ICT PSP – Health, Ageing and Inclusion Programme

Health monitoring and sOcial integration environMEnt for Supporting WidE ExTension of independent life at HOME

(Grant Agreement No 250449)

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Intermediate Trial Evaluation Report
Version 1.2

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Abstract

This deliverable reports on the intermediate trial evaluation of all pilot sites, emphasising the different deployment results and the lessons learned from it.

Key Word List

Trial evaluation, RCT, Help desk, Contact centre

Executive Summary

This report presents the intermediate trial evaluation for the Antwerp, Badalona and Louth pilot sites in the HOME SWEET HOME project.

The trials started in 2011, to evaluate the impact on older frail citizens of tele-monitoring of health vital sign devices, environmental sensors, domotic devices, e-Inclusion services, cognitive training, navigation support, and daily scheduler services.

Today, elderly citizens in Belgium, Ireland, Italy, and Spain have home monitoring and assistance provide by HOME SWEET HOME services. These services are proved by a simple user-friendly ICT system that monitors the health and well-being of the elderly. This, combined with environmental sensors, video conferencing and other support tools, gives the elderly the possibility to age well in the comfort of their own homes.

It has taken all the sites longer than expected to get the trials under way. In particular, recruiting participants into a randomised control trial was a lengthy process, and setting up new technology in organisations that have not been accustomed to a new way of delivering healthcare was resource intensive. Patients were no longer just patients, but citizens who could stay in the comfort of their own home and monitor their own chronic disease. Medical staff had to take on new roles as the organisation changed along with the introduction of technology, and the technology had to be adjusted to real-life situations.

The initial results of the project show that installing technology in elderly citizens' home can assist in ageing well. It shows that preconceived barriers in most cases are not as evident as expected, and it shows that eHealth and eInclusion are areas worthy of further exploration.

Of the services provided, health and environmental monitoring have been most used and best received. Section 7 provides more details on the conclusions available at this stage.

Despite many issues on e.g. technical functionalities, internet, delays and changed workflows, the HOME SWEET HOME pilots are continuing at a good speed and with great enthusiasm. Such issues are in general perceived to be a part of such a project, and do not seem to lower the morale of the participants significantly.

Change History

Version History:

0.1	14th February 2011	Initial ToC
0.2	26th November 2012	
0.3	27th December 2012	
0.4	4th March 2013	
0.5	9th April 2013	
1.0	12th April 2013	Version for release
1.1	16th April 2013	revised version for release
1.2	24th June 2013	Further version for release

Version Changes

0.1 Initial ToC
0.2 Revised ToC
0.3 Antwerp added
0.4 Louth added, section 2.4.3 updated
0.5 Badalona added, Executive Summary
1.0 Minor changes prior to release
1.1 Section 6 added
1.2 Section 5 Latina added

Outstanding Issues

Table of Contents

1. Introduction

1.1 Purpose of this document

This document provides an intermediate evaluation of the trials of the HOME SWEET HOME services in the various pilot sites.

It covers the start up of the trials, including recruitment of users and their assignment to trial (treatment) or control group, any issues on use of equipment, staffing, and any lessons learned and corrective actions needed. Furthermore, it presents additional details to deliverables D6.2 Sensor fitted homes, D6.3 Contact Centre Environment and D6.4 Help Desk.

It also covers the experiences of the trials for the first 12 months, highlighting any issues encountered. It also presents an analysis of the trial population.

Other documents that contain relevant information are:

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

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

1.2 Glossary

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

- **Init**: patient's initials, assigned to be unique in each country.
- **S**: Gender (M/F)
- **Age**: in years
- **DM**: Diabetes mellitus (yes/no)
- **CHF**: Chronic heart failure (yes/no)
- **COPD**: Chronic obstructive pulmonary disease (yes/no)
- **HMF**: History of myocardial infarction (yes/no)
- **HST**: History of stroke (yes/no)
- **HF**: History of falls (yes/no)
- **Hosp**: Hospitalisation within the last two years (yes/no)
- **HC**: participant enrolled in home care program (yes/no)
- **L**: current living situation of the participant: (A = alone, C = with caregiver, G = group of elderly residents).

Other terms are:

CC	Contact Centre
CHF	Chronic heart failure
CMA	Christelijke Mutualiteit Antwerpen, Belgian partner
COPD	Chronic obstructive pulmonary disease
DM	Diabetes mellitus
EFS	Edmonton Frailty Scale
GP	General Practitioner
HIS	Health Information Systems, provider of the equipment
ICT	Information and Communication Technologies
PHN	Public Health Nurse (Ireland)
VOORZORG	Thuiszorg Antwerpen vzw, Belgian partner

2. Antwerp – Pilot site

2.1 Clinical protocol and preparation for trials

2.1.1 Ethical approval

The ethical approval was set up on 24th November 2010.

It was prepared in cooperation between Zorgbedrijf, Digipolis, ZNA, CMA and Voorzorg.

2.1.2 Recruitment of the users and random allocation to the intervention or control group

In Antwerp, recruitment of candidates started in the service flats of Zorgbedrijf. In five centres we gave a very extensive demonstration of what the project could mean to a participant. All the devices were shown, and people could ask questions. After that, all interested candidates could subscribe to collaborate in the project.

As we did not find enough candidates at Zorgbedrijf, some participants from Voorzorg and CMA also signed on.

After these subscriptions, the therapists visited the candidates to check the inclusion criteria and to determine the result on the Edmonton Frailty Scale (EFS). At that point, the informed consent was signed.

A few candidates, who had previously subscribed, did not want to continue anymore when they were visited for inclusion. Some were not supported by their family. In Antwerp, we also had the disadvantage that no GP was involved, as they did not want to cooperate in this project.

Another disadvantage was that the potential candidates did not know us at the start of the project. There was no relationship, no trust, the older people still had to get to know us. So there was a lot of doubt, many questions to answer, and many people who did not want to join the project.

This is why the recruitment period took longer than expected. We started the information sessions in 2010, and repeated them until we had found enough people willing to participate.

After participants had been included and signed the informed consent form, their data was sent anonymously to the Medical Coordinator who randomised them into intervention and control group.

This procedure of randomisation was carried out five times in 2011, in five groups, until all the participants were randomised. This happened because we did not find 60 candidates on the same time. It took a period of 5-6 months before we had all participants randomised. The results are stored in a google doc file shared with the project team. At the end of 2011 we had all our candidates.

Unfortunately several randomised participants dropped out immediately after randomisation because they were not included in the group they preferred. Some of them preferred the intervention group, but were included in the control group, and vice versa. This is why in the end we had randomised more than 60 candidates. The drop outs were replaced by new recruits while we were giving the demo sessions looking for new participants.

2.1.3 Informed consent form signature

Every participant has signed the Informed consent after the **inclusion criteria** were checked:

- Aged 65 years or over?
- Living at home or in the community, i.e. not in a nursing home, acute or sub-acute clinical or care setting?
- Scoring 'mildly frail' or 'moderately frail' in Edmonton Frail Scale (EFS)?

And **exclusion criteria**:

- Willing to participate (e.g. signing informed consent form)?
- Participant's living situation suitable for independent living? (E.g. in case of a full time caregiver: NO inclusion).
- Physically, mentally or otherwise adequately able to use and / or operate HSH devices / instruments?
- Able to administer self-assessment measurements (e.g. monitoring vital signs; questionnaires)?
- Not having a significant impairment of language comprehension or expression (e.g. aphasia)?
- Not enduring active medical illness with a significant shortened life expectancy (< 6 months), based on mortality prognosis?
- Not living without access to ISDN or ADSL service?
- Not living with another HSH participant in the same home?

2.1.4 Description of the resulting trial population

The demographic of the trial population is given in Table 1.

Table 1: Antwerp: Demographic profile

Intervention Group				Control Group		
Patient ID	**Sex**	**Age**		**Patient ID**	**Sex**	**Age**
ANTID001	M	88		ANTID002	F	74
ANTID004	M	91		ANTID003	F	83
ANTID007	F	79		ANTID005	M	83
ANTID009	M	73		ANTID006	M	81
ANTID011	F	78		ANTID008	M	81
ANTID012	M	76		ANTID013	F	72
ANTID014	M	89		ANTID018	M	83
ANTID015	M	88		ANTID020	F	82
ANTID017	M	87		ANTID023	F	80
ANTID021	F	85		ANTID025	F	87

Intervention Group				Control Group		
Patient ID	**Sex**	**Age**		**Patient ID**	**Sex**	**Age**
ANTID022	F	86		ANTID026	F	85
ANTID028	F	80		ANTID027	F	74
ANTID030	M	81		ANTID029	F	88
ANTID031	F	76		ANTID032	F	78
ANTID033	F	74		ANTID039	F	90
ANTID035	F	86		ANTID040	M	87
ANTID036	F	86		ANTID041	F	75
ANTID037	F	81		ANTID042	F	83
ANTID038	M	82		ANTID045	F	83
ANTID043	M	74		ANTID048	F	89
ANTID044	M	79		ANTID051	F	75
ANTID046	M	80		ANTID055	F	87
ANTID047	F	66		ANTID056	F	78
ANTID050	F	82		ANTID061	F	83
ANTID052	M	87		ANTID062	F	82
ANTID053	M	71				
ANTID054	F	85				
ANTID057	M	84				
ANTID059	M	85				
ANTID060	M	70				

Notes:

- Yellow = Drop-out

Mean age intervention group is 78.4.

Mean age control group is 81.7.

Distribution by gender is shown in Figure 1 below.

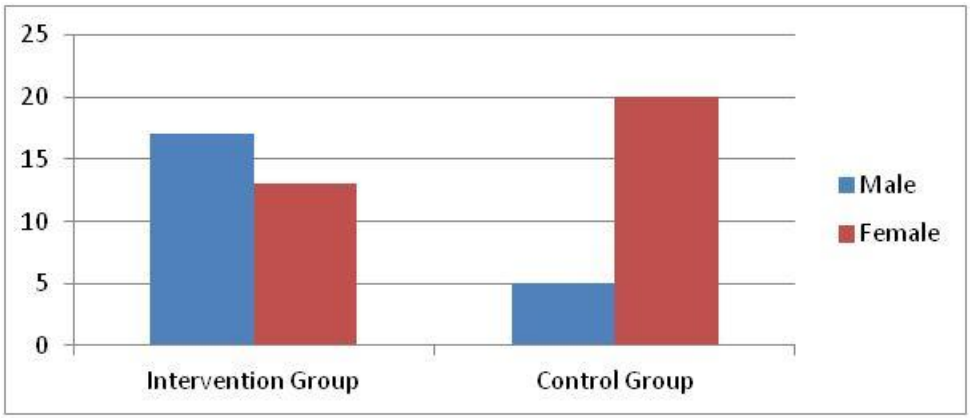

Figure 1: Antwerp: Distribution by gender

2.2 Personnel involved in trials

2.2.1 Authority staff: planners, financial and management

In Antwerp we worked with a project team consisting of different disciplines:

- Project leader: Lutgart Messens.

  Coordinating all the necessary actions to work towards a complete pilot site.

  Communication to the Consortium concerning the Antwerp pilot site.

- IT consultant: Lieven Van Gestel.

  Coordinating all the technical issues, questions with all project members and keeping in touch with the HIS team concerning technical issues.

  Communication to the consortium concerning the Antwerp pilot site.

2.2.2 Health & social care staff

- Medical coordinator: Dr. Prof. M. Vandewoude.

  Coordination and responsible of all medical issues

- Three therapists:
  - Sara Peeraerts (Zorgbedrijf);
  - Stefanie Steemans (CMA);
  - Caroline Van Herck (Voorzorg).

  Visiting, guiding, training the participants, taking CRF, questionnaires, first check up when device issues come up.

  Communication to the project team.

- Alarm central Mutas: Tom Lenie.

  Responsible on follow up alarms and alarm protocols

  Communication to the project team and the consortium

- Responsible of the therapists:
  - CMA: Hugo Goedeme: communicates to the consortium.
  - Voorzorg: Linda Huybrechts: communicates to the consortium.
  - Zorgbedrijf: Dimitri De Rooze – General coordinator Home Sweet Home.

2.2.3 Technical staff

All the installations have been done by Electro Zwijsen http://www.groupzwijsen.eu/.

They had training to correctly install all the devices at the homes of the participants.

When technical issues or replacements of devices had to be done, this was also carried out by Electro Zwijsen. Some devices can be replaced and installed by the therapists (health monitoring devices) or by the IT consultant (resetting devices) or IT Zorgbedrijf (re-install or reset devices).

- Elektro Zwijsen: Steve Heirman.

- IT Zorgbedrijf: Edwin Houdevelt and Patrick Heirman.
- IT consultant: Lieven Van Gestel.

2.3 Equipment

Table 2: Antwerp: Distribution of health sensors

IEM Stabilograf	IEM weight scale
BP meter	Weight
19	19

2.4 Installation issues

2.4.1 Sensor fitted homes

All the installations were carried out by Elektro Zwijsen.

While installing the smoke detector in the sometimes very small flats, it was very critical to find the right spot. When it was placed too close to the kitchen, too many false alarms were made.

The water leak detector had to be attached to the wall. When it is just lying loose on the floor, one could easily fall or hurt himself while stepping on to the pins. Or the detector can be misplaced while cleaning the bathroom.

The domotic devices, i.e. the winmatic, climatic and keymatic, were not installed. There were two issues:

- You have to have the right type of window lock, radiator and door lock respectively, to be able to install these devices.
- Also some people who rent a flat did not wanted to ask the owner permission to install those devices.

The training of the devices is done by the therapists/

2.4.2 Help desk

First line contact of the participants is the therapist. We established a very good relationship between the therapist and their participants. They know each other very well, and there is a bond of trust. So this is the person to contact by the participants.

When the therapist finds an issue she cannot resolve, she contacts the project team to ask for help. The project leader and the IT consultant then check what is the best solution, and take action.

2.4.3 Contact Centre

The Contact Centre (CC) is Mutas.

The Mambo alarms and the alarms of the environmental sensors are followed by Mutas.

The clinical alarms (BPM and scale) are followed by Dr Maurits Van De Woude, the clinical coordinator, and mailed to the GP when a situation occurs that needs follow up.

2.5 Initial trial results

2.5.1 Drop outs

These are the reasons for the 11 participants to drop out of the intervention group:

- Two transferred to nursing home.
- Hospital → rheumatism: can't handle devices with hands.
- Dementia.
- Passed away.
- Six dropped out:
  - Two never installed;
  - stress, forgets everything;
  - doesn't want the devices anymore;
  - not useful, had expected more from devices;
  - malfunctiong devices.

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

Medical devices

Most participants were very enthusiastic to use the medical devices such as the weight scale and the blood pressure meter. There are some participants who use them every day, and watch the statistics on the InTouch, or even show the results to the nurse or GP while they are visiting the participant.

Other participants find it too difficult in use and always forget how to use the weight scale and how to check the results on the screen. They cannot remember to wait for the beeps of the scale before they step off.

Some participants do not dare to step on the weight scale while home alone, or do not manage to put on the band of the BPM. They only take measurements when the therapist visits them.

Video conference

Only two or three candidates use the ello! regularly. The others think it is too difficult to use, or they are not motivated to use it because they have no one to talk to.

The installation of the software on the computers of the relatives is not that user friendly. Also, to add or change a contact, one has to contact the project team; the participants cannot do it themselves, they have to ask the therapist.

Some participants are on skype already and they do not want or need the extra TV-video communication.

Those who do not have skype think the ello! is too difficult, and those who are interested in the video conference already have skype.

InTouch

The screen is rather big and some participants do not like to install it in their small living room. There is not enough variety in the games and participants cannot add appointments themselves on the scheduler. They have to ask the therapist to do it.

Mambo

The Mambo is used by all participants in the intervention group. The waterproof keyfob is placed in the bathroom and some wear their second keyfob on them to be able to raise an alarm.

Alarm statistics from Mutas:

Table 3: Antwerp: Calls per month

Call type	2011					2012									Total	%
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep		
Test Mambo	16	10	1	5	0	4	0	0	3	1	0	2	0	0	**42**	35%
Alarms, no carer involved	20	8	2	8	12	1	0	0	1	0	0	0	1	0	**53**	44%
Alarms, carer involved	0	6	4	1	9	6	0	0	0	0	0	0	0	0	**26**	21%
Total	**36**	**24**	**7**	**21**	**21**	**11**	**0**	**0**	**4**	**1**	**0**	**2**	**1**	**0**	**121**	

2.5.3 T0 data

The questionnaires were administered between July 2011 and December 2011. Altogether, the numbers of participants completing these questionnaires is shown in Table 4 below.

Table 4: Antwerp data collection

Questionnaire	Intervention Group	Control Group
Edmonton Frail Scale (EFS)	30	30
Short Form -36 (SF36) Survey	30	30
Hospital Anxiety depression Scale (HADS)	30	30
Mini Nutritional Assessment® (MNA)	30	30
Clinical Global Impression (CGI)	30	30

Gait Speed Test (GST)	30	30
Timed Get Up & Go test (TGUG)	30	30
Clock Drawing Test	30	30
Hand Grip Strength (HGS)	30	30
Mini-Cog: recall of words	30	30
Katz Index of Independence Activities of Daily Living	30	30
Social Impact indicator	30	30

Almost all the participants needed help filling in the questionnaires. The questions had to be read to the participants. In different questionnaires, the same questions appear; this was rather confusing for the participants.

In the SF36 questionnaire, the questions are not well formulated.

We thought it was very important to measure each participant using the same rules and procedures. That is why we trained our therapists together under supervision of Dr. M. Vandewoude. Some movies, for example, showed how to take the Gait Speed Test, and made it clear how to measure this. These movies were shown to the entire Consortium at a PSC meeting. In this way, the Medical Coordinator could be checked that all countries use the same techniques. For example the grip meter should be a specific brand.

Sometimes the tests took too long, the participants were too tired and the therapist had to make a new appointment to see the participant a second time.

Separately from the CRF, we started to register the monthly diaries. Each therapist asks every month the clinical and non clinical questions to their participants. This happens during a visit or by telephone. While visiting the participant, the therapist checks whether all the devices work properly and if measurements of health sensors were taking place. If necessary, the therapist explains again the use of the devices. Repetition is needed! She can also call for help to a member of the project team if technical issues cannot be resolved immediately.

2.5.4 T12 data

The data collection T12 took place in November and December 2012. It went more easily than T0, as both therapists and participants were already aware of what questions and what tests have to be done.

3. Badalona

3.1 Clinical protocol and preparation for trials

3.1.1 Ethical approval

The Ethical Board that accepted the HSH project as a pragmatic trial for the BSA pilot site was the Clinical Investigations Ethical Committee (from Hospital Fundació Germans Trias i Pujol de Badalona).

Contacts with the Ethical Board of the Hospital Fundació Germans Trias I Pujol for approval of the HSH trials were initiated in April 2010, with a fianl meeting held on 27th August 2010.The trial was officially approved on 20th September 2010.

Below is a copy of the certificate issued by the Ethical Board of the Hospital with the approval for BSA to carry out the Home Sweet Home trials.

Germans Trias i Pujol
Hospital

Comité Ètic d'Investigació Clínica

A/A.: Soledad Velasco
Hospital Municipal de Badalona
C/ Galeta Soler, 6-8
08911 - Badalona

CODIGO	CIP-ICT-PSP-2009-3	PROMOTOR: Comisión Europea	REF. CEIC	EO-10-044

TÍTULO: Health monitoring and eOclal Integration environment for Supporting Wide ExTension of Independent life at HOME. (Versión 06 (30/11/2009))

INVESTIGADOR PRINCIPAL: Dr. J. R. Llopart López (HMB)

El Dr. Joan Costa Pagès, Presidente del Comité Ética de Investigación Clínica del Hospital Universitari Germans Trias i Pujol

CERTIFICA

Que en la reunión de fecha 27 de agosto de 2010 se aprobó el estudio arriba mencionado cumpliendo los requisitos establecidos en la legislación vigente para que la decisión del citado CEIC sea válida.

Que el CEIC, tanto en su composición como en los PNT, cumple con las normas de BPC (CPMP/ICH/135/95) y que su composición actual es la siguiente:

Presidente
Dr. Joan Costa i Pagès. Farmacología Clínica
Vicepresidente
Dra. Pilar Giner Boya. Farmacia
Secretaria
Dra. Carme Balañá Quintero. Oncología Médica (ICO)
Secretaria Técnica
Sra. Àngels Portes Vilagas
Vocales
Dr. S. Alonso Lozada. Geriatría
Dr. J. Ara del Rey. Dirección Médica
Sra. A. Devesa Pradella. Enfermería
Sra. I. Jiménez López. U.A.U.
Dra. A. López Andrés. Farmacología Clínica
Dra. E. Montané Esteva. Farmacología Clínica
Dr. A. Oriol Rocafiguera. Hematología y Hemoterapia (ICO)
Dr. A. Palomo Nicolau. Psiquiatría. Centres Assistencials Dr. Emili Mira
Dr. J. Peláez de Lofo. Inspección Farmacéutica. Área 6
Dra. C. Ramo Bello. Neurología
Dr. B. Romero González. Nefrología
Dr. J. Romeu Fontanillas. Medicina Interna
Dr. M. Solor Obradors. Medicina Intensiva
Sra. A. Vega Salcamarla. Enfermería
Sr. A. Vitoria Gómez. Jurista

Atentamente,

Comité Ètic d'Investigació Clínica

Dr. Joan Costa i Pagès
Presidente CEIC
Hospital Universitari Germans Trias i Pujol

Badalona, 20 de septiembre de 2010
JCP/mpm

c.c. Dr. J. R. Llopart López (HMB)

Germans Trias i Pujol
Hospital

Comité Ètic d'Investigació Clínica

INFORME DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA

El Dr. Joan Costa Pagès, Presidente del Comité Ético de Investigación Clínica del Hospital Universitario Germans Trias i Pujol,

CERTIFICA

Que este Comité ha evaluado la propuesta del promotor **Comissió Europea** para que se realice el estudio observacional código de protocolo **CIP-ICT-PSP-2009-3** titulado:

"Health monitoring and sOcial integration environMEnt for Supporting WIdE ExTension of independent life at HOME." (Versión: **06 (30/11/2009)) HOME SWEET HOME**

Hoja de Información al Paciente y Consentimiento Informado (versión: no consta)

y considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.

El procedimiento para obtener el consentimiento informado, incluyendo la hoja de información para los sujetos y el plan de reclutamiento de sujetos previstos son adecuados.

La capacidad del investigador y sus colaboradores, así como los medios disponibles son apropiados para llevar a cabo el estudio.

Y que este Comité acepta que dicho estudio sea realizado en el Hospital Municipal de Badalona por el Dr. J. R. Llopart López como investigador principal.

Lo que firmo en Badalona a 27 de agosto de 2010

Firmado:

Comité Ètic d'Investigació Clínica

Dr. Joan Costa Pagès

3.1.2 Recruitment of the users and random allocation to the intervention or control group

Badalona Serveis Assistencials offers health services to more than 400.000 people of the city of Badalona and the neighbouring towns of Montgat and Tiana. It is important to highlight that the setting of the Badalona pilot site is people living in a city environment with most of the population having a medium – low socio-economic profile.

To start the recruitment from such a big group we decided to select only those people that were 1) living alone and 2) over 65 years old. At this point, the eligible sample was up to 985 people.

In the next step for selection, we decided to search the target population that fit the inclusion and exclusion criteria, but limited to people living in the two main primary care areas of the city. Doing it in this way we achieved:

- Same people distribution, as the primary care areas had all population groups.
- Closer people distribution that led to an easier installation and monitoring phase.
- Centralised centres to contact primary care staff (nurses, social workers and practitioners) that helped with the adherence to the project.

At this point we had a smaller sample of 109 eligible candidates. We then performed a round of randomised phone calls to give a general description of the project and to ask 9 of the 11 questions of the Edmonton Frailty Scale, the essential scale for the inclusion criteria, followed by two home visits to those who met inclusion and exclusion criteria. Contact steps:

- First telephone contact: Project presentation and contact details, Exclusion criteria, EFS (except clock test & walking test); arranging a home visit (relative informed).
- First home visit: Exclusion criteria, EFS clock test and walking test. Inclusion criteria. If possible Informed Consent Form signed.
- Second home visit: Informed Consent Form signature, (visit with relative had to be arranged).

At this stage, 20 participants had been selected that we could include in the first centralised randomisation process. We had to search in a third primary care area to find the next 10 participants, randomised in the second centralised randomisation process.

3.1.3 Informed consent form signature

The signature of the Informed Consent Form had to be preceded by the adaptation / translation of the general Consent Form to Spanish and Catalan.

The signature could be done in some cases in the second home visit, always with the presence of a relative. If this was not possible, the signature was done when the platform was deployed in the house, before the start of the trial.

All participants, both control and intervention group participants, signed the informed consent form after being told about the conditions, requirements and rights they assumed when accepting participation.

3.1.4 Description of the resulting trial population

The demographic and health profile of the trial population are given in Table 5 (intervention group) and Table 6 (control group).

Table 5: Badalona: Demographic / health profile – intervention group

Init.	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	L
SP-01	F	68						X	X		A
SP-05	F	70		X	X	X			X		A
SP-06	F	78									A
SP-07	F	80							X		A
SP-09	F	72	X								A
SP-10	F	73									A
SP-14	F	78	X	X							A
SP-15	F	81		X		X	X	X	X		A
SP-21	F	83		X							A
SP-26	F	82		X	X			X			C
SP-28	F	86									A

Init.	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	L
SP-31	M	83		X			X				A
SP-32	F	80		X							A
SP-33	F	88	X	X	X	X				X	C
SP-35	F	84	X	X			X		X		A

Table 6: Badalona: Demographic / health profile – control group

Init.	S	Age	DM	CHF	COPD	HMF	HST	HF	Hosp	HC	L
SP-02	F	83		X				X			A
SP-03	F	78	X					X	X		A
SP-11	F	74	X	X	X						A
SP-16	M	82						X			A
SP-17	F	82		X				X			A
SP-18	M	84	X	X					X		A
SP-20	F	86	X	X	X			X	X		A
SP-22	F	89		X	X	X					A
SP-23	M	78	X	X	X	X	X	X	X		C
SP-24	F	75		X	X	X	X		X		A
SP-25	F	82						X			A
SP-27	F	83									A
SP-29	F	78						X			A
SP-30	F	80						X			A
SP-34	F	87		X				X			A

Notes:

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

Mean age intervention group:

The mean age of the intervention group is 79.06 excluding the pre-trial dropouts.

Mean age control group:

The mean age of the control group is 81.4 excluding the pre-trial drop-outs.

Distribution by gender is shown in Figure 2 below.

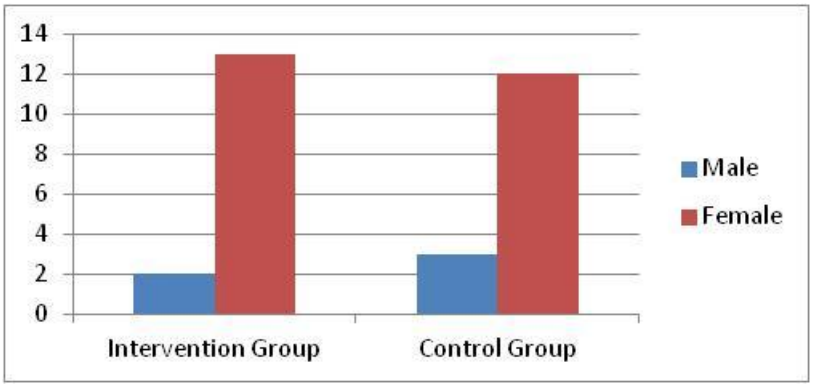

Figure 2: Badalona: Distribution by gender

The profile by pathology is shown in Table 7.

Table 7: Badalona: Profile by pathology

	COPD	DM	CHF
Intervention group	3	4	9
Control-group	5	5	9

Note that many patients have more than one pathology.

3.2 Personnel involved in trials

3.2.1 Authority staff: planners, financial and management

In Badalona, the project team is composed of:

- BSA Project manager: Dr. Josep Ramon Llopart

  Coordinating all the necessary actions to work towards a complete pilot site (plans, financial resources and management).

  Communication with the Consortium concerning the BSA pilot site.

- BSA Project coordinator: Dr. Ignasi Sáez

  Coordinating all the medical and technical issues, questions with all project members and keeping in touch with Call Center Asmedit and the HIS team concerning technical issues.

  Communication with the Consortium concerning the Badalona pilot site.

A close collaboration with Fundació TicSalut from the Department of Health of the Catalan Government, the other Catalan partner in the HSH project, was maintained during the whole trial process.

3.2.2 Health & social care staff

- Medical Co-ordinator: Dr Ignasi Saez

  Geriatrician.

  Responsible for all medical issues and research data quality.

- Staff:
  - Neuropsychologist: Maria José Ciudad

    Responsible for ASTRID. Contact person and follow up of participants.
  - Geriatrician medicine and home care nurses: Meritxell Oliveras, Teresa Pujadas, Sara Gámez, Verónica Delgado.

    Administration of questionnaires. Data collection.

- Social Health and Dependent Care: Dr. Joan Cunill
- Medical Practitioner: Dr. Sebastià Santaugenia
- Call Centre ASMEDIT : Dr. Carles Tristán

Responsible on 24/7 monitoring alarms and alarm protocols

3.2.3 Technical staff

- Technical Manager: Jordi Roque / David
  Management of home environment installations and ongoing maintenance.
  Communication to the technical HSH support staff.
- IT Technician: Jordi Piera

3.3 Equipment

Table 8: Badalona: Distribution of sensors

No	DM	CH	COPD	IEM Stabilograf	IEM weight scale	HMM Glab	Viasys	Nonin Avant 400
	Y/N	Y/N	Y/N	BP-meter	Weight	Glucose	PEF	PO2
SP-01				X	X			X
SP-05		X	X	X	X			X
SP-06				X	X			
SP-07				X	X			
SP-09	X			X	X	X		
SP-10				X	X			
SP-14	X	X		X	X	X		
SP-15		X		X	X			
SP-21		X		X	X			X
SP-26		X	X	X	X			
SP-28				X	X			
SP-31		X		X	X			
SP-32		X		X	X			
SP-33	X	X	X	X	X	X		X
SP-35	X	X		X	X			

3.4 Installation issues

3.4.1 Sensor fitted homes

The installation of the platforms at the participants' homes was done after the procurement of the devices, which was done in more than one consignment, and after we could test and install all platforms in our lab test. The latter was highly recommended as some bugs were detected at this stage and could be fixed before deployment to participant's house.

Installation was performed by the technical staff of BSA pilot team, with Jordi Roque as the chief manager. At each house, installation needed to be adapted, according to the layout of the flat, location of the plugs, and preference of each participant.

In the initial adjustments, change of batteries was needed in almost all devices, with the consequent effort of new home visits. Also, in some places adjustment was needed to the height of the smoke detectors and/or movement detectors.

For domotic HomeMatic devices, it was impossible to find a way to place them at participants' houses for different reasons.

- Winmatic were initially discarded due to old windows which could not be opened by such a system, the need to make holes the window, and participants refusing such a big installation.
- Climatic does not fit with participants' heaters, as old radiators placed in most of the houses and electric radiators in some others do not allow its installation.
- Keymatic sometimes does not fit the lock system of the old houses of participants. In some other cases, they did not give permission to install a device that could control their house entrance.

Training was performed before to the trial start, in two initial sessions, and with updates every time the participant was visited. Both technical and clinical staff solved doubts about functioning.

3.4.2 Help desk

As described in D6.4, help desk provision was agreed between the Contact Centre Asmedit and BSA pilot team. As the effort of monitoring 15 participants was not an issue for the global activity of Asmedit, action was divided as follows:

- Asmedit Call Centre would receive all incoming calls 24/7 following agreed algorithms of response depending of the kind of contact or the kind of alarm. They could also give response to different staff (nurses, social worker or practitioner) depending on each situation.
- BSA pilot team would contact the participants every time the Call Centre detected a special need. For a health problem, the first professional to give this contact is the neuropsychologist Maria J or the nurse. In case some medical decision was needed, the geriatrician I Sáez also gives an answer. In case of a technical problem, Jordi Roque is the first person to make contact, and the task is then distributed among the maintenance staff.

3.4.3 Contact Centre

The Contact Centre (CC) is Asmedit, a professional call centre that provides health and social telephone assessment covering all Spanish territory. Asmedit staff are trained in private companies, central and regional administration.

The objectives of Asmedit are:

- Ease of use: with an immediate access to all services through just a phone call.
- Accessibility: from any telephone, fix or mobile phones from any point from Spain or the EU.
- Privacy: access to their services is through a personal code, that keeps confidentiality.

- Professionalism: direct attention in all kind of consulting.
- Immediate: response: by the professional in each telephone contact.
- No limit: no limit to the number of phone calls, nor to their duration.

3.5 Initial trial results

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

Installation of all the environmental, medical and telecommunication devices of HSH platform was successfully done by the technical team of BSA. It was not possible to install any HomeMatic devices because the doors, windows and radiators encountered were not suitable.

We used the retention strategies adopted by the Project to improve adherence of the participants to the project.

After installation, participants were trained in the use of the devices through home visits by staff of BSA. The training of participants was adjusted to their abilities and devices that had to be used, in different sessions, and were conducted jointly by the clinical team and BSA technical staff.

Despite this, it should be understood that the profile of the pilot participants is heterogeneous; due to this, the results were different, which has caused significant differences in the use of the platform depending on the participant.

The devices that have been used more often, considering them easier and more accessible, are the weight scale, and to a lesser extent the tensiometer. Some participants who have used the tensiometer offered by the project consider it difficult to use. The glucometer data transmission has also been considered difficult to use. The Mambo phone has been well received, but often had technical problems; the weight to carry it outside the home has caused many of the participants not to use it.

The ASTRID program has also been warmly welcomed for its ease of access and use, and the feeling of working for prevention.

The videoconference *ello!*, which relatives of patients considered very interesting and useful for communication and contact with their family, has not been successful in use due to the difficulties of access to it by participants.

3.5.2 T0 data

The following questionnaires were administered to all participants in the Intervention and Control Group. These were administered in the CRF of BSA pilot site in the following order:

- Edmonton Frailty Scale (EFS) (including clock test and Timed Get Up & Go test (TGUG)).
- Katz Index of Independence Activities of Daily Living.
- Hand Grip Strength (HGS).
- Test Mini-Cog: recall of words and Clock Drawing Test.

- Clinical Global Impression (CGI).
- Hospital Anxiety Depression Scale (HADS).
- Mini Nutritional Assessment® (MNA).
- Gait Speed Test (GST).
- Short Form 36 (SF36) Survey.
- Social Impact Indicators Questionnaires.

The questionnaires were administered between July 2011 and the first week of November 2011. Altogether, the numbers of participants completing these questionnaires was 15 intervention participants and 15 control participants, as shown in the table below.

Table 9: Badalona T0 administration

Questionnaire	Intervention Group	Control Group
CRF: inclusion/exclusion, EFS, Katz, HGS, Mini-Cog, MNA, GST, HADS, CGA	15	15
SF-36	15	15
Social Impact	15	15

In general, T-0 CRF assessment went smoothly, without major problems. Intervention and control participants received assessment alternatively without any pre-established order, but adapting their schedule to the daily pilot team schedule. Some of the participants needed help or explanations about the meaning of some questions. For some other participants, it was necessary to perform the assessment of CRF, SF-36 and Social Impact in two visits as they felt tired doing it in one visit.

3.5.3 T12 data

The questionnaires were administered between January and February 2013. Altogether, the numbers of participants completing these questionnaires was 24 participants, 11 case and 13 control participants, as shown in Table 10 below.

Table 10: Badalona T12 administration

Questionnaire	Intervention Group	Control Group
CRF: inclusion/exclusion, EFS, Katz, HGS, Mini-Cog, MNA, GST, HADS, CGA	11	13
SF-36	11	13
Social Impact	11	13
User satisfaction	11	0

In general, T-12 CRF Assessments have been carried more easily than at T0. Increased adherence to the questionnaires has been observed because the participants knew the project and staff, and they have felt more comfortable than the previous time.

4. LOUTH

4.1 Clinical protocol and preparation for trials

4.1.1 Ethical approval

Ethical approval was applied for by Rodd Bond of the Netwell Centre through the HSE and DkIT research ethics boards in August 2010 and confirmation was received in February 2011.

4.1.2 Recruitment of the users and random allocation to the intervention or control group

In Louth, candidate selection was chosen from three approved lists:

1. HSE community care list: this is a list of all clients in receipt of home help services within the Louth Local Health region.
2. LCC housing list: this is a list of all clients residing in local authority housing.
3. Netwell network list: this is a list of vulnerable older people in County Louth who had interacted with the Netwell Centre (and in particular the Cultaca service) since 2006.

The Public Health Nurse (PHN) or the medical co-ordinator and the research team visited each individual older person to assess their interest in the project and to allow participants to discuss the implications further with their families. From this a list of 228 potential participants was drawn up.

A second visit was organised from this list to assess each participant using the prescribed Home Sweet Home inclusion and exclusion criteria. Results from the Edmonton Frailty Scale excluded a large percentage from the HSE and LCC lists – the HSE candidates being generally too frail and the LCC candidates being not sufficiently frail enough. Those who met the inclusion criteria were then asked to sign a consent form.

Each candidate identified their General Practitioner and a letter was sent to each GP informing them of their clients' choice to participate in the Home Sweet Home project and inviting them to get involved also.

Participants were randomised in three different groups as they were recruited in March, July and August 2011. The participants were immediately informed as to which group they were allocated to, and the implications. Participants were then given further time to reconsider their decision. A total of five participants dropped out at this stage, and hence the final randomisation in August 2011 was required to reach 60 candidates.

The Intervention Group were invited to view the test laboratory facility in DkIT in July 2011 with their families. Demonstrations were held showing how each device operated and how contact was made with the call centre.

4.1.3 Informed consent form signature

All participants, whether in the intervention or control group, signed the informed consent form at the outset of the project.

4.1.4 Description of the resulting trial population

The demographic and health profile of the trial population are given in Table 11 (intervention group) and Table 12 (control group).

Table 11: Louth: Demographic / health profile – intervention group

Patient ID	Sex	Age	Pathology		
			CHF	COPD	Diabetes
IRE:6	F	74			
IRE:9	F	83	X		X
IRE:16	F	68			
IRE:23	F	69	x	X	
IRE:27	F	82			
IRE:38	F	80			X
IRE:40	F	72			x
IRE:41	M	74	X		X
IRE:44	M	71	X		
IRE:47	F	82			
IRE:49	F	67			X
IRE:50	F	77	X		
IRE:52	F	80	X	X	
IRE:62	M	87			
IRE:65	M	77	X		
IRE:66	M	71			
IRE:86	F	71	X		
IRE:121	M	74			
IRE:122	F	73			X
IRE:129	F	69			
IRE:175	M	81	X		
IRE:184	F	89		X	
IRE:192	M	84		X	
IRE:195	F	82	X	X	
IRE:213	F	68			X
IRE:220	M	76	X	X	
IRE:222	F	75	X		
IRE:225	F	72			X
IRE:226	M	67		X	X
IRE:228	M	84			X

Table 12: Louth: Demographic / health profile – control group

Patient ID	Sex	Age	Pathology		
			CHF	COPD	Diabetes
IRE:4	M	79	X		
IRE:8	M	67			X
IRE:11	M	86	X		X
IRE:13	F	75			
IRE:21	F	79			X
IRE:22	F	86			X
IRE:32	F	78		X	X
IRE:39	F	75		X	X
IRE:46	F	76			
IRE:53	F	89			
IRE:56	F	73			X
IRE:61	F	70	X		
IRE:68	M	75			
IRE:84	M	77		X	X
IRE:100	F	94			
IRE:104	M	73		X	
IRE:115	M	74			
IRE:118	F	74		X	X
IRE:123	F	77			
IRE:124	F	76		X	
IRE:141	F	67			
IRE:142	F	68			
IRE:157	F	68			
IRE:164	F	77			
IRE:177	F	67			
IRE:182	F	73		X	
IRE:183	F	91			
IRE:216	F	85	X		
IRE:221	F	81	X	X	
IRE:223	F	78			

Notes:

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

Mean age intervention group:

The mean age of the intervention group is 75.97 excluding the pre-trial dropouts.

Mean age control group:

The mean age of the control group is 76.93 excluding the pre-trial drop-outs.

Distribution by gender is shown in Figure 3 below.

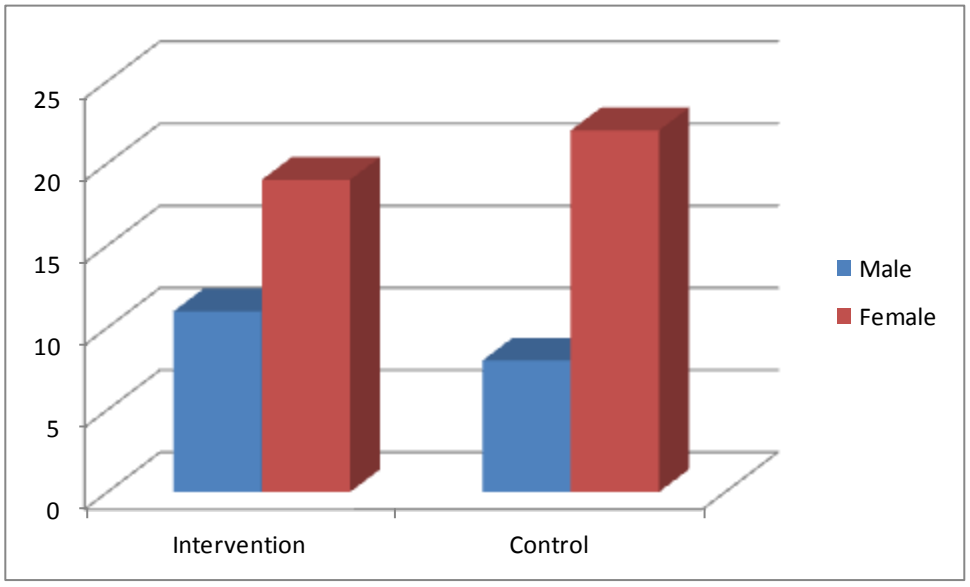

Figure 3: Louth: Distribution by gender

The profile by pathology is shown in Table 13.

Table 13: Louth: Profile by pathology

	COPD	DM	CHF
Intervention group	7	10	12
Control-group	8	9	5

Note that some patients have more than one pathology.

4.2 Personnel involved in trials

4.2.1 Authority staff: planners, financial and management

In Louth, the three Irish project partners formed a management structure with DkIT as the central research partner and the other partners contributing based on expertise.

Project Champions: Rodd Bond (DkIT), Willie McAllister (HSE) / Marie Dooley(HSE) & Joan Martin (LCC).

The project champions are tasked with promoting the project and its objectives within their respective organisations during a period of economic uncertainty in public sector bodies.

Other key personnel:

- Project Management: Stuart Quinn (DkIT)

  The Project Manager is tasked with project and financial management in addition to dissemination strategy and partner liaison.

- Operational Co-ordination: Mary McKearney (HSE), Willie Walsh (LCC) & Katherine Broderick (HSE) / Catherine Smyth (HSE)

  Management of home environment installations and ongoing maintenance and management of all care teams in the Louth Local Health Area.

- Project: Co-ordination: Joanne Finnegan (DkIT)

  The project co-ordinator is tasked with organising tasks and partner communications.

4.2.2 Health & social care staff

- Medical Co-ordinator: Dr Ann O'Hanlon (DkIT)

  The medical co-ordinator is responsible for all medical issues and research data quality.

- Researchers: Shauna McGee (DKIT), Hanora Cronin (DkIT), Frances O'Donnell (DkIT) & Catherine McConville (LCC)

- HSE Nurse: Josephine Marron (HSE)

  Data collection and follow up visits

4.2.3 Technical staff

- Technical Manager: Carl Flynn (DkIT)

  Management of data extraction and call centre integration

- Technician: Justin Sexton (LCC) & Ron Finegan (DkIT)

  Follow up visits and troubleshooting.

4.3 Equipment

Table 14: Louth: Distribution of sensors

ID No. / Device	BP Meter	Weight Scale	Glucometer	Asthma Monitor	Mambo	InTouch	Broadband Router	Smoke Detector	Water Detector	Motion Detector	Temperature Monitor
IRE:6	1	1			1	1	1	1	1	2	1
IRE:9	1	1	1		1	1	1	1	1	2	1
IRE:16	1	1			1	1	1	1	1	2	1
IRE:23	1	1		1	1	1	1	1	1	2	1
IRE:27	1	1			1	1	1	1	1	2	1
IRE:38	1	1	1		1	1	1	1	1	2	1
IRE:40	1	1	1		1	1	1	1	1	2	1
IRE:41	1	1			1	1	1	1	1	2	1
IRE:44	1	1			1	1	1	1	1	2	1
IRE:47	1	1			1	1	1	1	1	2	1
IRE:49	1	1			1	1	1	1	1	2	1
IRE:50	1	1			1	1	1	1	1	2	1
IRE:52	1	1		1	1	1	1	1	1	2	1
IRE:62	1	1			1	1	1	1	1	2	1
IRE:65	1	1			1	1	1	1	1	2	1
IRE:66	1	1			1	1	1	1	1	2	1
IRE:86	1	1			1	1	1	1	1	2	1
IRE:121	1	1			1	1	1	1	1	2	1
IRE:122	1	1	1		1	1	1	1	1	2	1
IRE:129	1	1			1	1	1	1	1	2	1
IRE:175	1	1			1	1	1	1	1	2	1
IRE:184	1	1			1	1	1	1	1	2	1
IRE:192	1	1			1	1	1	1	1	2	1
IRE:195	1	1			1	1	1	1	1	2	1
IRE:213	1	1	1		1	1	1	1	1	2	1
IRE:220	1	1			1	1	1	1	1	2	1
IRE:222	1	1			1	1	1	1	1	2	1
IRE:225	1	1			1	1	1	1	1	2	1
IRE:226	1	1			1	1	1	1	1	2	1
IRE:228	1	1	1		1	1	1	1	1	2	1

4.4 Installation issues

4.4.1 Sensor fitted homes

Initial installations of environmental sensors were carried out by Rigney Dolphin Group in conjunction with the project co-ordinator. Each individual dwelling was inspected before installation to ascertain the most effective positioning of environmental devices. Environmental sensors were installed first to minimise the amount of time troubling participants (it was part of the Louth retention strategy to ensure participants in the intervention group were treated with the utmost care and attention during the installation phase). Generally, smoke detectors were placed in hallways, water detectors were placed behind kickboards in the kitchen or bathroom, temperature sensors were placed in either the living room or kitchens and presence sensors were situated in bedrooms and living rooms / kitchens.

The second installation consisted of the InTouch devices, broadband router and medical devices. The positioning of the broadband router and the InTouch was a concern because, in order to accommodate the *ello!* devices, these pieces of

equipment would need to be close to the television set. Most participants wanted the devices placed in hallways and in some cases in bedrooms, which rendered the e*llo!* installation unfeasible. This provides the participants with more privacy when taking medical measurements. The final installation was eight glucometers and six asthma monitors based on the pathologies of the participants.

The third installation was the Mambo device.

The e*llo!* devices were not deployed because of problems encountered in the test lab facility with the broadband connectivity. It later transpired that the broadband provider (Vodafone) was intentionally blocking VOIP under the tariff we were using. This was resolved, however, problems still exist with the configuration and the system is not currently deployed.

It was not possible to install any HomeMatic devices because the doors, windows and radiators encountered were not suitable.

The intervention group demonstration gave an overview of how the devices worked, but individual training in the use of each device was provided by the project co-ordinator in conjunction with a technician in the participant's own home. This occurred at installation; follow up training is ongoing.

4.4.2 Help desk

The project co-ordinator is tasked with being the communication conduit for all issues. Technical issues are logged in a spreadsheet and reported to the technicians and/or HIS. Regular conference calls are made to HIS to follow up on open issues.

Issues in respect of the call centre are dealt with according to the protocol agreed in the service level agreement.

4.4.3 Contact Centre

The Contact Centre (CC) is Rigney Dolphin Group (RDG). Originally the Louth site had agreed to employ McElwaines Smart, but the supplier went into liquidation prior to the service going live. This caused a delay in our "go live" date due to integration issues.

Escalation paths have been agreed with RDG for Type 1 and 2 alarms. Medical measurements are reviewed on a 9 to 5 basis, Monday to Friday. Where alerts appear, the participant is contacted and asked to repeat the measurement a number of times. If the situation continues the participant is asked to contact their GP.

Emergency alerts – smoke detector and Mambo – follow a path leading to contacting the Emergency Services. Other passive alarms are escalated to the participant or next of kin.

4.5 Initial trial results

4.5.1 Use of equipment / Findings of test implementation with HIS / *ello!*

Medical Devices

In the initial rollout of devices, all the participants in the intervention group were fitted with a blood pressure monitor (BP) and a weight scale. In the subsequent rollout, and with reference to participant pathologies, eight glucometers and six asthma monitors were issued.

Not all participants use the medical devices on a daily basis, and require prompting from the project co-ordinator in conjunction with RDG. Some participants document the results themselves and bring them to the GP on their scheduled visits. Device issues discovered include:

- Incorrect readings from BP monitors – usually down to the cuff being placed incorrectly on the arm.
- Weight scales are heavy users of batteries.
- Glucometer readings are in a different format to what the participant is used to.

Mambo

The Mambo was deployed in 28 of the participants' homes in the intervention group. We were unable to install the Mambo device in two participants' homes because they had no mobile phone coverage in their area.

The Mambo phone is carried on their person when out of the house and a keyfob is worn when inside the house.

Video Conferencing

The video conferencing software was initially tested (as were all devices) in the Netwell Centre test laboratory using the DkIT broadband signal. However, when the system was tested using one of the Vodafone routers, all signals were lost. This was due to the VOIP blocking stated above.

After discussions with Vodafone's corporate social responsibility director, this exclusion was lifted on all our routers. Further testing was carried out in the lab but there were still issues in relation to bandwidth – audio without visual and vice versa. Other issues included:

- No wireless protocol – this meant that the system could be only deployed beside the broadband router, which is rarely situated in close proximity to the television set.
- Camera and microphone are not integrated into the device – unfortunately this leads to a lot of wiring around the television set area which is confusing to the older person.
- Adding new contacts was very complicated and required a family member registering through another computer.

- Contacts were not updating on the participant's television screen.
- Remote Control was confusing.

Astrid Games

The initial rollout of the Astrid games were translated from Dutch into English, however, the translation was difficult to understand. Subsequently, we find that participants do not use the games.

Further iterations require the Louth site updating the source code with new games. We were unaware of this and recruited a new researcher to take on this task. Full training was provided by Astrid, but unfortunately the new recruit moved on before updating any new games.

4.5.2 T0 data

The following questionnaires were administered to all participants in the Intervention Group and Control Group:

- SF-36.
- HADS.
- CGA: components include TGUG, Gait speed, Hand grip, MNA Mini-Cog, EFS and CGI.
- Social Impact questionnaire.

The questionnaires were administered between September 2011 and June 2012, although the vast majority were administered in September 2011. Altogether, the numbers of participants completing these questionnaires is shown in Table 15 below.

Table 15: Louth T0 data collection

Questionnaire	Intervention Group	Control Group
SF-36	30	30
HADS	30	30
CGA	30	30
Social Impact	30	30

Issues:

- Some participants required help with completing the questionnaires due to issues with eye-sight, literacy issues, or trouble with writing due to physical health issues such as arthritis etc.
- Restricted resources (in the form of researchers, volunteers and time) were an additional barrier to getting the data collected in a fast and efficient manner.
- Time constraints and participant availability sometimes posed an issue in that researchers aimed to minimise repeated visits of data collection with the intention of avoiding participant burden. However, often participants were

unavailable for an extended period of time, or visits had to be suspended due to participant fatigue, and data collection had to be carried out over a number of visits.

4.5.3 T12 data

The following questionnaires were administered to all participants in the Intervention Group and Control Group:

- SF-36.
- HADS.
- CGA: components include TGUG, Gait speed, Hand grip, MNA Mini-Cog, EFS and CGI.

The questionnaires were administered between November 2012 and January 2013, although the vast majority were administered in November / December period with only five participants interviewed in 2013. Altogether, the numbers of participants completing these questionnaires is shown in Table 16 below.

Table 16: Louth T12 data collection

Questionnaire	Intervention Group	Control Group
SF-36	30	30
HADS	30	30
CGA	30	30
Social Impact	0	0

Issues:

- Similar issues to T0 were encountered and are carried forward.
- An open day was held in DkIT for intervention group participants to view the research centre and take measurements. Not all intervention participants availed themselves of this opportunity.
- Some participants required help with completing the questionnaires due to issues with eye-sight, literacy issues, or trouble with writing due to physical health issues such as arthritis etc.
- Restricted resources (in the form of researchers, volunteers and time) were an additional barrier to getting the data collected in a fast and efficient manner. However, the team were successful in gathering the data in a relatively short time given the Christmas holiday period
- Time constraints and participant availability sometimes posed an issue in that researchers aimed to minimise repeated visits of data collection with the intention of avoiding participant burden. However, often participants were unavailable for an extended period of time, or visits had to be suspended due to participant fatigue, and data collection had to be carried out over a number of visits.

- The CGI questionnaire had an index that had no explanation. This was left blank in all cases.
- The Social Impact Questionnaire was not issued because participants had difficulties understanding some of the questions.

5. Latina

5.1 Clinical protocol and preparation for trials

5.1.1 Ethical approval

The ethical approval was given in March 2011.

It was prepared by ASL Latina and specifically with the contribution of Monti Lepini District Direction.

5.1.2 Recruitment of the users and random allocation to the intervention or control group

Potential participants were selected starting from a list prepared by GPs in the Monti Lepini area, where the trial was started. Taking into account the inclusion criteria set out in the CT documents, GPs selected from their patient lists those that were suitable for the trial.

Using this list, staff from ASL Latina visited each one in order to verify the adherence of candidates to the inclusion and exclusion criteria for the trial. In these visits, the project was explained to the patients, and any questions from them or their relatives were answered in order to give them a full understanding of the project aims, and the implications of their participation.

After the inclusion and exclusion criteria had been verification, and the patient had confirmed their participation, the informed consent form was signed, and he/she was included in the trial. Their data was then sent anonymously to the Medical Coordinator who randomised them into intervention and control group.

This procedure of recruitment and randomisation was carried out three times in 2011, in three groups, until all the participants were randomised. This happened because we were not able to find all the candidates at the same time. It took a period of 5-6 months before we had all participants randomised. At the end of 2011 all candidates were recruited.

63 patients were randomised, but before the study start there were three drop outs in the control group, and two in the intervention group. The final numbers were 58: 30 in the intervention group and 28 in the control group.

During the trial to date, we have had one patient who passed away; currently there are 29 in the intervention group, and 28 in the control group.

5.1.3 Informed consent form signature

Every participant has signed the informed consent form once the inclusion and exclusion criteria were checked:

5.1.4 Description of the resulting trial population

The demographic of the trial population is given in Table 17.

Table 17: Latina: Demographic profile

Intervention				Control		
Patient ID	**Sex**	**Age**		**Patient ID**	**Sex**	**Age**
IT1110304	M	79		IT1110302	F	77
IT1110307	M	67		IT1110303	M	73
IT1110309	M	74		IT1110305	M	68
IT1110311	M	72		IT1110306	M	73
IT1110312	M	67		IT1110308	M	66
IT1110314	F	76		IT1110310	M	77
IT1110316	M	73		IT1110313	M	71
IT1110318	F	66		IT1110315	M	76
IT1110319	M	76		IT1110317	F	78
IT1110320	F	69		IT1110321	F	75
IT1110324	M	78		IT1110322	M	82
IT1110325	M	92		IT1110327	F	69
IT1110326	F	76		IT1110328	M	75
IT1110331	F	73		IT1110330	M	75
IT1110336	M	77		IT1110332	M	76
IT1110337	M	69		IT1110338	M	80
IT1110339	M	70		IT1110340	F	66
IT1110341	F	66		IT1110342	M	68
IT1110343	M	83		IT1110344	M	74
IT1110345	M	74		IT1110346	M	77
IT1110347	M	74		IT1110348	M	83
IT1110349	F	85		IT1110350	F	84
IT1110351	F	82		IT1110352	M	79
IT1110353	M	74		IT1110354	M	69
IT1110355	M	72		IT1110361	F	85
IT1110359	F	83		IT1110364	F	77
IT1110363	F	81		IT1110366	F	82
IT1110365	M	79		IT1110368	M	70
IT1110367	F	82				
IT1110369	M	73				

Notes:

- Yellow = Drop-out

Mean age intervention group is 75.4.

Mean age control group is 75.2.

Distribution by gender is shown in Figure 4 below.

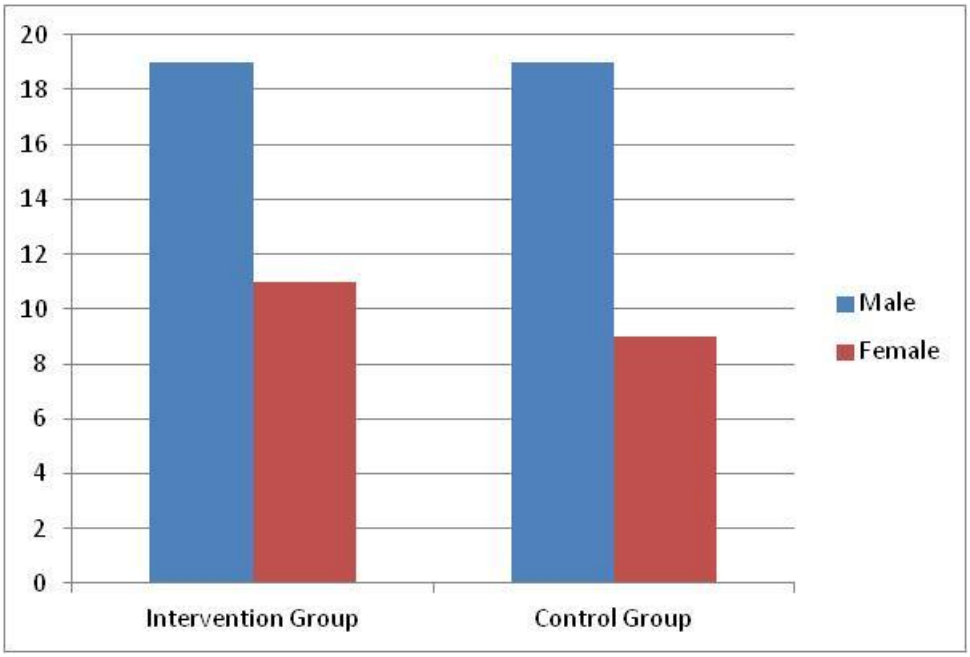

Figure 4: Latina: Distribution by gender

5.2 Personnel involved in trials

5.2.1 Authority staff: planners, financial and management

The Latina project team consisted of different disciplines:

- Project leader: Dr. Luigi Ardia

  Coordinating all the necessary actions to work towards a complete pilot site.

  Communication to the Consortium concerning the Latina pilot site.

- Project Manager consultant: Paolo Squillace

  Coordinating all the operational issues, questions with all project members and keeping in touch with all the other Consortium members and EU representative.

5.2.2 Health & social care staff

- Medical coordinator: Dr. Luigi Ardia

  Coordination and responsible of all medical issues

- Medical Collaborator: Dr. Angela Coia:

  Coordinating all the activities related with visiting, guiding, and training the participants, taking CRFs, questionnaires, first check up when device issues come up.

  Communication to the project team.

- Social Caregiver: Dr. Roberta Centra

- Three nurses part time:
  - Vincenzo Faustinella
  - Emanuela Morsello
  - Debora De Lulo

  Visiting, guiding, training the participants, taking CRF, questionnaires, first check up when device issues come up

5.2.3 Technical staff

All the installations have been done by SCH sas. They had training to correctly install all the devices at the homes of the participants.

- IT technician: Alessio Squillace.

5.3 Equipment

Table 18: Latina: Distribution of sensors

Medical devices installed	
- ECG	15
- Blood Pressure Meter	15
- Weight scale	All
- PO2	10
- Glucose	19
- PEF	10
Environmental devices installed	
- Smoke	30
- Water	30
- Motion	30
- Temperature	30

5.4 Installation issues

5.4.1 Sensor fitted homes

All the installations were carried out by SCH.

All the devices were installed in the houses of the patient. In the cases of patients who dropped out the devices were retrieved.

While installing the smoke detector in very small houses, some problems were encountered; when it was placed too close to the kitchen, too many false alarms were made.

The water leak detector had to be attached to the wall otherwise the detector can be displaced while cleaning the bathroom.

The domotic devices, i.e. the winmatic, climatic and keymatic, were not installed due to two main reasons:

- There was not the right type of window lock, radiator and door lock respectively, to be able to install these devices.
- Also some people who rent a flat did not want to ask the owner permission to install those devices.

The training of the devices was carried out by the medical staff.

5.4.2 Help desk

First line contact for the participants is the therapist. They established a very good relationship with participants. There was a direct personal trust and this helped the project very much.

5.4.3 Contact Centre

The Contact Centre (CC) is Darco Servizi.

The Mambo alarms and the alarms of the environmental sensors are monitored by Darco Servizi.

The clinical alarms (BPM and weight scale) are monitored by medical staff, and mailed to the GP when a situation occurs that needs follow up.

5.5 Initial trial results

5.5.1 Drop outs

This is the reasons for the participants to drop out of the intervention group:

- Passed away (patient IT1110343).

5.5.2 Use of equipment / Findings of test implementation with HIS / *ello!*

Medical devices

Most participants were very enthusiastic to use the medical devices such as the weight scale and the blood pressure meter. There are some participants who use them every day, and watch the statistics on the InTouch, or even show the results to the nurse or GP while they are visiting the participant.

Other participants find it too difficult in use and always forget how to use the weight scale and how to check the results on the screen. They cannot remember to wait for the beeps from the scale before they step off.

Some participants do not dare to step on the weight scale while home alone, or do not manage to put on the band of the BPM. They only take measurements when the therapist visits them.

Video conference

None of participants used the *ello!* device because it was not considered useful for them.

Most of patient's relatives live very near to them and so the main purpose of *ello!*, to keep in contact with patients, is not relevant.

InTouch

There were several problems with InTouch due to their sensitivity to sudden power failure. In the mountain area of Monti Lepini, sudden power failure during rain storms occurred several times; when this happens, InTouches crash and a technical intervention is needed.

Mambo

The Mambo is not used by participants who do not want to have another device in addition to their own cellular phone. This is the reason why they leave the Mambo unused at home.

5.5.3 T0 data

The questionnaires were administered between July 2011 and December 2011. Altogether, the numbers of participants completing these questionnaires is shown in Table 19 below.

Table 19: Latina T0 data collection

Questionnaire	Intervention Group	Control Group
Edmonton Frail Scale (EFS)	30	28
Short Form -36 (SF36) Survey	30	28
Hospital Anxiety depression Scale (HADS)	30	28
Mini Nutritional Assessment® (MNA)	30	28
Clinical Global Impression (CGI)	30	28
Gait Speed Test (GST)	30	28
Timed Get Up & Go test (TGUG)	30	28
Clock Drawing Test	30	28
Hand Grip Strength (HGS)	30	28
Mini-Cog: recall of words	30	28
Katz Index of Independence Activities of Daily Living	30	28
Social Impact indicator	30	28

Almost all the participants needed help filling in the questionnaires. The questions had to be read to the participants. In different questionnaires, the same questions appear; this was rather confusing for the participants.

In the SF36 questionnaire, the questions are not well formulated.

Sometimes the tests took too long, the participants were too tired and the therapist had to make a new appointment to see the participant a second time.

5.5.4 T12 data

The data collection T12 took place in January and March 2013. It went more easily than T0, as both therapists and participants were already aware of what questions and what tests have to be done.

6. Analysis of baseline population

The various charts below plot the intervention and control groups, to analyse for any significant heterogeneity. For all of the categories analysed, the charts demonstrate a good level of homogeneous between the two groups at baseline (T0).

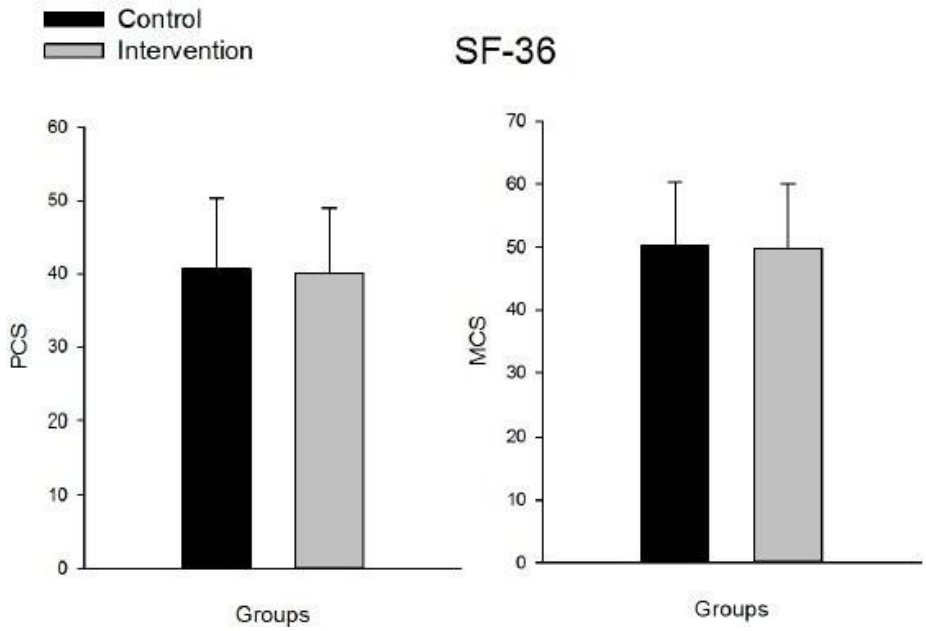

Figure 5: SF-36 scores at T0

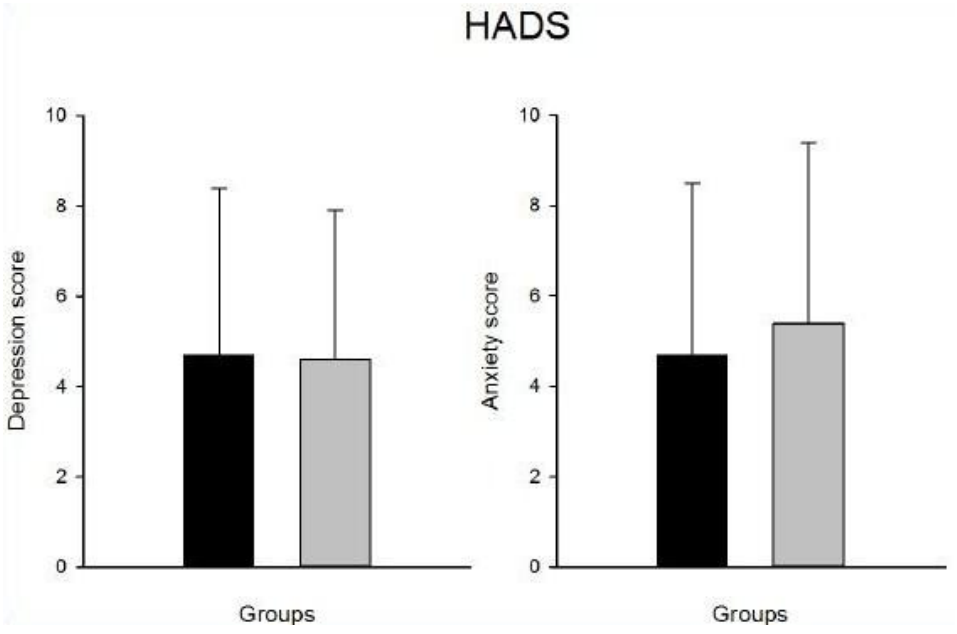

Figure 6: HADS scores at T0

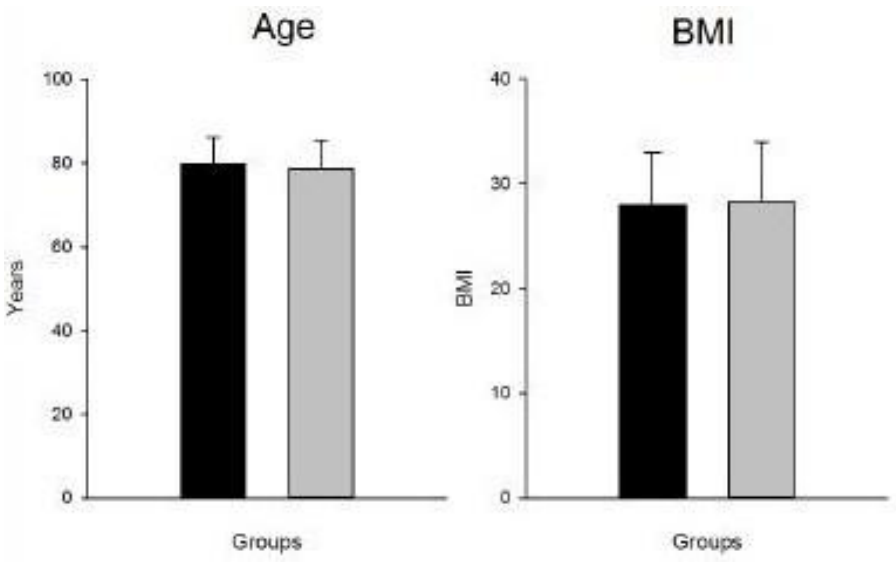

Figure 7: Age & BMI at T0

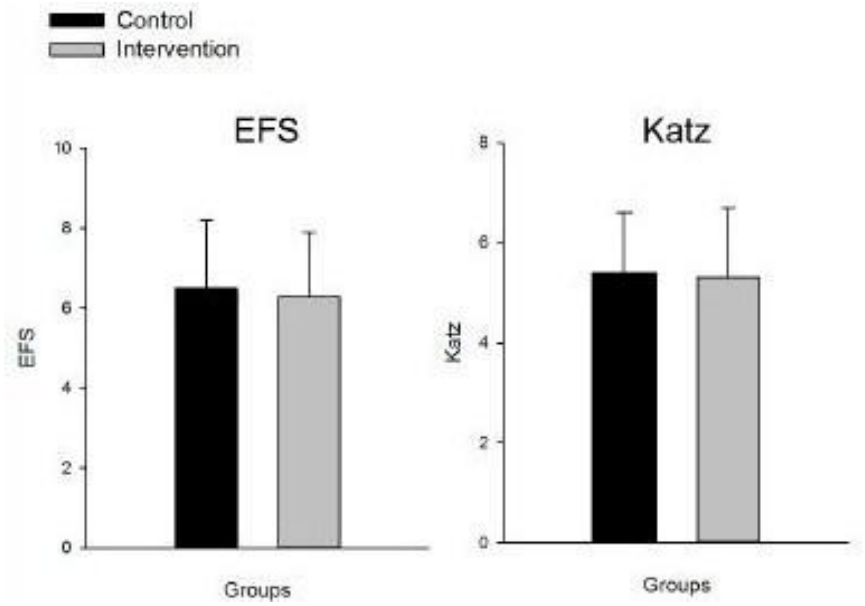

Figure 8: EFS & KATZ scores at T0

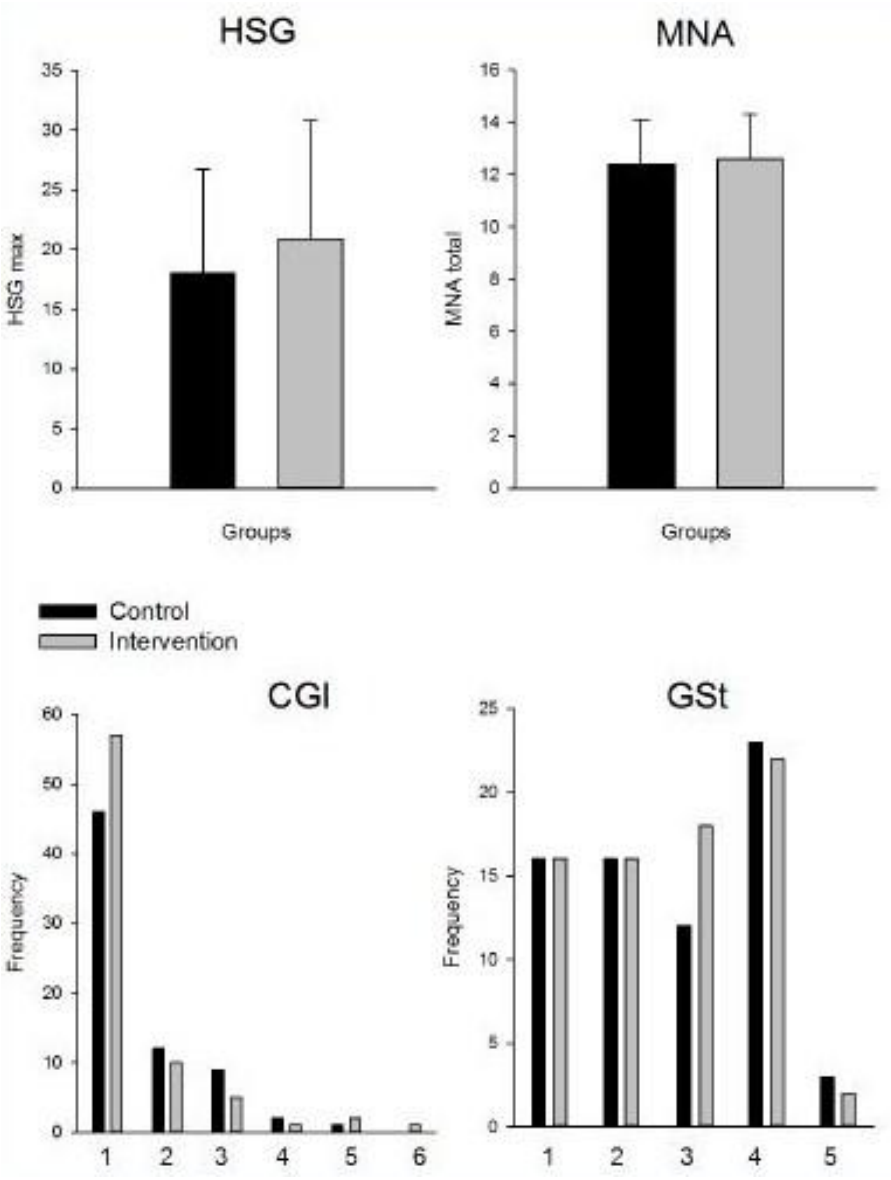

Figure 9: MNA & CGA component scores at T0

7. Conclusions

The conclusions on the finding of the project at mid-term are summarised below. These will be elaborated further in the Final Evaluation Report, including results from questionnaires and surveys.

7.1 Monitoring and Alarm Handling Subsystem

This contributes to the safety of the older person in terms of both their health, particularly when they suffer from chronic conditions, and their physical safety around the home.

Health monitoring

This has been well received, and is probably the most favoured of the services offered.

However, reliability of some of the devices has been disappointing, and battery life is an issue. The latter is related to the use of Bluetooth as the transmission standard. It is well known that Bluetooth is very much energy consuming, but no other standard is currently available from medical devices manufacturers.

Environmental monitoring

These have generally been found to be useful and accepted, though care is needed in where they are located, particularly the smoke and flood detectors.

7.2 eInclusion Subsystem

This provides videoconferencing services to help include the older person in the society.

Since the inception of the project, services such as Skype have made significant progress into society. While these services do not provide some of the protection for the older person, particularly against unwelcome third party callers, the *ello!* service has not been used very much.

For the future, it is more likely that eInclusion services will be met through existing products available free in the marketplace.

7.3 Domotic Subsystem

This supports management of the house by the older person even if he/she suffers from physical impairments, including assistance from the Contact Centre.

It has not been possible to install the device needed to provide this service, due to:

- The devices would not work with the windows and radiators in most of the participants' homes.

- Unwillingness of participants to have the necessary holes made in their doors and windows, especially where homes were rented.

7.4 Daily Scheduler

This is designed to assist in the organisation of the daily life of older people.

In principle, this service was welcomed by participants. However, without the ability for the older people themselves, or their carers, to enter events into the scheduler through the InTouch, its use has been severely compromised.

The InTouch currently does not have a keyboard. However, moving this to e.g. a tablet would remedy this, making it easier to implement entry of events by the older parsons and their carers / relatives if they were allowed to do so (this was not the case in HOME SWEET HOME).

7.5 Navigation Subsystem

This support the orientation of the older person when outdoor, providing the ability for the older person to ask for directions from the Contact Centre.

This has been used very little by participants, and at this stage no feedback has been gathered on its use.

7.6 Mental faculty maintaining or cognitive training

This supports the training and maintenance of mental / cognitive faculties, and the measurement of these.

This has proved very popular with the participants, but requires a large investment of effort to create and maintain the exercises, particularly those exercises which are language and culture dependent.

In the future, it service providers should seek to enter into collaborative agreements with existing providers of language / culture independent games (e.g. Sudoku, etc.) but providing more general knowledge type exercises could be more difficult.

However, a new generation of serious games with a more intuitive interface and more oriented to images rather than text could reduce the cost of adapting the tool to the local context.