK. Cybermoor represents a local network of stakeholders focused on the use of ICT for social issues. Through the Alston Healthcare project, launched by Cybermoor in 2007, the company has established a network of stakeholders



around health and social care. CYB works closely with the Cumbria NHS Partnership Trust and the Cumbria County Council Social Services, and will use this platform. CYB will also involve other NGOs in the region, to recruit users and run the pilot.

Having many remote communities to care for, efficient telehealth solutions is a top priority among the local stakeholders, and a special focus of interest related to the PhysioDom-HDIM solution.

## Setting

The pilot will be conducted in the region Cumbria, UK. Cybermoor is working with Age UK and other care organisations which have relationships with potential beneficiaries. Elderly people are living independently or in sheltered housing or nursing home. Local support staff will carry out initial interviews and monitoring (weight change, etc.)

- Age UK in South Cumbria have over 10,000 clients who access their services.
- 4,000 clients have continuous contact/care.
- 2,000 clients Heavy duty/intensive contact/care.
- 400 new clients each quarter.
- Aging population in Cumbria > over 50s only 17.6% use the internet [nat.average = 30%]
- Average age of clients is 74-5 years

#### Recruitment

The recruitment will be performed by the Age UK South Lakeland to identify potential beneficiaries (according to agreed criteria). They will check database of clients to see which meet inclusion criteria and will make potential beneficiaries aware of the benefits of the service / how works and beneficiary opts in to service. Informed consent will be asked. Potential participants will be duly informed about the study and will be free to sign or not the informed consent.

#### Deployment

Having many remote communities to care for, efficient telehealth solutions is a top priority among the local stakeholders, and a special focus of interest related to the PhysioDom-HDIM solution. In most cases 3G is unavailable and Cybermoor will require to install ADSL for the TV box connection with the server.

The population density is 0.2 people per hectare compared with a regional average of 5, and national average of 4.1. The day-today activities are limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months. This is much higher than the regional average of 17.9% .The area has a high population who retired residents who moved to Cumbria for a good quality of life but are not well equipped to cope when their health deteriorates as they get older, hence the higher number of people with limiting factors around their health.

We have assumed that up to 50% of the Cybermoor clients will be in areas where the mobile phone signal will not enable the standard connection to the STV box and we



will need to use an ADSL broadband connection instead. This will necessitate the installation of additional equipment and the associated monthly rental costs for the broadband connection. In addition there will be the need for the provision of engineering support for site survey, installation and decommissioning. The deployment will be performed by cybermoor own staff. The local monitoring service staff will visit the patient to install equipment and carry out training with the patient. Also technical staff will be in charge of the deployment of the communication system if required.

## Care suitable to be provided through PhysioDom.

Healthcare for any of the chronic diseases of the target population and will include several profiles of professionals such as doctors, nurses, nutritionists and social services professionals

- **Health Service:** Local General Practitioners are based around the County in villages and towns and they have a much greater role in managing budgets and purchasing services on behalf of patients. Cumbria Partnership NHS Trust (<a href="www.cumbriapartnership.nhs.uk">www.cumbriapartnership.nhs.uk</a>) – The Trust is charged with delivery of community services around the County and manages a number of hospitals.

Alston Medical Practice (<a href="www.alstonmedicalpractice.co.uk">www.alstonmedicalpractice.co.uk</a>) – The local GPs in Alston have worked with Cybermoor on previous telehealth projects and will provide an insight on this project into clinical issues and potential beneficiaries of the service. Alston Hospital League of Friends – The League of Friends links the hospital to the Community, they campaign for new services and support the purchase of new medical equipment. The volunteers who run the League of Friends are passionate about healthcare and innovation.

- **Social Services.** Social care is the responsibility of Cumbria County Council and they work with partners to deliver home care and run residential care for elderly citizens. The Council is investing heavily in superfast broadband; this project complements their objective to transform the delivery of public services. Eden Locality Stakeholder Group – The Stakeholder group represents patients and communities in the Eden Locality, acting as a vital bridge to the Clinical commissioning group. They meet regularly and cover social care issues through input from voluntary sector organizations.



## VI - The requirements in relation with the Home Health Record - HHR

## VI.1 - The requirements for the shared file - Home Health Record -HHR®

The Home Health Record – HHR will collect all the digital functions required to assist



professionals in organizing the Dietary Coaching for a population of seniors living at home, on a large territory. In PhysioDom, the HHR is presented in two parts:

- The HHR-Home consulted by the Beneficiary via the TV screen at home
- The HHR-Pro consulted by the Professional via the computer of his consultation room.

The proposed organization of the data management to be processed in

PhysioDom-HDIM is a priori compatible with the requirements listed below.

## VI.1.1 - Desired general functions<sup>1</sup>

- Security provided for data transfer within the network and for the entire hosting period
- Compliance with current confidentiality standards, the structuring of health data, tools to facilitate future interoperability
- The home network terminal will be of common usage and of low cost the digital TV connected to Internet seems to be a wise choice.
- The HHR will be available in three languages English, Spanish, Dutch.

### VI.I.2 - For the Beneficiaries at home

- To offer seniors relevant services at home at an acceptable cost - id est:
  - Display of the schedule of the types of home care, regularly updated
  - Display of the messages from the Professionals
  - o Daily data monitoring, favouring automatic data transfers using sensors in order to avoid manual entries
  - A simple way to qualify and notify changes in symptoms

<sup>&</sup>lt;sup>1</sup> The needs in relation with Ethics aren't placed here – See the D1.2



- A history of saved parameters
- A simple access to the General prescriptions from the health care- and social professionals
- A Dietary plan with individual follow-up
- To assure the traceability of the actions undertaken on the HHR in order to be able to answer the question: "who is consulting my file?"

In other words: a tool facilitating everyday life that is adaptable to each individual beneficiary.

#### VI.I.3 - For the Coordination

- To reduce the efforts and costs associated with the collection and retrospective control of the data, which can be manipulated in three classical ways – Sorted, Filtered, Exported
- To assure the traceability of the actions undertaken at the HHR
- To save the data for evaluation purposes

## VI.I.4 - For the Professionals

- Use of the HHR on PC or tablets (a requirement from the NL pilot site incorporated into the design).
- A single HHR to be manipulated by the professionals of two sectors -the Health and Social sector - while respecting their respective rights and duties



- To benefit from an interface (menu) which is simplified with respect to the one of PhysioDom-RVS
- To facilitate the entry of information thanks to lists with pre-existing data (drop-down menu)
- To reduce the time (costs) of data collection from homes
- To allow a simplified consultation of the stored parameters, including the preentered warning thresholds with warnings signs in the HHR-Pro and warning messages to the identified receivers
- To improve the accuracy of the home data by automating the data entry using communicating sensors
- To be able to send messages to the homes with express confirmation of receipt
- To reduce for each professional the efforts and costs associated with the collection and retrospective control of the data, which can be manipulated in three classical ways – Sorted, Filtered, Exported
- To assure the traceability of the actions undertaken at the HHR
- To offer easy tools for the management of Home Dietary Coaching
- The HHR should be a reliable tool for the evaluation study in its three dimensions usability, clinical efficacy and efficiency



#### VI.2 - What the current HHR will not be able to do

- No email system from Home
- No pre-registered food menus the coaching will be done by : messages to home, telephone, separate email, face-to-face visit
- No interoperability with the systems used in the health care and the social services of the Pilot Sites
- No direct internet access to general recommendations or other knowledge base
- No proposition of structured / semi structured recommendations; the written recommandations will be limited to advice (Text)
- The current HHR is not a tool for the staff management *id est*: To organize a daily automatic management of the beneficiaries' clinical care pathway with multiple professionals
- The HHR is neither a tool for drug prescription nor for measurement of clinical quality



#### **VII - Evaluation Studies**

#### VII.1 - The three studies

Following from an urgent political, scientific and societal need to develop and implement evidence-based, acceptable, and cost-effective strategies to tackle malnutrition and to promote active and healthy ageing, three evaluation studies are conducted:

- Clinical impact study. There have been several studies to applications of telemonitoring for the elderly (1, 2). These applications mainly focussed on monitoring of vital signs in older adults with chronic diseases like cardiovascular disease and diabetes. Studies showed positive results, especially for behavioural outcomes such as adherence to medication and self-efficacy (6). To our knowledge there has only been one study that focused on a telemonitoring instrument to improve nutritional status among community dwelling elderly (3). This pilot study focussed on elderly patients who were already malnourished and received oral nutritional supplements. A telemonitoring system was used to measure weight and adherence to the prescription of oral nutritional supplements. However, due to a limited sample size (N=26) and a high drop-out rate no effect size could be established. Clearly, more research is needed to show that telemonitoring is able to contribute to the prevention of undernutrition in the elderly. The PhysioDom project aims to answers to the need for scientific evidence by demonstrating the clinical impact of nutritional telemonitoring. Paragraph VII.2 describes the study design.
- Acceptability/usability study. Care organizations and care professionals call for systems that are acceptable to them, enhancing a user-friendly approach. This is for utmost importance for the sustainability of new interventions. PhysioDom aims to meet the need for a telemonitoring system which is acceptable to both the elderly end-users and their caregivers, by conducting a pilot study in which user-friendliness and acceptability will be thoroughly investigated. Paragraph VI.3 will explain more about the acceptability/usability study.
- Cost-effectiveness study. Europe faces an unprecedented increase in life expectancy and population ageing, with estimates that in the coming decades the proportion of citizens over 65 will nearly double to reach 30% by 2080 (4). An ageing population puts larger demands on health care resources. European governments are facing the challenge of providing high-quality health care within the available budget. Clearly, there is a need for cost-saving and cost-effective strategies that promote healthy and active ageing. Therefore, it is imperative



that PhysioDom HDIM demonstrates its cost-effectiveness. Paragraph VI.4 describes methods for a cost-effectiveness study.

## VII.2 - Clinical Impact Study design

Below, a brief overview of the objectives, study design, study population, sample size and measurements is given. The design of the clinical impact study follows from the needs and requirements as stated by the ethics committees of the participating pilot sites countries. For a more detailed overview, we refer to the research protocols submitted by each pilot site to the local ethics committees.

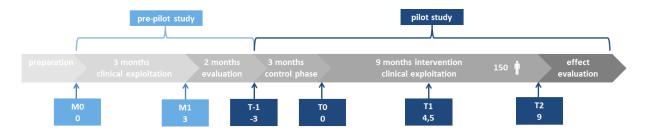
## VII.2.1 - Objectives

- The first objective is to study the effectiveness of PhysioDom HDIM in stabilizing or improving quality of life and nutritional status in elderly home care clients.
- The second objective is to study the effects of PhysioDom HDIM on nutritional parameters (appetite, weight, BMI, fat mass/fat free mass), and on physical activity and blood pressure in case of hypertension.

## VII.2.2 - Pre-test post-test design

Firstly a five months <u>pre-pilot study phase</u> will take place at the pilot sites in Spain, the United Kingdom and the Netherlands to test the study procedures and the technique of the PhysioDom HDIM telemonitoring system. This pre-pilot study phase consists of:

- three months exploitation of PhysioDom HDIM telemonitoring system among 20 elderly end-users
- two months evaluation of the pre-pilot study results. During this period, the
  PhysioDom HDIM technology can be adjusted if necessary, on the basis of the
  results of the pre-pilot study, with the goal of a better match between the
  telemonitoring system and the needs of the elderly end-users and their caregivers.



After the pre-pilot study, the <u>pilot study phase</u> will take place to evaluate the effects of PhysioDom HDIM. The pilot study will include 150 elderly end-users and consists of the following components:



- a control phase of three months. Participants of the pilot study will be their own controls, as the period between T-1 and T0 is regarded as the control phase. This control phase is necessary, facilitating a comparison of results of end-users between a phase without PhysioDom and with PhysioDom (within person comparison)
- a clinical exploitation period of nine months, in which the telemonitoring system is in operation.

## <u>During the pre-pilot phase</u>, measurements will take place:

- at the beginning of the pre-pilot study (M0),
- at the end of the pre-pilot study (M1),
- between M1 and T-1: adjustment and validation of PhysioDom HDIM components.

## During the pilot study phase, measurements will take place:

- three months before the start of the clinical exploitation (T-1),
- at the start of the intervention (T0),
- halfway during the intervention (T1).
- at the end of the intervention (T2).

During the measurement moments M0, M1 and T-1 to T2, researchers will conduct measurements concerning primary and secondary outcomes ad described in 3.5.1.5.

## VII.2.3 - Study population – inclusion/exclusion criteria

As malnutrition is, in absolute numbers, mostly encountered among vulnerable community-dwelling elderly, there is a need to implement and study strategies tackling malnutrition in this target population (5, 6). Furthermore, it is seen that (multi)morbidity is associated with increasing levels of malnutrition, which results in a need to develop and test interventions targeted at malnutrition in diseased elderly as well (7, 8). Concluding, we have defined the following inclusion and exclusion criteria to be eligible for participation in the pre-pilot study or the pilot study:

## **Inclusion criteria**

- Pre frailty
- Undernutrition
- Dehydration
- Overweight
- Minor cognitive impairment
- Chronic pathologies
- Cardiac insufficiency level I-II
- Renal insufficiency
- Hypertension (first phases)
- After chemotherapy (> 1 month)



COPD (first phases)

#### **Exclusion criteria**

- < 65 years</li>
- Not having television at home
- People who are dependent (unable to walk or bedridden)
- People with visual impairment (not able to watch TV)
- People with physical impairment unable to use the remote control or the devices
- People who do not give their informed consent
- Short Life expectancy (< 9 months)
- Severe cognitive impairments such as Alzheimer.
- People receiving chemotherapy (as low compliance of this group is expected)

## VII.2.4 - Sample size

The sample size of 20 participants for the *pre-pilot study* is based on the assumption that with 20 participants we are able to study the <u>acceptability</u> and <u>usability</u> of the PhysioDom HDIM technology and to test study procedures. The small scale will give the researchers the opportunity to keep a close overview of the implementation process and test the study procedures.

Based on sample size calculations, the pilot sites have agreed to include 150 participants in *the pilot study*. This number will be sufficient to detect clinically relevant effects on the primary outcomes nutritional status and quality of life. By including 150 participants per pilot site, we deviate from the number of 250 participants per pilot site mentioned in DOW. The rationale for this is that from an ethical point of view, following the data minimization principle, it is required to include no more participants than necessary for detecting a pre-specified effect size. According to our sample size calculations, this minimum number is 150 participants per pilot site, taking a realistic drop-out rate into account.

#### VII.2.5 - Measurements

The **primary study parameters** <u>quality of life</u> and <u>nutritional status</u> are chosen to demonstrate effects of nutritional telemonitoring on nutritional status and quality of life. Including both measures is important as it answers to the need for showing not only effects on the more clinical outcomes (nutritional status), but also the more sustainable outcomes (quality of life). Below is explained how measurements of quality of life and nutritional status are conducted using the following:



- Quality of life QALY. Quality of life is measured by the SF36, one of the most widely used generic health status measures. It includes eight dimensions of quality of life: physical function, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The SF36 provides scores for each of the eight dimensions, and provides physical component summary (PCS) and mental component summary (MCS) scores (9).
- Assessment (MNA). The MNA is an assessment tool that identifies persons aged 65 and higher who are malnourished or at risk of malnutrition (10, 11). It was developed in the 90's by practicing geriatricians in the United States and Europe and is one of the most well validated nutrition screening tools for elderly. The MNA has two forms, the MNA Short Form (MNA-SF) which is used for screening (this part we will use for telemonitoring), and the full MNA which includes the assessment of nutritional status and which we will use for effect evaluation. The full MNA consists of 18-items and classifies a person as normally nourished (0-16), at risk for malnutrition (17-23.5), or malnourished (24-30).

The **secondary study parameters** below are selected as they give an enhanced insight into the various of effects associated with using the telemonitoring system. It is expected that through the Home Dietary Intake Monitoring (HDIM) and adherent diet coaching, appetite will improve and weight-related outcomes will be improved (weight, BMI, fat mass/fat-free mass).

- Appetite will be measured by the Simplified Nutritional Appetite Questionnaire (SNAQ), which has been proven to be reliable and valid in identifying elderly people at risk of unintentional weight loss (12). The SNAQ consists of four questions addressing several aspects of appetite. The outcome is a score ranging from 4 to 20, with a higher score indicating more appetite. Furthermore, a score of <15 indicates a significant risk of at least five percent weight loss within six months (12).</p>
- Weight, BMI and fat mass/fat free mass will be measured by weighing scales from the brand A&D, type UC-411PBT-C. Participants will be instructed when and how to weigh themselves.
- Blood pressure and heart rate will be measured in a selection of participants.
   Blood pressure measurement devices (type UA-767PBT-CI) are Bluetooth connected to the TV Box.
- <u>Physical activity</u> is monitored by a pedometer from A&D, type UW-101B.



## VII.3 - Acceptability/usability study

A process evaluation is carried out by measuring the use, usability, acceptability and satisfaction of PhysioDom HDIM. Based on the PhysioDom intervention elements and guided by literature on (determinants of) implementation, a process evaluation is performed to measure the process indicators reach, acceptability, and implementation fidelity. Measurements of acceptability/usability will take place at the end of the prepilot study (M1) and in the middle and at the end of the pilot study (T1 and T2).

# VII.4 - Cost effectiveness study

A cost effectiveness evaluation will be conducted from a societal perspective, as from a political and societal point of view, it is important to map all real costs involved in **PhysioDom HDIM**. The personnel costs will be shown in the form of person\*months.

Data on health care utilization will be collected using cost questionnaires. Costs that will be included are direct health care costs (e.g. medicine costs, visits to health care providers, hospital admission), direct non-health care costs (e.g. travelling costs, informal care), and indirect non-health care costs (e.g. lost productivity loss during volunteering work). Lost productivity costs for paid labour will not be included, because only participants with an age exceeding the retirement age of 65 will be included.

We will perform a cost effectiveness analysis where the effectiveness is measured by the mental score (or physical score) issuing from the SF36. The performance of the PhysioDom intervention compared to no intervention, will be estimated with the cost effectiveness increment ratio, which measures the cost of an additional unit of the mental score (or physical score) of the SF36 due to the PhysioDom intervention as compared with no intervention.

Using a simulation model (bootstrapping), uncertainty around costs and effects will be determined. This will result in a cost-effectiveness and cost-utility plane from which we can judge whether the intervention is cost-effective (given a fixed threshold chosen by society of policy maker).

The results of the cost-effectiveness analyses will be complemented with one or more sensitivity analyses for the main assumptions. In a sensitivity analysis, the effect of changes in the main assumptions on cost-effectiveness will be investigated.



#### VII.5 - References

- Barlow J, Singh D, Bayer S, Curry R. A systematic review of the benefits of home telecare for frail elderly people and those with long-term conditions. Journal of telemedicine and telecare. 2007;13(4):172-9. doi: 10.1258/135763307780908058.
- 2. van den Berg N, Schumann M, Kraft K, Hoffmann W. Telemedicine and telecare for older patients A systematic review. Maturitas. 2012;73(2):94-114. doi: DOI 10.1016/j.maturitas.2012.06.010.
- 3. Kraft M, van den Berg N, Kraft K, Schmekel S, Gartner S, Kruger J, et al. Development of a telemedical monitoring concept for the care of malnourished geriatric home-dwelling patients: a pilot study. Maturitas. 2012;72(2):126-31. doi: 10.1016/j.maturitas.2012.02.011.
- Eurostat. Population structure and ageing. European Comission; 2014 [cited 2014 2
   December 2014]; Available from:
   <a href="http://epp.eurostat.ec.europa.eu/statistics">http://epp.eurostat.ec.europa.eu/statistics</a> explained/index.php/Population structure a nd ageing.
- 5. Schilp J, Kruizenga HM, Wijnhoven HA, Leistra E, Evers AM, van Binsbergen JJ, et al. High prevalence of undernutrition in Dutch community-dwelling older individuals. Nutrition. 2012;28(11-12):1151-6. doi: 10.1016/j.nut.2012.02.016.
- Kaiser MJ, Bauer JM, Ramsch C, Uter W, Guigoz Y, Cederholm T, et al. Frequency of malnutrition in older adults: a multinational perspective using the mini nutritional assessment. Journal of the American Geriatrics Society. 2010;58(9):1734-8. doi: 10.1111/j.1532-5415.2010.03016.x.
- 7. Halfens R. Rapportage resultaten. Landelijke prevalentiemeting zorgproblemen. Maastricht: Maastricht University; 2012.
- 8. Morley JE. Undernutrition in older adults. Family practice. 2012;29 Suppl 1:i89-i93. doi: 10.1093/fampra/cmr054.
- 9. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical care. 1992;30(6):473-83.
- 10. Vellas B, Villars H, Abellan G, Soto ME, Rolland Y, Guigoz Y, et al. Overview of the MNA--Its history and challenges. The journal of nutrition, health & aging. 2006;10(6):456-63; discussion 63-5.
- 11. MNA® Mini Nutritional Assessment.: Nestlé Nutrition Institution; [cited 2014 10 September]; Available from: http://www.mna-elderly.com.
- 12. Wilson MM, Thomas DR, Rubenstein LZ, Chibnall JT, Anderson S, Baxi A, et al. Appetite assessment: simple appetite questionnaire predicts weight loss in community-dwelling adults and nursing home residents. Am J Clin Nutr. 2005;82(5):1074-81.



# **VIIII - Indicators**

Metrics to assess project progress have been noted in the DOW – B3.4. The list has been refined and could be modified function of the pre-pilot study.

# **VIII.1 - Table of the Indicators**

	PhysioDom-HDIM Table of Indicators (Main expected results)								
Partner To be involved in the task	Indicator No.	Relating to which project objective / expected result?	Indicator	Method of measurement	Year 1	Year 2	Year 3		
Viveris + Pilot sites To be published in the D4.3	1	Perform a large scale pilot	Deployment	Number of visits of a screen (the home page for instance) during a given period		60	450		
Viveris + Pilot sites To be published in the D4.3	2	General use of the PhysioDom- HDIM platform by professional end users	Platform usage professionalS	Percent of professional weekly connected to the system		50%	80%		
Pilot sites To be published in the D4.3	3	Use and correct functionality of the HDIM service	HDIM functionality	Number of corrective actions taken by care professionals per		0,5	0,8		



620992 - PHYSIODOM-HDIM D3.1						
		(implementation fidelity)		HDIM alert. Netherlands: process evaluation questionnaire including self- reported use of HHR Home and HHR Pro (subjective data), log data from HHR Pro and HHR Home (objective data)		
Pilot site To be published in the D4.3	4	Improvement of health, well being and independency	Health status of primary end users and health care use	Reduction in number of hospital admissions / doctors visits versus previous period without PhysioDom-HDIM		-25%
SF 12 / SF 36 Uren + Pilot sites To be published in the D5.1	5	Improvement of health, well being and independency	Quality of life of primary end users	Questionnaire before and after 12M use; % of respondents reporting increased quality of life		60%
H&S + Pilot Sites To be published in the D4.3	6	Change Management	Satisfaction of professional users	Questionnaire after 12M use; % of respondents stating PhysioDom-HDIM improves their work.		65%
H&S + Pilot sites To be published in the D5.1	7	Acceptability by primary end users	Satisfaction of primary end users and informal carers	Questionnaire after 12M use; % of respondents satisfied with the system		80%
CST + Pilot sites To be published in the D6.4.2	8	Impact as a reference project among professionals and academics	Dissemination to professionals	Part of dissemination report: participation in conferences etc.	tails Indic 8 and 9	ators



	-			
CST + Pilot Sites To be published in the D6.4.3	9	Positive perception among policy makers	Support among policy makers	Numbers of letters of support received from government related organisations in the pilot site countries.

#### VIII.2 - Details

### **Indicator No1**

This indicator concerns HHR-Home)

There is not properly an action corresponding to a connexion of the user to HHR-Home (the box is self connected) so connexion can't be numbered

The history of number of visits of the screens of HHR-Home can provide an indicator This information will be available from log activity of the last 30 days, viewed on sportal which is the administration tool provided by Sirlan

An access to sportal will be granted to a few stakeholders among the pilot technical teams.

#### **Indicator No2**

His indicator concerns HHR-Pro)

Number of connexions to HHR-Pro is logged by IDS our hosting provider.

The history of connexions to HHR-Pro can provide an indicator

The connexion logs can be viewed through the IDS administration tools, only accessible by Viveris

Viveris will transfer this information to pilots in order to allow them to process the related measure such as "Percent of professional weekly connected to the system" for instance

## **Indicator 3**

This indicator give information about the use of the HHR-Pro by the professionals particularly the use of the Alert function in the day working.

We will analyse in detail this parameter with 20 persons in the four main populations targeted by the project – See §VII.2.3 – Pre-frailty, Overweight, Undernutrition, Chronic pathologies. H&S will gather the results published by each Pilot site and put it in the D4.3;

#### **Indicator 4**

This indicator will give information on the number of visits of professionals at home and the number of transfers to hospital or nursing home /assisted living.

We will analyse in detail this parameter with 20 persons in the four main populations targeted by the project – See §VII.2.3 – Pre-frailty, Overweight, Undernutrition, Chronic pathologies. H&S will gather the results published by each Pilot site and put it in the D4.3



#### **Indicator 5**

This Indicator will result naturally from the Clinical Efficay Study, without any additional works-See the § VII.2 - Clinical Impact Study design.

#### **Indicator 6**

The changes in the organisation of the home cares involved in PhysioDom-HDIM are closely linked to the degree of satisfaction of the Professionals working on the project.

We will analyse in detail this parameter with 20 professionals – MDs, nurses, nutrition specialist, social workers,

<u>This questionnaire</u>, which investigates the perception of the professionals concerning the e-Health application – PhysioDom-HDIM, is made of 10 questions.

- 1. Have you experienced technical difficulties which may affect the quality of care delivered by the telemedicine service?
- 2. Have you experienced difficulties in your collaboration with other professional groups in relation to the telemedicine service?
- 3. Have you experienced difficulties in your collaboration with the staff at other institutions in relation to the telemedicine service?
- 4. How would you describe the usability of the telemedicine application for you?
- 5. Has the use of the telemedicine application had any effect on your use of time?
- 6. Has the use of the telemedicine application had any effects on your tasks?
- 7. Has the use of the telemedicine application had any effects on the communication within your institution?
- 8. Has the use of the telemedicine application had effects on the communication with other institutions?
- 9. Would you like to continue to use the telemedicine service?
- 10. How would you describe your overall satisfaction with the use of the telemedicine service?

The responses are given on the Likert scale through five parameters - Strongly Disagree, Disagree, Agree, Strongly Agree, Not sure/not applicable

The data analysis is made by H&S.

#### **Indicator 7**

This indicator is focused on the level of satisfaction of the primary end users – Beneficiaries, families and other informal carers;

We will analyse in detail this parameter with 20 persons in the four main populations targeted by the project – See §VII.2.3 – Pre-frailty, Overweight, Undernutrition, chronic pathologies.

The domain of the satisfaction level is explored through the Web Services Devices – WSD Questionnaire well adapted to the remote home cares with home equipment. This questionnaire is made of 22 questions concerning the Home PhysioDom Kit (The kit)

- 1. The kit I received has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often.
- 2. The kit I received has interfered with my everyday routine.



- 3. The kit I received has increased my access to care (health and/or social care professionals).
- 4. The kit I received has helped me to improve my health.
- 5. The kit I received has invaded my privacy.
- 6. The kit has been explained to me sufficiently.
- 7. The kit can be trusted to work appropriately.
- 8. The kit has made me feel uncomfortable, e.g. physically or emotionally.
- 9. I am concerned about the level of expertise of the individuals who monitor my status via the kit.
- 10. The kit has allowed me to be less concerned about my health and/or social care.
- 11. The kit has made me more actively involved in my health.
- 12. The kit makes me worried about the confidentiality of the private information being exchanged through it.
- 13. The kit allows the people looking after me, to better monitor me and my condition.
- 14. I am satisfied with the kit I received.
- 15. The kit can be/should be recommended to people in a similar condition to mine.
- 16. The kit can be a replacement for my regular health or social care.
- 17. The kit can certainly be a good addition to my regular health or social care.
- 18. The kit is not as suitable as regular face to face consultations with the people looking after me.
- 19. The kit has made it easier to get in touch with health and social care professionals.
- 20. The kit interferes with the continuity of the care I receive (i.e. I do not see the same care professional each time).
- 21. I am concerned that the person who monitors my status, through the kit, is well mandated to know my personal health/social care history.
- 22. The kit has allowed me to be less concerned about my health status.

The responses are given on the Likert scale through five parameters - Strongly Disagree, Disagree , Agree, Strongly Agree , Not sure/not applicable.

The data analysis is made by H&S.

## **Indicator 8 and 9**

Both indicators have to measure the efforts to make known PhysioDom-HDIM, and appreciate the results through the number of publications, congrés ... and the letters or documents from the main stakeholders – politics, administrations, professional syndics ...

All that parameters are published in the Dissemination plan.- see § 5. key performance indicators.

Dissemination activities	KPI	Indicators	Success indicator (year		(years)
			1	2	3
Newsletter	Number of published newsletters	Number of newsletter	2	3	3



	Number of visits	Number visits/year	>100	>100	>100
Website	Minutes spend on the site per visitor	Visitors spending more than 2 minutes	30%	40%	50%
	Countries of website visitors	Number of different countries	5	10	20
	Attendance at meetings/ conferences /workshops	Number of meetings attendance	2	3	5
	Posters presented	Number of posters presented	1	1	1
Scientific	Presentations at meetings	Number or presentations at meetings	1	2	3
Dissemination	Scientific Scientific scientific publications publication				1
	Meetings with	Number of meetings attendance		2	3
	professionals	Number of scientific enquires		5	5
Networking events	Networking meetings	Number of meetings attendance		1	3
	Number of meetings with new companies	Number of meetings with specific companies	2	3	5
	Leaflets/Brochures	Number of leaflets delivered	1	2	2
Marketing materials	Video	Video visualized on the web page Videos issued	1	50	100
Dissemination			2	5	10
events	local agencies	Number of attendees	50	70	200



	Meetings with patient associations	Number of meetings organized	1	4	4
	Meetings with political decision-	Number of meetings organized	1	3	10
	makers	Letters of support			9
	Press release	Number of press releases	1	2	4
Users information request  Non scientific publications		Number of enquires received		1	5
		Number of publications			1
		Number of contacts		30	10
	Facebook	Number of enquires received		2	5
		Number of contacts		20	50
Social Media	Linked in	Number of enquires received		2	5
	Twitter	Number or tweets released		3	10
	You tube	Number of video visualization		50	50

**All these Indicators will be gathered by H&S** and published at the end of each year in a specific document for an internal publication, and in the Summary reports of the use of the platform PhysioDom-HDIM, in the D3.3 and D3.4.



# <u>Annexe 1 – Details of the end users needs studies</u>



# PhysioDom-HDIM - 2014



# **PhysioDom-HDIM**

# **Needs study**

Detail of the actions on each Pilot site

- 2014 -



	- 2014 -				
	When	Meeting	Parti- cipants Number	Feedback and inputs of this end-users	
WAGENINGEN UR For quality of life					
Cargivers					
GP	27-11-2014 and several e-mails	Artine de Jonge (project leader of the working group 'Elderly care' in the region North-West Veluwe)	1	PhysioDom connects well to current projects of the working group, but they do not have resources (e.g. time) to integrate PhysioDom in other projects and connect PhysioDom to GP's in the region. Involving GP's in PhysioDom should depend on the initiative of Wageningen University only. She didn't see clear advantages of PhysioDom over the current way of working of GP's and expected that it is difficult to engage GP's in such a project, as GP's tend to adhere to their own working procedures.	
Specialists					
Nutritionist	Summer & autumn 2014	Every 6 weeks with Marit Vorsthof and with her successors Sabine van den Berg and Petra de Haan	3	In general, dietitians give specific advice, tailored to the patients. So within the PhysioDom system there should be space to enter free text, instead of predefined diets and advice as proposed by UREN. Those are not suitable to be applied in the Dutch context and should be adapted.	



Older People as such				
Municipality	9-3-2015, 14-4-2015 2 meetings w	vith Bep Franken		Positive about the project and sees PhysioDom as a way to connect different stakeholders in the field of elderly care (e.g. social care, home care, GP's). The municipality is willing to take the role of connecting different stakeholders to contribute to PhysioDom implementation.
Others				
Social Cares	14-avr-15 social worker Het Venster,	rs from SWON, Oranjehof		Having doubts about whether patients are willing to be engaged in the project. Expect that a telemonitoring system with feedback via TV is sufficient to support the elderly in improving their diet and levels of physical activity.
Homecares	Summer & Ina Nieland ( autumn care organiza 2014 successor Fre	reks meetings with region manager ations ZNWV) and ed van der Velden secretary ZNWV)	2	The care organizations currently does not do anything in the area of prevention or monitoring of patients with a chronic disease. They only provide care on the basis of a care referral from the GP. Everything related to prevention or monitoring of health related parameters is not financed and thus should be as affordable and efficient as possible. PhysioDom should comply to this. They regard tablets as part of the PhysioDom project as relevant, as it is expected that tablet use within home care will increase in the future. For the care organization it is important to invest in this and to build expertise.
Nurses	autumn successors	eeks with Ariene Morren and her Thea de Vries and rid Looije	3	The functions of PhysioDom should not be implemented generically for each patient; for every patient, specific functions like weighing or blood pressure measurements should be selected to be implemented among patients. They have concerns about privacy of patients and willingness of patients to be monitored. Messaging function may not be relevant for nurses; this will be too time-consuming. On the other hand, they realize that this is the way how home care will develop in the future. The PhysioDom model as proposed for the Netherlands (with the district nurse receiving monitoring alerts) fits well into new developments in which the district nurse receives a more central and coordinating role in elderly care.



Older People meetings	26/03/2015	Lunch for elderly of care organization ZNWV	6	Feedback on the dietary quality assessment tool: difficult to use the tablet, difficult to select the answers on the screen (radio buttons should be larger), questions about diet are in general easy to answer, dietary advices are easy to understand, it takes longer than expected to answer the questions.
Associations				
Ethics committee				
	Autumn 2014	Ethics council review		The focus of PhysioDom is on undernutrition, but you should also think about overweight elderly; how is the system suited to that? There should be clear protocols concerning who will receive patient's data from telemonitoring measurements. It is not desirable if all telemonitoring data are received by all involved caregivers. Think carefully about the access rights of involved caregivers and describe this carefully in protocols.
Cybermoor Se	ervices			
Cargivers				
GP	09/05/14	Kathleen Walton	1	As per minutes of meeting 140509.doc
Specialists				
Nutritionist		Katrina Brown		We should assess savings to the NHS on People moving from Medium to Low Risk on the MUST scale e.g. around reduced admissions  We should to be able to say that people on the PhysioDom programme moving from medium to low risk save x admissions (fractures etc) / x GP visits / fewer strokes / fewer pressure sores.  It would be useful to see evidence about the use of shakes & supplements moving people from Medium to Low Risk on the MUST scale. This would be a useful benchmark for PhysioDom to aim for and surpass.



Nurses	09/05/14	Michelle Walton, Brenda Wright	3	As per minutes of meeting 140509.doc
Homecares				
FairFoods	16/09/14	Mark Lloyd	2	Social interaction is key for most meals on wheels users. They would like more time with volunteer delivering their meal. System screens look OK, but some users may find it difficult to weight themselves.
Social Cares				
Cumbria County Council	27/06/14	Peter Knock	2	Screens of the HHR - Pro would appear to place a big burden on social workers to complete information that is not normally collected.
Darlington Borough Council	26/11/14	Social workers and nurses	8	Enthusiastic about the look and feel, but concerned about follow up on patients who do not weigh themselves.
Others				
Cumbria Clinical Commissioning Group	26/08/14	Sally Jenkins	1	Discussion of system overview. System seems simple to use, there may be issues around internet connections in Eden. Clinicians are not keen to learn how to use new systems as their time is very pressured so it has to be easy.
Older People as such				
Older People meetings				
Alston Pensioners Lunch	04/11/14	Variety of elderly people	10	Screenshots were positively accepted, would have liked to have seen a demonstration. Some people who were younger were receptive to the idea as they had smartphones and were used to the technology e.g. using Skybox. Older respondents were not convinced of the value, and concerned about the data.
Associations		-		
Alston Hospital League of Friends	09/05/14	Malcolm Forster	2	As per minutes of meeting 140509.doc



Bolton Exchange	26/08/14	Barbara & Derick Cotton	12	Hard to understand why I would look a the TV for these messages, would prefer a phone call or someone to pop around. What about people who are unable to balance on the scales. Doreen pointed out the slow broadband speed in the locality and that most of the over-65s have their computers/routers separate from their TVs. INterest in using the system to monitor diabetes, as one person was a diabetic.
Age UK - Carlisle and Eden		Alison Ambrose	1	Liked the look and feel of the new screens.
Age UK - South Lakeland		Hugh Tomlinson	1	Questions about who was allowed to access to the information.
Age UK - West Cumbria	04/08/14	Steve Barna	3	Potential difficulties getting people to input their steps and also weigh themselves every week.
<b>Ethics committee</b>				
Cumbria CVS	01/07/14	Jane McFarlane	2	Social care organisations would be interested to use the system, but entering diet plans could be too onerous if it had to be done weekly, suggest that this is removed.
CST Fundació Joan Costa Ro	oma			
Cargivers				
GP			3	Removal - the messaging - from home to the professionals in their cabinets. Changes in the design of the TV screen from the previous design used in. Added - a list of symptoms to be evaluated by the Beneficiary thanks to a scale 0/10. Added - an Alarm on the first screen as soon as a new information is updated from the healthnets. Add- a new alert function at the disposal of the Professionals. Reduction of Messaging services. Removal - the messaging between Professionals. Removal - the information on drug prescriptions. Added - the Alarm function from the thresholds



Specialists	2	Added - a list of symptoms to be evaluated by the Beneficiary thanks to a scale 0/10. Add- a new alert function at the disposal of the Professionals.  Simplification of the Dietary (Shared dietary program) and the Physical Activity Plans.
Nutritionist	2	Removal - the daily dietary menu - Diet coaching. Added - the Questionnaires to measure Nutrition state, Appetite and muscle power and global results on the quality of life of thre beneficiary.
Nurses	4	Removal - the Questionnaires to be filled up by the Beneficiary at home. Removal - the messaging - from home to the professionals in their cabinets. Changes in the design of the TV screen from the previous design used in. Added - an Alarm on the first screen as soon as a new information is updated from the healthnets. Add- a new alert function at the disposal of the Professionals. Removal - the daily dietary menu - Diet coaching. Reduction of Messaging services. Simplification of the Dietary (Shared dietary program) and the Physical Activity Plans. Removal - the messaging between Professionals. Removal - the information on drug prescriptions. Added - the Questionnaires to measure Nutrition state, Appetite and muscle power and global results on the quality of life of thre beneficiary. Added - the Alarm function from the thresholds. Simplifications of health dates from beneficiary.
Homecares		
Social Cares	1	Changes in the design of the TV screen from the previous design used in
Older People as such		
Older People meetings		Changes in the design of the TV screen from the previous design used in.
Ethics committee		



|--|

# PhysioDom - Vercors-Santé - 2011



# PhysioDom-Réseau Vercors Santé Study on the Beneficiaries' expectations - 2011 -



Who	When	Meeting	Parti- cipants Number	Feedback and inputs of this end-users	
Beneficiaries	Nov - 2011	Face to	11	a TV remote control more adapted to the oldest people living at home	



Families	Face	3	a TV screen navigation more simple some alarms on the TV screen integration of services for the person (coaching) integration of physiological devices - glucometer, BP Monitors
			TV is OK to consult the Home Health Record but the Professionals should be more involved



PhysioDom - Vercors-Santé - 2005



# **PhysioDom**

Involvement of the End-Users in the First Design of the Platform dedicated to "Vercors-Santé" - 2005 -



Who	When	Meeting	Participants Number	Feedback and inputs of this endusers
	Jan/Sept 2005	Commission of Needs Three general meetings + personnal interviews		PhysioDom
Cargivers				First Design
GP			15	
Specialists			2	
Nurses			14	
Homecares			1	
Social Cares			1	



Pharmacists	3	
Kinesiologists	7	
Chiropodist	1	
Emergency services Hospital - Grenoble	1	
Older People as such		
Associations	1	
Health Nets		
Patients groups		
Cardiac	1	
Cancer	1	
Diabetes	1	
Disabled	1	