COMPETITIVENESS AND INNOVATION FRAMEWORK PROGRAMME

ICT PSP call for proposals 2008 - ICT PSP/2008/1

Project Acronym: **Long Lasting Memories**

Project Number: **238904**

Project Type: **Pilot Type B**

Project Full Title: **Long Lasting Memories**

ICT PSP Main Theme addressed: **1.4: ICT for ageing well with cognitive problems, combining assistive and independent living technologies**

D.4.1 Project Deployment Plan

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[1] Please use a new number for each new version of the deliverable. Add the date when this version was issued and list the items that have been added or changed. The 'what's new' column will help the reader in identifying the relevant changes. Don't forget to update the version number and date on the front page and the header.
[2] A deliverable can be in either of these stages: "draft" or "final". For each stage, several versions of a document can be issued. *Draft:* Work is being done on the contents. *Final*: All chapters have been completed.

Table of Contents

1. Overview

This deliverable gives a brief description of the planned project and the purpose of the system to be validated. Special emphasis is placed on the project's deployment complexities and challenges. Previous Deliverable D3.1 gathers the needs and requirements for site infrastructure (hardware and software).

1.1 Purpose

This document is intended to list/document the plans for deploying LLM service to it's production environment(s) and placing it into use by the customer and user organizations.

LLM pilot deployment plan purposes are:

- Ensure that the system works properly in the business environment.
- Ensure that the design meets the business requirements.
- Test the deployment process.
- Train the installation team.
- Create documentation for the full deployment.
- Train the support and Help desk teams.
- Train the administrative teams.
- Gather information for estimating future support requirements.
- Gather information for estimating actual hardware requirements.
- Meet the baseline requirements for functionality that were established in testing.
- Develop and test end-user training materials.

Although LLM has to conduct multiple pilots, the objectives are the same for all of them. At the end of the pilots these objectives will be evaluated based on the following set of metrics:

Technical Requirements:

- Availability
- Performance
- Reliability
- Scalability
- Ease of integration
- Cost of integration

End-Users feed-back:

- Accessibility
- Availability
- Affordability
- Usability
- Acceptance & satisfaction

These will be used to evaluate the success of the pilot and to estimate the level of support required.

LLM deployment strategy deals with 3 different scenarios: living **At Home**, **Day Care Centres; Hospitals** and **Clinics**.

Main objectives are

- Integrate two (2) existing ICT solutions: (eHome and Brain Fitness Power and/or alternative solution) with physical training.
- Demonstrate the impact potential of LLM service in five (5) different countries.
- Verify the technical, organizational and legal feasibility along the value chain of stakeholders.
- Verify the sustainability, scalability and applicability of LLM services across Europe.

The LLM project aims to deliver an integrated ICT solution that will provide cognitive and physical training for elderly people inside the framework and safety of an assisted living environment. The service will be installed in homes and institutions and will ensure the accident-free, personalized and monitored corporal and mental training of its users. Meanwhile, users will be able to take advantage of the features of an independent living solution. This will be accomplished by home automations that will compensate for the disabilities of people with cognitive problems or mild dementia during their daily activities. Finally, an elaborate distributed sensor network will guarantee immediate response in case of an emergency, by calling for help through public telephone lines. In this respect, LLM aims at a unified solution that will combine independent living solutions with cognitive and physical training, according to recent research claims on the effectiveness of moto-sensory training on senior citizens with cognitive problems or mild dementia.

The purpose of the Pilots Deployment Plan is intended to determine as best as possible under test conditions whether the pilots deployment to take place during the pilot duration, satisfy the system requirements and also meet the business goals.

LLM uses pilots as segmented deployments with the end aim of carrying out the validation (practical, supportive and cost-effectiveness) of the LLM platform providing ICT services for an Independent Living, addressed to elders, people with cognitive problems or mild dementia and their care providers. LLM field pilots are expected to help End-Users evaluate LLM Services needed for full deployment and will confirm LLM capabilities.

1.2 Business Context

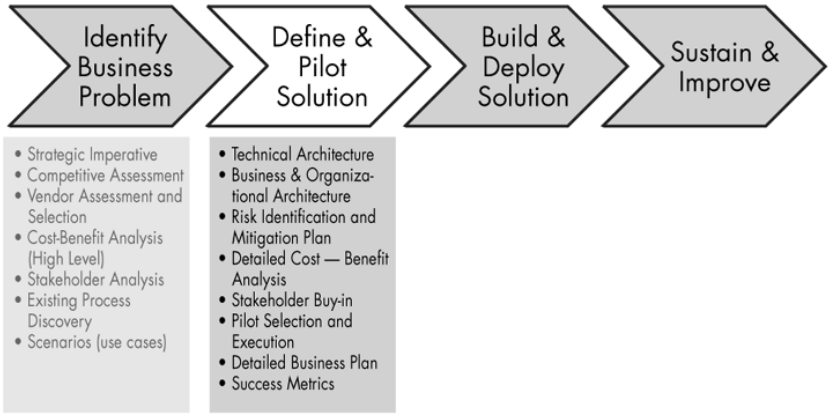
From the business point of view, the LLM service is designed to provide its features to elderly people **living at home**, staying at **day care centres** or being **hospitalized** in a simple user-friendly way. Though these three categories significantly differ from one another they can all utilize the LLM platform, by gaining different benefits each time.

Accordingly the Business processes will adapt to each of the three Service modalities and also they will have to be considered by separate so much in the market assessment as in the drawing of the Business Plan(s).

1.3 Summary

Summary of the Deployment Plan, including an overview of activities necessary to get the product/service into a production environment such as installation, configuration, and initial operational activities.

The following diagram synthesizes the activities needed to get LLM service into a production environment



LLM ultimate goal is to penetrate a niche market (the physical and cognitive brain fitness) and getting a presence in it, either by complementing other already existing solutions and/or by displacing them. On the way to that goal are some difficult issues such as operational funding, scope of services, perceived value, and sustainability.

The success of LLM will depend upon its ability to effectively engage users and provide services they choose to use and accept because feel are what the want/need. Wherever possible local branches or agencies exist they will be offered professional services to significantly extend their outreach.

LLM would assertively engage local industry in offering its services and trying to create, whenever possible, a three-way partnership with public authorities, industry and their needs and the carers audience and all those willing and able to serve addressed users given the necessary resources.

The path to success here is to begin small, be at all times self-sufficient, possess the necessary tools to realize production commitments and strive at all times to include as many people as possible in the day-to-day operations of LLM.

2. Assumptions, Dependencies, Constraints

2.1 Assumptions

Description of the assumptions about the current capabilities and use of the product/service when it is released to production.
Assumptions should also include a description of stakeholder groups in the pilot.

LLM Capabilities

Is an integrated ICT platform, which:
Combines state-of-the-art cognitive exercises against cognitive decline with physical activity in the framework of an advanced ambient assisted living environment.

LLM will offer support to elderly people and their relatives and families, by monitoring of day-to-day activities of senior citizens and identifying imminent hazards, increasing their self-esteem and alleviate symptoms relevant to cognitive decline, their loneliness and potential depression.

Long Lasting Memories' main objective is to deploy new services and interaction modalities to extend and simplify the access to tools for cognitive task training complemented with physical exercises, in particular by the elderly, through the use of the LLM innovative ICT system.

The strategic objective of the **LLM** project is to integrate two existing ICT solutions with physical training equipment, thus delivering an innovative system for ageing well and validating the resulting service in various sites all over the EU. The reasoning behind our project is our belief that a unified solution of different components from ambient-assisted living and self-training will be able to surpass existing unilateral approaches.

The **LLM** service is designed to provide its features to elderly people living at home, staying at Day Care Centres or being hospitalized in a simple user-friendly way. Though these three categories significantly differ from one another they can all utilize the **LLM** platform, by gaining different benefits each time.

LLM prototype will be based in:
The integration of the **Cognitive Training Component** (CTC) and the **Physical Training Component** (PTC), with the **Independent Living Component** (ILC) or eHome solution.

The CTC will support the cognitive exercising procedure provided by the BrainFitness software (and/or the alternative software chosen by the pilot partner).

- Software: BrainFitness and/or alternative
- eHome (touch screen)
- Central Management System (CMS): Regular low-cost personal computer close to the minimal running requirements of any brain fitness software
- Delivery: Wiring with the rest of the system

The ILC is based on the eHome system and is comprised of a network of distributed wirelessly operating sensors connected to an embedded system (the e-Home central unit). It includes features such as intelligent learning of normal and exceptional patterns of

behaviour (dangerous situations or indicators for emerging health or social problems), raising of alarms and as an optionally controlling of elements which are typical for a smart-home environment.

- User Interfaces: **Local Interface** and **Remote Interfaces** (on a PC or sent to a cell-phone).
- Sensors: Multi-Sensor-Box ((temperature, accelerometer, reed-switches, illumination detectors), SW: Simple on/off switch
- Facility to connect Actuators: Act: e.g. for moving blinds, door opener, window opener
- Facility to connect Sens+Act IPO: Instrumented Power Outlet (sensors for voltage and current, remote switch)
- Home Control Unit: (e-HCU) (eHome information processing)
- Connection from Local to Remote Interface over broadband

INTERFACES
Around the embedded system forming the e-HOME-Central-Unit (e-HCU) which is managing the sensor and actuator network and carrying out the inference-drawing, **two user tailored multi-modal interfaces**, are being deployed: one for local and one for remote interaction with the system are provided for the inhabitants, the relatives, as well as for formal and informal carers.

As for the PTC the only requirement is to be able to extract the stored information of the exercises in order to send it and integrate it in the CMS

Use of LLM Service **TO BE DETAILED**

At Home:
- As entertainment
- As therapy supplement
- Gaming as a mean of social cohesion
- As part of healthy life style

At Day Care Centres:
- As entertainment
- Gaming as a mean of social cohesion
- ….

During Hospitalization:
- As therapy supplement

Stakeholders Group in the Pilot

Besides the Deployment Team, LLM stakeholders taking part in the pilots are composed of several profiles:

- Hospitals and Clinics (Geriatrics & Psychologists Departments)

- Public Authorities: Day Care Centres; Residences; Tutelage Flats; National Health Services
- Seniors' Communities (Retirement Houses; Residential Facilities)
- Private Families

Although none existing actually within the Consortium or committed to it, **Insurance Providers** and also specialized **Gyms** are showing a growing trend as one of the most eager consumers for this type of Services to add value to their offer. Thus LLM Consortium will do its best to engage them in the project as soon as possible

2.2 Dependencies

Description of the dependencies that can affect the deployment of the product/service.

- Is the technical architecture scalable and flexible enough to meet the project's business needs?

As with any technology, LLM and other Internet based technologies have the potential for technical problems. As soon as we are aware of LLM problems and/or downtime, LLM support team will respond day or night to restore service.

There are two types of technical problems you may encounter with Internet based technologies: complete downtime where the system in not accessible or a speed so slow the system is unusable.

LLM pilots will have support during operating working hours (Monday through Friday from 8:30 am to 5:00 pm or after hours and weekends by individual request) and users will be able to call the LLM Help Desk during the pilot period for resolution of problems.

Deployment dependencies in relation with the project plan are those preceding work activities in WP3 that is the work package carrying out the more technical work of the project.

The integration process of the 3 different components constituting the LLM service:

1. The eHome AAL environment
2. The Cognitive Training Component (CTC)
3. The Physical Training Component (PTC)

is from a technical perspective, the most challenging point and deployment dependencies are mainly related with it.

On the hardware side: dependency on devices availability and/or in their performance (difficulty to find physical training devices able to connect with the CMC; faulty performing of sensors; ...
And in the software side: LLM service offer unable to "adapt" the solution to user's requirements/needs because of dependency on third parties (cognitive applications owned by third parties and not open)

2.3 Constraints

Constraints should be understood as the factors that may limit the ability to deploy LLM service. In LLM we have identified the following

- An undesired performing of the solution – failure of some of the components preventing the use of the solution and / or not reliable enough
- Too expensive –not affordable for users
- Too much demanding of resources: people, time, money (professional trainers, doctors, technology supporters, non-professional carers, volunteers,…)
- Not accepted by end-users and/or potential clients
- Users prefer single solutions vs an integrated solution that make their lives more complicated (too demanding for an older and/or disabled person in terms of time and personal efforts)

3. Overall Pilot Deployment Plan and strategy for long term viability

3.1 Overall pilot deployment plan and strategy

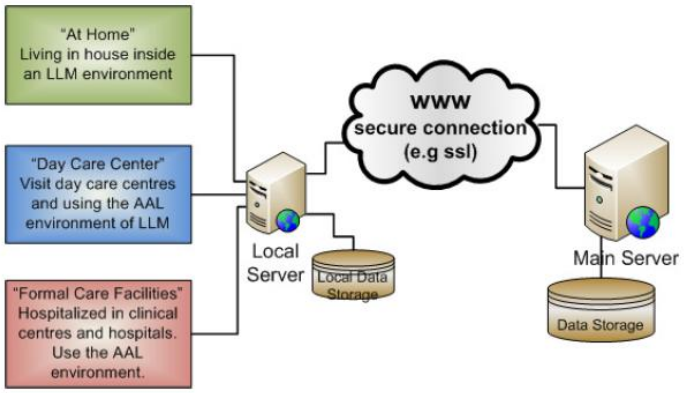
Elderly people have physical as much psychical problems to work with the newest technologies, as well as an inherent reaction to learn new things. So LLM will use simple software interfaces avoiding the use of the typical interfaces and the inherent elderly people limitations (hardware as much software) to interact with the systems in a more intuitive way.

In LLM technology is a tool through which new services are to be spread to wide population. Its goals are focused on to make easier the elderly life and its objective relate with improving the quality of the day to day life of elderly people, making easier for them the use of therapy and physical training systems (cognitive training and stimulation as well as physical exercises) with a more intuitive interface.

The most important thing in LLM is the deployment of services applying ICT technologies to exploit their advantages for the elderly people by using Physical and Cognitive Rehabilitation (amusing use, simple and adaptable interfaces).

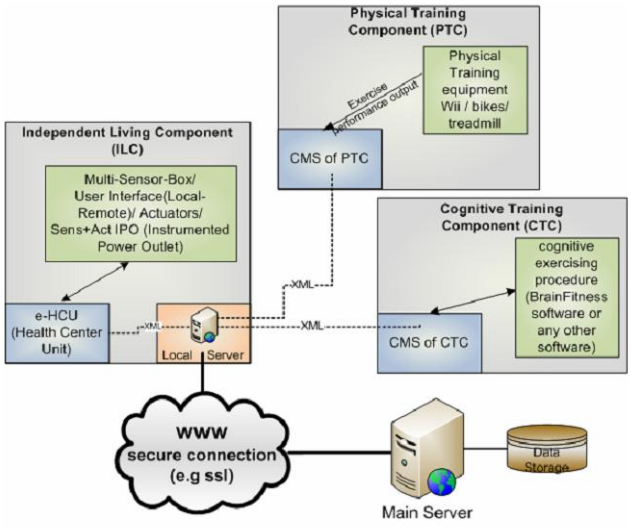
This deliverable gives a brief description of the planned project and the purpose of the system to be validated. Special emphasis is placed on the project's deployment complexities and challenges. Deliverables D3.1 gather the needs and requirements for site infrastructure (hardware and software).

- **LLM** deployment strategy deals with 3 different scenarios:



3.2 Deployment Diagram

Description and figure depicting where all system products/services will reside within the operational site.



Does the project require different deployment diagrams to address the 3 different environments? Are differences in deployment anticipated from a technical perspective?

3.3 Phased Rollout

Description of activities for a phased function rollout or a phased user base rollout.
This section should also explicitly describe how updates from each iteration of the pilot will be rolled back out (as necessary) for improving on the subsequent iteration. To delete

LLM primary pilot objectives are:

- Ensure that the system works properly in the business environment.
- Ensure that the design meets the business requirements.
- Test the deployment process.
- Train the installation team.
- Create documentation for the full deployment.
- Train the support and Help desk teams.
- Train the administrative teams.
- Gather information for estimating future support requirements.
- Gather information for estimating actual hardware requirements.
- Meet the baseline requirements for functionality that were established in testing.
- Develop and test end-user training materials.

LLM deployment procedures use an iterative approach.

Pilots will be held in 4 iterations of 3 months with one month in between for adaptation and will be held in five EU Member countries. The partners involved in the coordination of the pilots for each country are:

- Austria: RALTEC
- France: E-Seniors
- Greece: IGNA
- Spain: INTRAS
- UK: GSI and MKC

The pilots will be held over a period of 15 months, as shown in the timeline below:

Project month	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Pre-pilot			Iteration 1				Iteration 2				Iteration 3				Iteration 4			
Austria																			
France																			
Greece																			
Spain																			
UK																			

Each implicated partner will be responsible for:

- Recruiting and randomising participants according to criteria set in the deployment plan (according to factors like age, medical history, suffering from mild dementia or other cognitive disability etc) over 3 weeks per iteration
- Training the participants on the usage of the system over one week
- Running the LLM service, according to the quality assurance reports and the training procedure preceding the pilots
- monitoring the procedure for the entire 8 week period
- noticing problems especially in ease-of-use, general usability, motivation effectiveness and general interest shown to the service by the elderly – for medium and wide scale deployments
- technically supporting the users of "At Home" installations throughout the pilots' duration
- holding interviews and handing out questionnaires to acquire the direct opinion of the system's users
- complying with internal pilot reporting requirements.

4. Pilot Deployment Plan

This Plan has the objective to ensure the smooth deployment and completion of the pilots by clarifying the tasks and roles of the release management team and the pilot participants.

All the pilots will follow the same working scheme agreed after several working discussions and setup by the leaders of the corresponding WP and Deliverables.

What follows is the Plan followed by each pilot partner in order to prepare, set and deploy the pilot(s) at their site(s).

1. PILOT SITE PROFILE
- **1.1 Organizational Background**
- **1.2 Pilot Site(s) Description**
  - **1.2.1 Site Location and Organization**
  - **1.2.2 Physical Description**
  - **1.2.3 Access to Pilot Target Population**
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- **2.1 Staffing & Training Plan**
- **2.2 Recruitment Plan**
  - **2.2.1 Participation Targets**
- **2.3 Recruitment Methodology**
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  - **2.3.2 Recruitment Materials**
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3. PILOT ACTIVITIES
- **3.1 Timeline for Pilot Iterations**
- **3.2 Screening**
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  - **3.2.3 Screening Tests**
- **3.3 Pilot Conduct / Procedures**
  - **3.3.1 Programme Protocol**
    - **3.3.1.1 Cognitive Exercise**
    - **3.3.1.2 Physical Exercise**
  - **3.3.2 Monitoring Procedures**
  - **3.3.3 Discontinuation Criteria**
  - **3.3.4 Data Reporting**
- **3.4 Risks**

4. POST-PILOT ACTIVITIES
- **4.1 Post-Pilot follow-up with participants**
  - **4.1.1 User Survey**
  - **4.1.2 Outcome Measures**
- **4.2 Data Analysis**
- **4.3 Dissemination**
- **4.4 Pilot Debriefing**

4.1 Deployment Plan Pilot AUTH (Greece)

Kommentar [WS1]:

Kommentar [WS2R1]:

PILOT SITE PROFILE

4.1.1 Organisational Background

Since 1990, The Lab of Medical Informatics (LOMI) at AUTH has evolved into one of the major research and development centers in the field of Medical Informatics and Biomedical Engineering both in the Greek and European arena. LOMI has been very active in the fields of biomedical processing of brain and heart signals, medical database development, modeling of brain and cardiac electrophysiological processes, and telematics in health-care. Relevant experience also includes: Home care pilot studies, vital parameters human based identification, decision support systems and data mining, Software Agents, medical image processing, Physiological measurements (hypoxia, alertness), Physiological Computing and Interactive Interfaces (evaluation methodologies, emotional intelligence, affective computing), affective and assistive technologies for the disabled and the elderly, as well as, e-learning, collaborative learning and content sharing in medical education. LOMI has participated in a number of European projects such as the ESPRIT II project ISSS (dealing with intelligent alarming and Neural Network applications in processing of cardiovascular signals), the FP5 IST for health projects IST-1999-13352 (CHS) and IST-2001-33369 (PANACEIA-iTV), where pervasive telematics applications for the management of health at home were developed. LOMI also participated in SENSATION, an FP6 IST-IP. The lab has also participated in the e-Ten (e-health) project InterLife and has been the subcontractor for numerous other projects and organizations. Last but not least, another numerous e-learning on health projects have been successfully completed by the lab team members (CrossborderHealth/INTERREG CBC and IntraMEDnet/INTERREG ARCHIMED, WideMEDnet/INTERREG ARCHIMED), as well as a project (AFFECTION) on affective computing and emotional understanding, in collaboration with The RIKEN Brain Science Institute of Japan.

4.1.2 Pilot Site(s) Description

4.1.2.1 Site Location and Organisation

The intervention will be held at the buildings of the Greek Association of Alzheimer's Disease and Relative Disorders – St. Eleni which is a non-speculative company founded in 1995. The aims of the association are to promote the comprehension and support along with the action of people having relation or interest in this illness and to establish contact with other similar foreign associations. One of their primary actions is to promote the scientific research, import new therapeutic methods in our country and the development of day centres in order to alleviate the patients' relatives and to organize subsidiaries of the Association in across Greece. Therefore, it encourages the research and educational activity addressed not only to health professionals but also to those that do not have any relation to the field. Today it counts more than 2000 members and is managed by a seven member Administrative Council, which is elected every 2 years and an eight member Scientific Committee.

4.1.2.2 Physical Description

The Long Lasting Memory LLM solution will be installed in two distinct rooms located at the buildings of the Greek Association of Alzheimer Disease and Relative Disorders – St. Eleni. The

Cognitive Training Component CTC intervention will be performed in a comfort room equipped with 15 personal computers (PCs) and an equal number of headphones in groups of 20 participants. The second room will be equipped with both Independent Living Component (ILC) and the Physical Training Component (PTC) equipments consisting of sensors detecting falls, Wiis, ergometers, bikes, treadmills, blood pressure cuffs, spirometers, etc. A limitation posed by the physical layout of this room is the fact that the PTC will be performed in groups as the CTC intervention. Therefore, the ILC function has some limitations since the fall detection is feasible but the participant's identity cannot be extracted.

4.1.2.3 Access to Pilot Target Population

Describe the type of individuals to be included in the pilot, indicating the types of groups that will be included, for example:

- Mild Cognitive Impairment (MCI)
- Mild Dementia (Alzheimer)
- Cognitively Healthy Elderly
- Control Group(s) – control groups may be defined as related to any of the above types
    - Active Control Group (group with cognitive stimulation and performing daily life activities, but not LLM solution)
    - Passive Control Group (no cognitive stimulation; treatment as usual; waiting list for future iteration of pilot)

Indicate how the organisation has access to the target population (own facility, relationship with other facilities, and a profile of those facilities). All the participants would not have undergone previous intervention programs. The staff at the Greek Association of Alzheimer Disease and Relative Disorders – St. Eleni as well as with additional psychologists and technicians will help during both recruitment and intervention.

4.1.2.4 LLM Configuration

As already stated in section 1.2.2 LLM components will be installed in two different rooms. A room equipped with 15 computers and exact number of headphones will host the CTC. Both PTC and ILC will be installed in a separate room where the physical training will take place. The most likely solution for PTC equipment is 10 Wii balance boards, Wii Remotes and equal number of screens, combined with several stationary bikes.

Concerning the LLM service maintenance, specialized trained staff with the assistance of AUTH technical team will be responsible for any arising problems during trials.

Timeline for deployment at the site

- Acquisition of equipment (already acquired and tested a sample of Wii devices)
- Acquisition of total equipment – February 2010.
- LLM system completion – Late March – early April 2010
- Equipment installation and system configuration April 2010
- Initial Users tests May-June 2010
- Initial active use in a planned pilot phase - September 2010

4.2 PRE-PILOT ACTIVITIES

4.2.1 Staffing & Training Plan

For the pilot procedure there is a need to define the appropriate staff that will be recruited and assigned their responsibilities for the trials. The personnel will be experienced on the intervention procedure. On the contrary, technical support and training about LLM service and its components has to be provided to the technical stuff that will be engaged during the trials. Below a more detailed description of personnel categories and their responsibilities is given in combination with appropriate training wherever is required:

- **Administrative personnel**

Its main responsibility will be to schedule and supervise the LLM trial procedure and ensure the smooth progress of the pilots. People involved in this part should be trained regarding the LLM intervention structure and the timetable of both the cognitive and physical intervention that the subjects will follow. Another possible responsibility of this team should be the on-line recording of the subjects' medical history, e.g. chronic diseases such as diabetes, pulmonary, cardiovascular and orthopedic diseases

- **Physicians**

Physicians are general practitioners whose responsibilities include examining participants hearing and vision status at the pre-trial stage and provide first aid to participants in case of emergency during cognitive training and especially physical exercise.

- **Nursing staff**

Nursing staff will be responsible for assisting participants during their training and provide trainers with assistive support.

- **Trainers**

Trainers should perform the physical assessment and exercise intervention program. Trainers should be familiar with techniques applied to LLM assessment and intervention procedure and especially the physical protocol that will be strictly followed by the participants and the physical tests they will undergo in between intervention periods.

- **Psychologists**

Trained psychologists will administer the neuropsychological tests and prepare consent forms for the participants to sign. They will also be responsible to guide the procedure of the cognitive intervention.

- **LLM consortium staff**

LLM scientific and technical staff should be responsible for performing the neurophysiological assessment and the evaluation of the LLM intervention. The people recruited for this activity need to be well informed and deeply understand the ultimate goals of LLM intervention program.

- **Specialized trained staff (computer science)**

They will perform the computerized cognitive and physical intervention. They need to be trained concerning the philosophy of the cognitive training software (BrainFitness) that will be used and the interconnection between the physical devices (devices to be used during physical exercises) and LLM CMS (Central Management System). Furthermore another duty for the technical team will be to maintain LLM database connection, act instantaneously fixing arising problems and to help system recover after any hardware failure. Therefore, except from fair knowledge of digital networks, computing and electronics, technical staff should be familiarized with overall functionality of LLM service.

- **Engineers**

The engineering team will consist of LLM consortium technical members who will be responsible for the installation of LLM service equipment (proper setting of sensor boxes, PCs, Wii devices, touch screens, physical training equipment) and software (configuration of central management system and installation of Brain Fitness into several computers). Engineers should be of best knowledge about the LLM service architecture and ensure the integrity and security of the system by means of several evaluation tests.

4.2.2 Recruitment Plan

4.2.2.1 Participation Targets

The trials carried out in Thessaloniki will involve patients suffering from Mild Cognitive Impairments (MCI), Mild Dementia (Alzheimer Type) and Cognitively Healthy. Each one of these three groups is consisted of 100 elderly people. Therefore, the trials are expected to employ 300 senior citizens.

The aforementioned participants will be divided in four study groups as indicated in the following table. More specifically the first group will perform the LLM Intervention by means of cognitive and physical training in the rooms equipped with the Independent Living Component (ILC). The second group will perform only cognitive intervention, which is the same used for the LLM intervention. Moreover, there would be an active control group performing cognitive stimulation. Finally, the 4th group would be a passive control group which is consisted of senior citizens belonging to the awaiting list for future involvement in the LLM solution. Each one of the four study groups described above would be consisted of 75 senior citizens (25 MCI, 25 Mild Demented and 25 Cognitively Healthy).

	LLM (Cognitive & Physical) Intervention	Cognitive Intervention	Active Control Group (Cognitive Stimulation)	Passive Control Group	***No. Participants / Cognitive Group***
Mild Cognitive Impairment (MCI)	25	25	25	25	100
Mild Dementia (Alzheimer)	25	25	25	25	100
Cognitively Healthy Elderly	25	25	25	25	100
No. Participants / Intervention	**75**	**75**	**75**	**75**	

4.2.3 Recruitment Methodology

4.2.3.1 Inclusion Criteria

- Aged 65 and older
- Native speakers of the trial language
- Ability to make time commitment
- Written consent for participating in the LLM intervention program (acquired before screening)
- Subjects should not have any significant mobility impairment (upper or lower extremity)
- Diagnose MCI by means of the selected assessment neurophysiological (neuropsychological) tests able to discriminate between MCI-demented patients and between MCI patients-healthy participants
- Fulfill the hearing and vision criteria set by a specialized physician (hearing and vision criteria anticipate that both could be augmented, i.e., via eyeglasses or hearing aids)
- Do not suffer from depression or other emotional abnormalities according to the BDI and BAI tests.
- In case of any chronic diseases such as hypertension, diabetes, etc., there should be consultancy with the responsible doctor in order to keep their condition under control
- Personal physician's consent.

4.2.3.2 Recruitment Procedures

Define any materials required to be used in recruiting individuals for the study. Also, determine whether the materials are required to be approved by any national review boards.

- Search of the records of the trial site for recruiting senior citizens waiting in the list for other interventions or their citizens.
- Include participants of previous interventions only if they ceased to participate for at least a year ago.
- Recruit persons in day care centers, churches, hospitals
- Recruit persons that come for first time in the trial site
- Information letter about the experimental and intervention procedures tasks the participant has to carry out during the trial
- Informed consent letter combined with a letter of information on the rights that the elderly individual has as well as the tasks and responsibilities that he will have to take on.
- Information on the LLM project and its objectives (brochure, dossier, etc.)

4.2.4 Pilot Programme Approvals

The pilot programme will be described in detail regarding the tests and the intervention programmes as well as with the personnel and the remaining pilot procedures. The potential risk factors and the proposed solutions will be extensively mentioned. Special care would be given to the prevention of harmful results to the participants (physical accidents, heart problems, etc.)

All the pilot tests will be carried out according to the relevant conventions and guidelines, In particular they will comply with:

- National legislation. All the project activities should be approved by the Ministry of Health and Social Solidarity. More specifically, there is the Central Health Council which is responsible for the observance of the protocol and the Directory of Education and Research which is responsible for the co-ordination of each research program.
- EC legislation.
- The charter of fundamental rights of the European Union.
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- During the project the European and International standards (EN 12182 and EN ISO 10535) will be considered

4.3 PILOT ACTIVITIES

4.3.1 Timeline for Pilot Iterations

There will be 2 pilot iterations that will carried out in the buildings of the Greek Association of Alzheimer Disease and Relative Disorders – St. Eleni. The iteration's duration was formed considering both the intervention requirements and the limitations posed by the greek holidays (summer, Christmas, New Year's Eve and Easter). Therefore the first one starts in mid September (month 16) till mid December (month 19) while the second one in mid January (month 20) till mid May (month 24) as indicated by the blue code. Before the initiation of the first iteration, the screening and assessment tests will be performed for all the participants. This procedure is going to take place between mid August till mid September as indicated by the yellow code) . Between the two program iterations as well as after the end of the second iteration, the program's evaluation will take place as indicated by the green code.

2010					**2011**					
Aug.	**Sept.**	**Oct.**	**Nov.**	**Dec.**	**Jan.**	**Febr.**	**March**	**April**	**May**	**June**
	Screening & Assessment	*First Iteration*		*First Evaluation*	*Second Iteration*				*Final Evaluation*	

4.3.2 Screening

4.3.2.1 Informed Consent

Potential participants are expected to express their interest to the staff after they have received the recruitment material. Then personal or group meetings will be arranged towards clarifying any misunderstanding may occur. Then, those who have already decides to participate will be asked to sign the consent letter and will be informed of the following actions. On the other hand, those who have not reached to a decision yet, will be asked to return the signed consent in the future or to inform the staff for their negative decision.

The specifications that an informed consent should fulfil are the following:

Psychologists should:

1. Ensure that the potential participants are given ample opportunity to understand the nature, purpose and the anticipated consequences.
2. Keep adequate records of when, how and from whom consent was obtained.
3. Remain alert to the possibility that potential participants may lack legal capacity for informed consent.
4. Avoid intentional deception of clients.
5. Support the self-determination of clients, while at the same time remain alert to potential limits placed upon self-determination by personal characteristics or by externally imposed circumstances.
6. Ensure from the first contact that clients are aware of their right to withdraw at any time from the receipt of research participation.
7. Comply with requests by clients who are withdrawing from research participation that any data by which they might be personally identifies, including recordings, be destroyed.

The procedure of the informed consent will include the following steps. A psychiatrist and a neuropsychologist will ensure that the elderly individual is able to give his consent, presenting adequate levels of understanding and reasoning. After that, the neuropsychologist will give clear explanations to the participants about the contents of the document:

- Summary of the objectives of LLM project
- Information on the rights and responsibilities of the participants as well as the nature of the tasks/activities he will have to undertake
- Signature of the informed consent form

A sample of the informed consent in English is included in the Annex.

4.3.2.2 Exclusion Criteria

Exclusion criteria to be applied as initial pre-screening for volunteers include the following:

1. Major neurological or psychiatric illness history
2. Any recent (within 6 months) history of stroke, transient ischemic attack, traumatic brain injury, ALS, MS, PD
3. Current substance abuse.

4. Acetylcholinestearase inhibitor use is not excluded, so long as use has begun 4 months prior to enrolment in study, and is stable and during course of the study remains consistent.
5. Significant communication impairments (e.g., unable to respond to questions in screening).
6. Concurrent enrollment in other studies.
7. Statin users may be excluded unless use is consistent during the course of the study, and is stable.
8. Interference of Zig-bee, Blue Tooth etc. with pacemakers.

4.3.2.3 Screening Tests

The following table contains the tests that will be used for screening and assessments as well as for measuring the primary outcomes. These tests would be performed for all the participants. In addition to them, the medical history of each participant would be recorded as well as with imaging and blood tests. Moreover, the MCI and mild demented patients would be screened by means of a short interview each month in order to detect potential deterioration of their cognitive status.

Test No.	Test Name/ Description	Will be used for...	Cognitive / Physical Functions Assessed	Time of administration)
1	Mini Mental State Examination (MMSE)	Screening for MCI (must be used with the MOCA because it is not sensitive enough on its own)	Orientation, Registration, Short-term Memory, Attention, Calculation, Visuo-spatial skills and Task execution	10
2	MOCA	Screening for MCI (it was specifically designed for this purpose and is sensitive enough to do it)	Working memory, Visuo-spatial abilities, Executive Function, Attention, Language (Understanding, Production & Fluency), Orientation to time and place	10
3	BDI	Screening measure for depression	Depressive Symptoms	5
4	BAI	Screening measure of anxiety, not contaminated by depression	Anxiety Symptoms	15
5	Senior Fitness Test (Fullerton Fitness Test)	Screening physical conditions	Muscle strength, Static & dynamic balance, Co-ordination, Agility, Flexibility of upper and lower body, Aerobic endurance	15

6	Balance assessment tests	Screening balance	Dynamic & Static Balance	10
7	CNSVS	Primary Outcome Measure (pre & post LLM intervention)	Verbal memory, Visual memory, Psychomotor speed, Information processing speed, Cognitive flexibility, Vigilance, Sustained attention	30
8	Sociodemographic data, social activity + part of the IADL (shortened)	Screening	Activities of Daily Living Living	15
	Total Time Required			110

Moreover, additional tests would be conducted in order to derive secondary outcome measures regarding the brain functions (executive function, sensory discrimination and resting state activity). Moreover the Alzheimer's Disease Assessment Scale (ADAS) would be conducted in order to estimate the cognitive function of the mild demented participants.

Test No.	Test Group	Test Name/Description	Time Required
1	ALL	EEG: Error-related Negativity	15
2	ALL	EEG Mismatch Negativity	15
3	ALL	EEG: ASWA paradigm	5
4	Mild Demented (Optional since we have included MOCA + MMSE)	ADAS Alzheimer's Disease Assessment Scale	45
		Total Time Required	80

4.3.3 Pilot Conduct/Procedures

4.3.3.1 Programme Protocol

The intervention will be held in Saint Eleni buildings in Thessaloniki, organized into 12 groups, of 12 participants each and 12 groups of 13 participants each, per day. The participants will be expected to complete 30-40 cognitive and 20-30 physical sessions over the course of the first iteration (1 (clear time) hour per day cognitive training, 5 days per week, for a period of 12 weeks) and (1 (clear time) hour per day

physical training, 3 days per week, for a period of 12 weeks. The participants will be expected to complete 40-50 cognitive and 30-40 physical sessions during the second iteration keeping the same rate per week as with the previous iteration. However, the second iteration would be one month longer than the previous one.

The training procedure includes both cognitive and physical exercise components:

Cognitive Exercise

The cognitive training procedure is expected to utilize 20 PCs equipped with headphones. During each training session, the participant is expected to work with four of the six exercises for 15 minutes per exercise.

Physical Exercise

The physical exercise programme, is a systematic one, which contains four basic types of exercise:

- Endurance
- Strength
- Balance (static and/or dynamic) and
- Flexibility

The types of exercises considered for incorporation into the programme include:

- Exercises such as gait, swimming, running and cycling target to the improvement of the cardiorespiratory system. They should be executed on a daily basis for at least 30 minutes
- Muscle strength exercises are related to weightlifting. These kind of exercises shall be executed 2-3 times a week
- Balance targeted exercises are important because they prevent falls. They could be incorporated into a daily program of muscle strengthening
- Flexibility exercises (distensions) conserve muscle flexibility and protect from injuries. Distensions should be executed in the beginning and at the end of every training program

A training program in order to induce changes in physical condition of the participant should be applied for at least three times a week and for at least three months. The design of the training session for this pilot, as evaluated, is:

Duration is 1 hour per day, 3 times per week, consisting of: three portions:

- Warm up (20 – 25 min)
    - Use of ergometer bikes, treadmills
    - Control of steady speed (15 – 16 km/h)
    - Measurement of time, speed and elapsed distance

- Main part (30 – 35 min)
    - In early stages each exercise shall be executed in *2 sets* of *8 repetitions* with *1 minute interval*
    - Maximum number of sets: 3
    - Maximum number of repetitions: 15
    - Equipment to be used → Wii related devices, PCs, touch screens, gymnastics tires, weights of one kilo each, rhythmic gymnastics ball (16 cm diameter), gymnastics bars (1 meter), fitness classes
    - Accompanied software needed to accomplish exercise program executed with Nintendo Wii.

At this point it has to be stated that the use of Borg scale questionnaire is recommended in order to help therapist check subject's potential to cope with the intensity and duration of each exercise and adjust subject's training program accordingly.

- Recovering (5 – 10 min)
    - Stretching exercises and breathing exercises
    - Main target is the relaxation of the subject and reset of heart rate at normal levels

4.3.3.2 Monitoring Procedures

How to ensure compliance with the intervention. Identify who is responsible for monitoring, how documented, etc. Include steps for validating ongoing compliance to determine whether a participant must be discontinued from the study based upon participation levels.

During LLM intervention it has to be assured that each participant should comply with the procedure and adhere as much as possible to his/her scheduled training program. For this purpose the administration office of each trial site should record and check day/time participation level of each subject, so to ensure that he/she should continue or not the rest of the intervention.

Furthermore, physicians should periodically check participants' overall well being and in case there are any reports concerning the health instability of a participant suffering from a chronic disease, they should advise them to interrupt the intervention program and discontinue them from the study if the problem remains for an extended period of time. Moreover, in case subjects suffer from an injury during physical training, physicians and / or trainers should evaluate their status and ability to participate in physical activities and decide whether they should be discontinued from the study or not. In case subjects are diagnosed not to be able to continue LLM intervention, administrative officers should be noticed and communicate with scientific staff in order to decide whether previous results of the subject should be included and taken into consideration during the post pilot analysis study.

Finally, it has to be stated that in case a subject will decide at any time that he/she would like to withdraw their previous signed written consent, administration office should exclude him/her from the sequel of the study.

4.3.3.3 Discontinuation Criteria

1. Participants that skip more than 20% of the sessions. Discontinuation would be evaluated beginning after 4 weeks of the intervention.
2. Those who during the study no longer met the inclusion criteria.
3. Those who during the study met the exclusion criteria.
4. Those voluntarily withdrawing their consent.

4.3.3.4 Data Reporting

Include a discussion of data reporting, record keeping, and data protection procedures. Include a description of how manual/paper files will be stored, as well as how data will be anonymised and encrypted. Efforts should be made towards data minimisation, and how this will be accomplished should be described.

During LLM intervention procedure data concerning participants' performance should be recorded and stored to the remote database of LLM service for each participant. But qualitative or overall quantitative metrics should be defined and transferred to database as an indicator of participants' progress level and not the whole set of data that is recorded by each component's software. Therefore by defining general purpose indicators we will be able to minimise data amount that need to be sent via LLM service to the remotely located database, thus ensuring data integrity and stable functionality of the system. Additionally, data of previous sessions could be depicted in a graphical manner by LLM system in order to provide therapists with subjects' performance progress information.

An additional major aspect concerning data recording is to ensure data protection through several techniques such as authorisation, encryption and anonymization. LLM central management system will be responsible to authenticate users in day care centres. It has to be stated that users shall be registered to the LLM system by creating a profile with the guidance of technical staff. After registration process each participant should log into the LLM system using his/her username and password. After successful logging into the system, participants may start the intervention program assigned to them and access rights will be attached to them accordingly.

As mentioned before, data being stored to LLM database during intervention procedure should be minimised and send through internet to a remote server. Data communication will be accomplished by using LLMWS (LLM Web Service) storage methods. Web services architecture being incorporated into LLM

service uses the HTTPS communication protocol as the main transport protocol. HTTPS includes data encryption methods, thus reinforcing safety and integrity of data transport through internet.

4.3.4 Risks

Describe any risks in executing the pilot plan as outlined here, including specific steps to be taken to mitigate such risks.

Risk	Likelihood	Impact	Risk Mitigation Plan
User complaints for poor advantages after the end of the LLM intervention	Medium	High	Objective outcome measures (both primary & secondary) should be re-checked. In case there is disagreement between subjective and objective measures the participant will be motivated to repeat the LLM intervention. Otherwise, a date with an expertized psychologist should be performed in order to increase the participant's confidence.
Problems dealing with user commitment due to loss of interest, fatigue or conflict with other daily activities, problems in their transport	High	High	The intervention team will deal with motivation issues from the very beginning of the pilot tests. A support vehicle will be available for the displacements of the intervention team (van) Date re-arrangements carried out whether it is possible with sufficient time in advance
Difficulties in recruiting participants that fulfill the inclusion criteria	High	High	The intervention strategy will be expanded in more day care centers, unions of senior citizens, churches, private practicioners and hospitals or hospitalized institutions.
PTC-training is too demanding	Medium	Medium	The PTC training will become as possible personalized according to the person needs and physical status
Participants get injured during the performance of the PTC program	Low	High	Direct supervision of the intervention team. Personalized sets of physical exercises.
Problems in the arrangement of the schedule of the sessions	High	Medium	Date arrangements carried out with sufficient time in advance
The participant is not motivated to comply	High	Medium	Requirement of a formal consent form and letter of commitment The intervention team will deal with motivation issues from the very beginning of the pilot tests
The system (or any of its parts, CTC, PTC or ILC) is difficult to implement	High	High	Assignment of a well- balanced number of highly qualified professionals. A support vehicle will be available for the displacements of the intervention team (van)
The participants are geographically too dispersed	Medium	Low	Assignment of a well-balanced number of professionals. A support vehicle will be available for the journeys of the treatment team (van)
The participant suffers a health problem caused directly by the use of the LLM devices.	Low	High	Personalized sets of physical exercises. Consent of their personal physician. Supervision of two geriatric specialists.
System failures	Medium	Medium	Trained team of professionals. Technical support provided by the LLM consortium
Recruitment of users too time demanding	High	High	Screening and recruitment tasks done with sufficient time in advance
Too much personal data gathered	High	High	Compliance with European and national laws on data protection Design procedures for the storage and adequate treatment of the materials containing personal data

4.4 POST-PILOT ACTIVITIES

4.4.1 Post-Pilot Follow-up with Participants

4.4.1.1 User Survey

Short surveys should be conducted at the end of each trial iteration in order to examine LLM service acceptance and ease of use by the end users, which could be both seniors and therapists. This could help enhance the already developed service and further develop its functionalities.

Furthermore, at the end of the whole set of trials interviews will be held with each participant in order to define useful characteristics of LLM service and to evince its great potential in the market business. Characteristics that must be investigated include:

- User acceptance
- Accessibility issues solved
- Whether seniors believe LLM service can help them improve their overall health (really important issue for elderly people)
- Entertainment during LLM training
- Socialize?

4.4.1.2 Outcome Measures

Post-pilot testing, utilising the screening tests will be performed. Indicate the timing of this testing.

After the end of each intervention's iteration the primary outcome measure (CNSVS) will be re-conducted as well as with the secondary outcomes recording the brain temporal activity.

4.4.2 Data Analysis

Data from the trials will be recorded in a central database and this data will be used as the source for analysis of the projects' outcomes. Any localised analysis of results (e.g., if additional outcomes, beyond the standard set) particular to the pilot site is to be completed, describe that analysis procedure here.

4.4.3 Dissemination

Describe the plan for dissemination of scientific results from the project.

Dissemination plan concerning the promotion of scientific results of LLM trials will include the publication of scientific papers in several well – known medical and/or technical conferences, as well the publication of journal articles with high impact factor. In addition a number of scientific workshops concerning the LLM project will be organised and scientific results achieved by LLM will be presented and discussed in front of representatives of a vast range of parties that may be interested in LLM solution.

ANNEX 1 – AUTH Informed Consent Form

AUTH INFORMED CONSENT FORM

NAME:

DEPARTMENT:

PERSON RESPONSIBLE:

DATE

ISSUE NUMBER:

Long Lasting Memories is an integrated Information and Communication Technology platform which combines state-of-the-art cognitive exercises with physical activity in the framework of an advanced ambient assisted living environment. By combining cognitive exercises and physical activity LLM delivers an effective countermeasure against age-related cognitive decline, thus actively improving the quality of life of the elderly.

The duration of the project will be ……., from …… till ……..

Each session will last …….. hours and will take place …….times per week. The duration and the difficulty level of the training will be adapted to each individual, in order not to cause any discomfort and to avoid any risks.

Any findings or diagnoses during the project will be revealed to the participant confidentially.

Well trained scientists will be supervising the trials and the progress of each participant individually. They will also be at the participants' disposal for any questions, discontent or complaints.

The personal data of the participants will be safely stored and will be available only to project staff until the completion of the project. The results of the research will be published anonymously in confidential and public reports.

Participation is voluntary and participants are free to withdraw at any time without any consequences.

INFORMED CONSENT

I, the undersigned ……..…… voluntary agree to participate in the activities of the LLM project as described in the information letter.

Thessaloniki, …….

Signature

Annexes should include copy of forms unique to the pilot site – standard forms used by all sites will be included in D4.2.

4.2 Deployment Plan Pilot CEI RALTEC (Austria)

1. PILOT SITE PROFILE

1.1 Organisational Background

The Central European Institute of Technology (CEIT) gemeinnuetzige GmbH (www.ceit.at) is an extra-faculty research and development institute. CEIT was founded in April 2006 by the municipality of Schwechat which also is the owner and the provider of the basic funding. CEIT processes knowledge from the fields of Information and Planning Technologies and passes it on through technology transfer to broader society. CEIT is the main actor of the "Living Lab Schwechat", which is a member of the European Network of Living Labs (http://www.openlivinglabs.eu/pdfs/schwechat.pdf) since 2007. CEIT consists of 2 departments CEIT ALANOVA and CEIT RALTEC:
At CEIT-ALANOVA modern technologies for Urban and Regional Planning in connection with Information Society tools and under the guidance of the principles of sustainability and environmental protection (ePlanning) are being developed.

CEIT RALTEC - Rehabilitation and Assisted Living Technologies - focuses on research and development of novel technologies in the area of Ambient Assisted Living (AAL), eHealthcare and eHomecare including dedicated services for older citizens and persons with special needs. The aim of RALTEC's activities is to support elderly people and their carers to live as independently as possible. The researchers at RALTEC have a broad expertise, covering ICT and assistive technologies and also non-technical areas as sociology and ethics. Some of the projects which have been started since 2006 are described below:

- eSHOE: Development of an intelligent shoe sole equipped with integrated sensors to analyze the gait of old persons.
- eHOME: Development of a wireless sensor system for measuring different physical paramaters in a old person's home to detect abnormal and dangerous conditions in daily life and to generate automatic alarms in case of dangerous situations.
- development of an intuitive, senior-specific voice-over-IP videotelephone and performing a user-acceptance and usability study
- AAL Living Lab: Implementation of a Living Laboratory for assistive technologies to support old persons.
- Ethical Supervision: Review and support of research projects which are involving vulnerable people.

MUNICIPALITY OF SCHWECHAT

Schwechat, a town with some 16.000 inhabitants but 20.000 workplaces lies directly south east of Vienna. It's a modern industrial town home to several leading companies; e.g. OMV, Austrian Airlines or Vienna International Airport.
LivingLab Schwechat is part of Schwechat's Information Society Initiative eSchwechat.at. It focuses on rehabilitation and Ambient Assisted Living technologies as well as on modern urban and regional planning technologies. It's open both to companies and research institutes. Schwechat's municipal facilities represent a perfect context for trying out ICT developments. The small town structure, manageable population numbers and short distance to the municipality administration enable an effective environment for user centric product development. The Municipality's commitment to deploy and demonstrate new technologies provides a good basis for a sustainable LivingLab.

The municipality of Schwechat is owner and operator of the local senior's centre. This senior's centre houses a day care centre (up to 30 guests per day), a nursing unit (22 beds) and about 70 supportable independent living units (apartments). Besides that it acts as a general service and meeting point for senior citizens.
The senior's centre also acts as the head of the local coordination platform for local social service providers; members are all local care taking services, representatives of the community and of CEIT RALTEC.

An important role within Schwechat is fulfilled by the senior's advisory board ("Seniorenbeirat"): members of this board are active senior's, representatives of the municipality and of the senior's centre. The board is coordinating activities for seniors and is also an important interface between elderly people and CEIT RALTEC.

1.2 Pilot Site(s) Description

1.2.1 Site Location and Organisation

The two partners Raltec and Schwechat will be the only partners in the LLM consortium planning to run a so-called "pre-pilot-trial". Additionally, they will carry out "pilot trials" as the other test sites will do but in at-home-installations and in a smaller scale. The main goal of the "pre-pilot-trial" is to evaluate the level of difficulty of the training program and the test procedures in general.

The trials ("pre-pilot-trial" and "pilot-trial") in Schwechat will be conducted at two different types of sites:

Senior Citizen Centre
The "pre-pilot-trial" will be conducted in the senior citizen centre of Schwechat).

Private Homes
During "pilot trials" 5 LLM-prototypes will be installed in apartments of elderly people. Those can either be apartments in the senior citizen centre or somewhere else in the municipality of Schwechat.

1.2.2 Physical Description

Senior citizen centre:
The LLM-prototype will either be installed in the fitness room or a room provided for CEIT RALTEC projects will be adapted adequately.

Private homes:
It is likely that the space in many of the private homes is limited. If the apartment is too small to be equipped with a treadmill or ergo-bike, the person has to use either a Wii-training set or the PTC installed in the senior citizen centre.

1.2.3 Access to Pilot Target Population

Only cognitively healthy people and a corresponding passive control group will take part in the trials in Schwechat.

Most of the participants will probably be members or former members of the senior gymnastics group held in Schwechat's senior citizen centre. CEIT RALTEC cooperates closely with the fitness trainer of this group. The staff at the senior citizen centre and members of the advisory board of senior citizens ("Seniorenbeirat") who already supported a couple of CEIT RALTEC's previous projects will help in recruiting the remaining participants.

1.2.4 LLM Configuration

Senior citizen centre:
For the pre-pilot-trials LLM will be installed in the senior citizen centre. This installation will remain in those facilities for the pilot-trials, if the users of the at-home-installation don't have enough space to use the PTC in their flats.

- **All LLM-components** will be installed in the same room
- **Service maintenance: "easy tasks"** will be done by fitness trainer or personnel at site, **technical problems** will be solved by RALTEC

Private homes:
The LLM-installation in private homes will only be used for the pilot trials.

- ILC in the whole apartment
- PTC and CTC: wherever the participant wants them to be placed in his/her flat – if there is not enough space for PTC, the person could use the PTC being part of the LLM system installed in the senior citizen centre. It can be assumed that available space is limited for PTC in private flats, thus it might depend heavily on the concrete PTC prototype and its physical dimensions (e.g. Wii like or treadmill).
- Service maintenance: done by RALTEC
- At-Home-installations in total (over all 3 consecutive pilot-iterations to be carried out) – at most 2 installations being active at the same time.

2. PRE-PILOT ACTIVITIES

2.1 Staffing & Training Plan

Recruitment phase:
- Schwechat staff (supported by RALTEC staff): inform potential test participants, conducting recruitment tests, prepare test participants for the training phase
- Psychologist (conducting and evaluating the cognitive recruitment tests) – project partner from UKON
- Supervisor for the physical recruitment tests – doctor of Senior citizen centre / fitness trainer
- Fitness trainer (Schwechat staff) – aid in selection and contacting of participants

Installation phase:

- RALTEC staff: installation of the LLM-Service (including internet connection if necessary) in senior citizen centre and private homes

Training phase:

- Fitness trainer (Schwechat staff) – training and supervising the use of the PTC
- Caretaker of Senior citizen centre (Schwechat staff) – assistance in using the training components (if needed)
- RALTEC staff – supervision of participants in At-home-installations, solving technical problems

2.2 Recruitment Plan

2.2.1 Participation Targets

There will be one iteration with two users in the pre-pilot trials:

At-Home-Installation:

Three consecutive pilot-iterations will be conducted. Participants in the passive control group of one iteration can be users of the LLM-installation in later iterations.

Study Group	# of participants per iteration
Cognitively Healthy	2
Passive Control Group (cognitively healthy)	2
Total…	**4**

2.3 Recruitment Methodology

2.3.1 Inclusion Criteria

- Aged 65 and older
- Speaking fluency in the language of the trial
- Ability to make time commitment
- Written consent for participating in the LLM intervention program (acquired before screening)
- Subjects should not have any significant mobility impairment (upper or lower extremity)
- Diagnose MCI by means of the selected assessment neurophysiological tests able to discriminate between MCI-demented patients and between MCI patients-healthy participants
- Fulfill the hearing and vision criteria set by a specialized physician (hearing and vision criteria anticipate that both could be augmented, i.e., via eyeglasses or hearing aids)
- Do not suffer from severe depression or other emotional abnormalities according to the GDS and/or NPI test
- In case of any chronic diseases such as hypertension, diabetes, etc., there should be consultancy with the responsible doctor in order to keep their condition under control

- Personal physician's consent.

For At-Home-installations:
- Living in a single-person-household (without cat/dog)
- The size of the person's apartment must not exceed 3 rooms.

2.3.2 Recruitment Materials

CEIT RALTEC has material available from previous projects and will modify them accordingly.

- Information letter about the project and the tasks the participant has to carry out during the trial
- Informed consent letter

If approval of the materials by a national review board is needed, is currently under investigation by an ethical expert.

2.4 Pilot Programme Approvals

This question is currently (Oct/Nov 2009) under consideration by an ethical expert.

3. PILOT ACTIVITIES

3.1 Timeline for Pilot Iterations

- **Prepilot**: the prepilot-trial will be conducted in the Senior Citizen Centre for a period of 3 months beginning with month 12 (May 2010).

- **Pilot**: There will be 3 pilot iterations in Schwechat with a duration of 3 months each. The first one starts in month 16, the second iteration in month 20 and the last one in month 24, allowing for one month of evaluation and service adaptation in between every iteration.

3.2 Screening

3.2.1 Informed Consent

To be defined

3.2.2 Exclusion Criteria

Exclusion criteria to be applied as initial pre-screening for volunteers include the following:

- Participant is not capable of giving informed consent or is unable to comprehend and/or follow instructions
- Major cardiovascular event, stroke, transient ischemic attack (TIA), or traumatic brain injury within the past 5 months

- Participant is enrolled in a concurrent clinical study that could affect the outcome of this study.
- Participant is unable to use the technical devices (CTC, PTC) or perform the pre/post tests
- Major neurodegenerative disease or condition, e.g. multiple sclerosis, amyotrophic lateral sclerosis, or Parkinson's Disease
- Current diagnosis of psychiatric illness, e.g. major depressive disorder, bipolar disorder, schizophrenia, post traumatic stress disorder
- Current use, or use within the past 3 months, of medications with substantial central nervous system (CNS) effects, including acetylcholinesterase inhibitors and medications with either anticholinergic or antidepressant properties.
- Current substance abuse, including alcoholism

3.2.3 Screening Tests

The total time required for screening one person should not exceed one and a half hours (including physical and cognitive screening). One or two psychologists from UKON will travel to Schwechat to do the Neuropsychological Testings. The fitness trainer of the senior citizen centre will design an appropriate physical screening test.

Test No.	Test Name/Description	Resources Required for Test[3]	Time Required
1	MMSE	One-on-one-Test, Test Material	5 min
2	IADL	One-on-one-Test, Test Material	5 min
3	Digit Span Test	One-on-one-Test, Test Material	5 min
4	California Verbal Learning Test II	One-on-one-Test, Test Material	15 min
5	Trail Making Test	One-on-one-Test, Test Material	8 min
6	Senior Fitness Test	One-on-one-Test, Test Material	15 min
7	Reaction Time	Computer	10 min
8	WHOQOL-BREF	Questionnaire	10 min
9	Sociodemographic data and social activity	Questionnaire	10 min
10	Check for inclusion/exclusion criteria	One-on-one-Test, Test Material	5 min
	Total Time One-on-one-Test, Test		**58 min**
	Total Time on Computer/Questionnaire		**30 min**

[3] Indicates, if any, specialised knowledge, training, or equipment is required to conduct the test. For example, indicate whether a physician with a specific background/specialization is needed, or a particular medical device is required.

As the number of participants is very limited, only the standard screening tests will be conducted at the trial site in Schwechat.

3.3 Pilot Conduct/Procedures

3.3.1 Programme Protocol

The intervention will be held in the senior citizen centre of Schwechat and in 5 private homes in the municipality of Schwechat. The training procedure includes both cognitive and physical exercise components. In both settings the ILC will be part of the deployed LLM prototype and will be used to enhance safety and support communication and alarming abilities of independently living users:

3.3.1.1 Cognitive Exercise

The cognitive training procedure is expected to utilize one LLM-computer equipped with headphones per trial site. The participant is expected to do the training one hour per day, three times a week, whereas it is possible to split this time into a couple of shorter sessions per day.

3.3.1.2 Physical Exercise

The physical exercise program is a systematic one, which contains four basic types of exercise:

- Endurance
- Strength
- Balance (static and/or dynamic) and
- Flexibility

The types of exercises considered for incorporation into the programme include:

- Exercises such as gait, slow jogging and cycling target to the improvement of the cardiorespiratory system.
- Muscle strength exercises are related to weightlifting.
- Balance targeted exercises are important because they prevent falls. They could be incorporated into the program of muscle strengthening
- Flexibility exercises (distensions) conserve muscle flexibility and protect from injuries. Distensions should be executed in the beginning and at the end of every training program.

It is supposed that most of the participants can be categorized as beginners. To avoid that the program is too challenging for them, the training program should be applied two times a week and for at least three months. The design of the training session for this pilot, as evaluated, is:

Duration is 30 minutes per day, 2 times per week, consisting of three portions:

- Warm up (10 min)
    - Use of ergometer bikes, treadmills
    - Control of steady speed (15 – 16 km/h)
    - Measurement of time, speed and elapsed distance

- Main part (15 min)
  - In early stages each exercise shall be executed in 2 sets of 8 repetitions with 1 minute interval
  - Maximum number of sets: 3
  - Maximum number of repetitions: 15
  - Equipment to be used: gymnastics tires, weights of one kilo each, rhythmic gymnastics ball (16 cm diameter), gymnastics bars (1 meter)

- Recovering (5 min)
  - Stretching exercises and breathing exercises
  - Main target is the relaxation of the subject and reset of heart rate at normal levels

The program must include CTC 3 times per week, and PTC 2 times per week, but the sequence and mix does not matter.

Independent Living Component:

The participants do not necessarily have to use the functions offered by the ILC, but the component will support them during their daily living activities by increasing the safety of the independently living user. Some of the features of ILC will also be active during cognitive and physical training and thus help in evaluating their training efforts.

Pre-pilot-trial in senior citizen centre (multi-user-situation):

The following range of functions will be tested:

- Comfort and safety of the participant:
  - Voice- and Video telephony

    The participants have the possibility to call somebody by using the specially designed hands-free touch screen-telephone on the User Interface of the ILC. This can be especially useful for communication with the carer or trainer. For calls to the latter a video-call will be established. To ensure that each participant got in touch with that functionality, a staff member of CEIT RALTEC will call each participant during at least one of his / her training session.

  - Simple emergency-call to carer
  - reminder-function during training session e.g. reminder for drinking after a certain period of training
  - remote powering on/off of physical training components by eHome-actuator (→ energy saving), if the participant forgets to turn them off after the training

- Evaluation of physical training:
  - recognition of usage of physical training equipment by ILC-sensors
  - measuring of activity-level
  - during physical training by ILC-sensors for further analysis by the LLM-service

Note that the guidance of the users through the cognitive and physical training sessions is done by the CTC and PTC (not by ILC).

Pilot trial in at-home-installations (single-user-situation):

The same functionalities as in the multi-user-version will be tested in the at-home-installations. In addition the participants will not only be supported by the system during their physical training, but also during the rest of the day as long as they are at home by

- the recognition of falls
- personal reminders like reminders for medication or certain appointments and
- cooker surveillance

3.3.2 Monitoring Procedures

- regular visits and interviews by RALTEC staff and/or fitness trainer
- user diary

3.3.3 Discontinuation Criteria

As CEIT RALTEC and Schwechat are planning to set the focus on deploying the LLM prototypes in the area of independently living people the initial compliance might be lower than in a rehabilitation setting. Thus the discontinuation criteria should be adjusted accordingly.
As long as the user's acceptance and the perceived benefits of LLM is satisfying from user's and carers' point of view the trials should be continued. This will allow exploring potential of LLM in the private market of independently living elderly people, as here the individual satisfaction of using the LLM system and the subjective perception of usefulness might be of crucial importance.

3.3.4 Data Reporting

Every user will get an individual ID right from the beginning. The connection between Username and ID will be stored in a database. All other user data and all documents concerning a certain user will only use that ID as a reference.

3.4 Risks

Risk	Likelihood	Impact	Risk Mitigation Plan
PTC-training program is too demanding	Medium	High	Reduce physical effort Reduce time effort
CTC-training program is too demanding	High	High	Distribute it over time, follow advise of partners with expertise in CTC
Two participants want to use the "public" LLM installation at the Senior	Low	Low	Every participant gets its own time slots for using the public installation;

Citizen Centre at the same time			A procedure is defined how the users can modify their slot on request
Participant gets injured conducting the physical training program	Low	High	None Approval by General Practitioner (GP) before starting test, inform about risk before test
System failure to log usage data occurs	Low	Medium	Run Lab Test Define quality criteria to be met before starting pilot Use pre-pilot to gather experiences
Users indicate to not see the benefit of the trial	Medium	High	Try to find the reason for this opinion. Maybe the training program is not demanding enough
User needs additional on site motivation	Medium	Medium	Visit and / or talk to the participants regularly
Recruitment of users too time demanding	Low	Low	Start recruitment phase as early as possible
Delayed availability of system components for pre-pilot trials	Low	Medium	Reschedule test Prepare initial time schedule with buffer time Reserve buffer time in technical work packages
Logged data not sufficient for recognition of system usage / user activities	Low	High	confirm sufficient data quality during lab tests and pre pilot integrate regular supervision of logged data during pilot to discover potential problems quickly (limit the amount of missing / not sufficient data)

4. POST-PILOT ACTIVITIES

4.1 Post-Pilot Follow-up with Participants

The pilot project results will be evaluated to provide information to proceed or not proceed (i.e. go/no-go decision) with the deployment of the technology, to improve future pilots and provide recommendations to improve the technology piloted.

4.1.1 User Survey

As a part of the post-pilot activities, a user survey will be conducted to develop insights relevant to market acceptance, usability, etc. Describe the procedures for presenting participants with the user survey, collection and collation of results.

Important aspects for CEIT RALTEC and Schwechat will be to investigate the user acceptance and subjectively perceived usefulness of the system. In addition to the pilots

under controlled settings in rehab centres the deployment at users' homes in Schwechat will allow to explore the potential of LLM in the private market.

After each iteration the participants will be interviewed individually about their experiences with and opinions about the LLM-installation.

In the end of the trials a focus group with all seniors and experts who participated in the trials will be conducted.

4.1.2 Outcome Measures

Post-pilot testing, utilising the screening tests will be performed.

After the trial-period the same tests as in the screening sessions will be performed with each participant. Those tests should not exceed a duration of one hour per person.

4.2 Data Analysis

Data from the trials will be recorded in a central(?) database and this data will be used as the source for analysis of the projects' outcomes. Any localised analysis of results (e.g., if additional outcomes, beyond the standard set) particular to the pilot site is to be completed, describe that analysis procedure here.

To be defined for next draft / after discussion in Consortium.

4.3 Dissemination

Describe the plan for dissemination of scientific results from the project.
t.b.d.

4.4 Pilot Debriefing

Debriefing, is understood in LLM as the mean to get those users involved in the pilot together for a few minutes after performing pilot tasks to discuss in a friendly way what the team did right and to identify those areas where they need to improve, as the way to improve consistently over time.

Debriefing in LLM is about proactively engaging users in the running of the pilots. With the aim of focusing on what they can do with what they have and identify how they can improve their well being, safety and care.

Through lessons learned from pilot experiences we should be able to identified opportunities for refining LLM solution/services. The experience gained will also support the development of a suitable transition strategy for moving towards the market.

On completion of the pilots, piloting responsible will meet with the users to solicit their thoughts on the LLM services and thank them for their participation and effort in the project pilots.

4.3 Deployment Plan Pilot INTRAS (Spain)

1. PILOT SITE PROFILE

1.1 Organisational Background

INTRAS is a non-profit organisation founded in August 1994 aiming for quality in research and intervention in the social-health field. Nowadays it is composed of 8 centres in 3 different provinces in Spain (located in Valladolid, Zamora and Salamanca) and 48 professionals mainly from psychiatry, psychology, social, and economic fields who combine research, training and healthcare duties.

The main fields of work of the Foundation are: research, development and innovation and social-health assistance. The main target group is people suffering from mental disorders, disabled people, elderly people, and people at risk of social exclusion.

INTRAS has a solid experience both in the field of European projects and the development of new technologies and programmes for improving the quality of life of its beneficiaries. It has coordinated and participated as a partner in a large number of European and national R&D projects, in programmes as the HEALTH Programme, IV, V and VI Framework Programme, Competitiveness and Innovation Programme, and cooperation projects with Latin America.

INTRAS also has vast experience in running projects at educational and social level in programmes such as Equal, Interreg, Socrates, Lifelong Learning, Daphne, and Youth, among others.

INTRAS' main objectives are the following:

- to promote and develop treatment programmes;
- to promote and develop psycho-social intervention programmes and professional integration;
- to promote and develop technological research and innovation projects;
- to encourage the adoption and effective implementation of technological advances in mental health and other disabilities groups;
- to promote and develop technological research and innovation projects in cooperation with other EU Member States;
- to promote cooperation and research projects in the public health field together with developing countries
- to improve the quality of research and treatment programmes

INTRAS is member of the following international networks:

- HUSCIE (Humanitarian Social Committee in Europe)
- INTERDEM (Early Detection & Timely Intervention in Dementia)
- RIBERDISCAP (Latin American Network of Support Technologies for Disabled People)
- ALZHEIMER EUROPE

Furthermore, INTRAS is in permanent collaboration with national and international research centres, and universities and holds common lines of action with the University of Valladolid and the University of Salamanca in Spain.

Within the research, development and innovation area INTRAS promotes the evaluation and creation of programs based on new technologies that could be used in the neuropsychological rehabilitation field, in order to provide high quality socio-health assistance.

The research, development and innovation field involves three main departments/ areas at INTRAS:

- In the **R&D&Innovation Area**, several specialists in psychology and psychiatry conduct research in brain sciences and run projects on new technologies applied to treatment in mental health, such as virtual reality for treatment of schizophrenia, psycho-education, e-Health, etc.

- The **Gradior Department** is composed of a team of psychologists who carry out research and treatment projects in the area of new technologies and cognitive intervention and rehabilitation. INTRAS has developed the Gradior program for the rehabilitation of cognitive functions (attention, memory, perception, orientation, reasoning, calculation, etc) in people with symptoms of schizophrenia, cerebral paralysis, mental retardation, cerebral trauma, dementia, etc., through different kinds of exercises.

- The **Department of Technological Developments** is made up of a team of professionals who work together with the Gradior Department and R&D&Innovation Area in order to develop IT solutions to improve the quality of life of people with mental health problems or neurological diseases.

1.2 Pilot Site(s) Description

1.2.1 Site Location and Organisation

INTRAS will test the LLM service in three provinces of the region of Castilla y León (Zamora, Valladolid and Salamanca)

Castilla y León is one of the Spanish regions with the highest percentage of elderly people and depopulation. Given that there are a large number of rural and remote areas, its inhabitants find some difficulties in the access to socio-health services, as they have to move to the urban centres. This fact implies a great opportunity for the health services delivered through IT.

The sites involved in the pilot study that Fundación INTRAS is going to carry out will be of a different nature considering the target population of elderly people:

- **Population 1: Pathological and non-pathological community population**

1) Non-pathological community population.
    a. Pilot Sites: INTRAS Memory Clinics in Valladolid and Zamora.
2) Pathological community population (MCI or dementia):
    b. Pilot sites: primary care centres and mental health services in Zamora. INTRAS will access this population through the Zamora Provincial Hospital

- **Population 2: Elderly population at residential facilities or other institutions**

1) Elderly people at nursing homes
    c. Pilot sites: "Virgen del Canto" residential facility in Toro (Zamora) and "Mi Casa" residential facility in Valladolid
2) Elderly people with Alzheimer's
    d. Pilot sites: National Reference Centre for Alzheimer Disease (CREA) in Salamanca

None of these pilot sites presents any limitation in space or other conditions for the LLM equipment to be installed.

1.2.3 Access to Pilot Target Population

Profile of the pilot sites:

The sample of elderly people to be included in the pilot is composed of 200 final participants after the screening tests. INTRAS will access this population through the formal agreements reached with the health services of Zamora (Zamora Hospital), the Reference Centre for Dementia Disease in Salamanca (CREA) and two residential facilities: Virgen del Canto in Toro (Zamora) and Mi Casa in Valladolid.

The two Memory Clinics in Valladolid and Zamora (INTRAS' own facility):

The memory clinics are composed of a team of psychologists who carry out research and treatment tasks in the field of memory and new technologies. Their main objective is to improve the quality of life of elderly people through research and treatment, as well as the design of cognitive treatment programmes based on IT, such as the GRADIOR programme. Furthermore, these clinics provide GRADIOR courses, aimed at training in the operation of this programme. At these facilities, memory training sessions addressed to elderly people have been carried out for 10 years. 60 final elderly participants (after screening) will be involved in the LLM pilot.

The Psychosocial Rehabilitation Centre at the Zamora Province Hospital Zamora:

It is the public hospital of the city of Zamora. It offers sanitary services to people with mental illness, among them, elderly people. It has a special unit for the families and carers of the patients, aiming to provide the families with the possibility of leaving the patients for specific moments, in a supervised and controlled environment. The unit is composed of other structures such as supervised flats, where the patients have the opportunity to spend some full days. These structures are addressed to people with psychiatric/mental illnesses including elderly people, who do not need to be fully hospitalized but need a family support treatment. The LLM service will involve 40 participants.

The Reference Centre for Alzheimer Disease (CREA) in Salamanca

This centre is a public centre specialised in research, analysis, evaluation, and knowledge of the best models for socio- health services and the improvement of the quality of life of people suffering from Alzheimer's and other dementias, as well as their families and carers. With regard to the services provided, the centre promotes basic and applied research in the

socio-health field throughout the country. It offers permanent and temporary residential services to patients, with approximately 112 places. It promotes all aspects related to treatments and care provision models, rehabilitation and maintenance of the patients with Alzheimer's or other dementias, and support training of the professionals and carers. The centre will involve 30 final participants in the pilot.

The "Virgen del Canto" Residential Facility in Toro (Zamora)

This residential facility offers 152 places for elderly people (over 60 years), and will involve 35 final participants in the LLM pilot.

The Mi Casa Residential Facility: This residential facility will involve 35 final participants

Profile of the participants

The cognitive profile of the participants will be:

- People presenting MCI
- Alzheimer/ dementia
- Cognitively healthy with complaints of memory loss

Control Group

The control group will also be composed of two populations:

1. Community control group (passive control group):

   - People on the waiting list, that will be included in the pilot study
   - Randomized assignment

2. Control group for pathological population (active control group):

   - People receiving usual treatment and performing a psycho stimulation activity, to be determined
   - Randomized and open assignment

1.2.4 LLM Configuration

LLM installations

Population 1: Pathological and non-pathological community population: At home installation

- ILC
- CTC
- PTC: Bicycle

All the components will be installed in one room

Population 2: Elderly population at residential facilities or other institutions: Day Care Centre installation

- ILC (the number of units to be determined)
- CTC (the number of units to be determined)
- PTC: Bicycle (the number of units to be determined)

All the components will be installed in one room

Service maintenance:
An easier and more basic maintenance will be done by the professionals that supervise the elderly individual's performance, while the technical maintenance will be done by the engineer of Fundación INTRAS

2. PRE-PILOT ACTIVITIES

2.1 Staffing & Training Plan

INTRAS will involve 5 highly qualified neuropsychologists (Master Degree) and already trained in the operation of the GRADIOR CTC component, having years of research and treatment experience in INTRAS' Memory Clinic. These professionals are existing staff and will be coordinated by the INTRAS director of R&D area. Their main tasks will be that of supervising the elderly person's cognitive and physical activity and, in order to determine LLM's effectiveness, recordkeeping, reporting and data analyzing

Moreover, 3 psychiatrists will take part in the pilot to assess visual and auditory function and gather data for the medical history. Although they are not staff, INTRAS holds permanent collaboration with them.

Finally, 2 external geriatric specialists will also cooperate by medically assessing the participants and advising the INTRAS R&D team.

All these specialists will be involved at every stage of the pilot, that is, the recruiting stage, implementation, and final assessment.

The technical support and maintenance tasks will be performed or supervised by the engineer of the Foundation.

Recruitment phase:

Participation targets

Study Group	# of participants per iteration
MCI	50
Mild Dementia	50
Cognitively Healthy	75
Dementia/ Alzheimer	25
Active Control Group (define relationship to other study groups -- i.e., MCI, Mild Dementia, Healthy)	50
Passive Control Group (define relationship to other study groups – i.e., MCI, Mild Dementia, Healthy)	50
Total…	**300**

2.3 Recruitment Methodology

2.3.1 Inclusion Criteria

3 different kinds of inclusion criteria have been considered according to the healthy or pathological condition of the participants:

1. Inclusion criteria for healthy population complaining of memory loss

- Over 60 years
- Formal informed consent to take part in the LLM treatment programme, that will have to be obtained before the screening tests
- Normal scores in the screening protocol
- MMSE/MEC ≥ 25
- Personal physician's consent
- Absence of severe vision or auditory impairment
- Absence of significant mobility impairment
- Fluently and correctly speaking
- Ability and willingness to engage to the LLM treatment and to comply with time /date assignments
- Absence of a diagnosis of depression or other mood diseases

2. Inclusion criteria for elderly people suffering from MCI

- Over 60 years
- Formal informed consent to take part in the LLM treatment programme, that will have to be obtained before the screening tests
- Ability to carry out daily life activities, compared with previous periods of his life
- Scores at screening and memory tests indicating losses of memory. MMSE/MEC ≤24
- Personal physician's consent
- Absence of severe vision or auditory alterations
- Absence of significant mobility impairment
- Fluently and correctly speaking
- Ability and willingness to engage to the LLM treatment and to comply with time /date assignments
- Absence of a diagnosis of depression or other mood diseases

3. **Inclusion criteria for elderly people suffering from MDI**

- Over 60 years
- Formal informed consent to take part in the LLM treatment programme, that will have to be obtained before the screening tests
- Normal scores in the screening protocol
- Difficulties in carrying out daily life tasks involving basic or instrumental skills, compared to previous periods of his life. MMSE/MEC ≥15
- Scores below normal threshold in more than one cognitive function
- Personal physician's consent
- Absence of severe vision or auditory alterations
- Absence of significant mobility impairment
- Fluently and correctly speaking

- Ability and willingness to engage to the LLM treatment and to comply with time /date assignments
- Absence of a diagnosis of depression or other mood diseases

2.3.2 Recruitment Materials

To be presented at a personal interview with the candidate:

- Letter of informed consent.
- Letter of information on the rights that the elderly individual has as well as the tasks and responsibilities that he will have to take on.
- Information on the LLM project and its objectives (brochure, dossier, etc.)

Screening materials

- MEC/Minimental Test
- HVLT-R (Hopkins)
- CTT (Color Trails Test)
- Dígitos WMS (Weschler Memory Scale)
- Textos WMS (Weschler Memory Scale)
- Memory Complaints Scale
- G.D.S (Yesavage)

The materials do not require to be approved by any national review boards

2.4 Pilot Programme Approvals

All the pilot tests with the participants are non-invasive and will be carried out according to the relevant conventions and guidelines. In particular, they will comply with:

- National legislation. All legal and ethical requirements of the member states in which the project activities are carried out, including the appropriate authorisations from an ethical board of each centre involved.
- EC legislation.
- The charter of fundamental rights of the European Union.
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- During the project the European and International standards (EN 12182 and EN ISO 10535) will be considered

International conventions

- The principles of Helsinki Declaration

None of the tests involves any additional risk for the participant. All the experimental protocols will be approved by the respective Ethical Committees of the centres that will take part in the project.

All subjects must sign an informed consent form (see annex 1) and will be allowed to abandon the test at any moment without any justification or explanation. Personal data records will be handled confidentially throughout the procedures involved in the pilot.

3. PILOT ACTIVITIES

3.1 Timeline for Pilot Iterations

Oct																
May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct

The Spanish pilot will start in July 2010 and entail executing 3 iterations of 4 months. Each iteration will be followed by one month for the service adaptation, assessment of the participants and the corresponding data analysis to determine the results of the treatment.

Before the beginning of the pilot iterations two months will be devoted to the screening test in order to select the participants.

3.2 Screening

3.2.1 Informed Consent

The procedure of the informed consent will include the following steps. A psychiatrist and a neuropsychologist will ensure that the elderly individual is able to give his consent, presenting adequate levels of understanding and reasoning. After that, the neuropsychologist will give clear explanations to the participants about the contents of the document:

- Summary of the objectives of LLM project
- Information on the rights and responsibilities of the participants as well as the nature of the tasks/activities he will have to undertake
- Signature of the informed consent form

3.2.2 Exclusion Criteria

These criteria are common to each population

- History of psychotic diseases, epilepsy, sclerosis
- History of cranial traumatism or stroke
- Substance abuse
- Significant alterations in communication skills
- Concurrent enrolment in other research studies
- Foreseeable changes in cognitive-influencing medication (nemantine, acetil colesterase inhibitors, statines)

- Medical treatment with anti-psychotic drugs, anti-colinergic, L-dopa, anti-Parkinson's drugs

3.2.3 Screening Tests

Standard tests to be utilised for screening for all participants include the following. The screening tests will be used to measure outcomes, and will serve as the key source of information to derive scientific support for the deployment and use of the LLM solution.

Test No.	Test Name/Description	Resources Required for Test[4]	Time Required
1	MMSE	Psychologist	5 min
2	Psychiatric/medical history	Psychologist/G.P	5 min
3	IADL	Psychologist	5 min
4	Digit Span Test (subtest of Hawie)	Psychologist	5 min
5	California Verbal Learning Test (CVLY-II)	Psychologist	15 min
6	Trail Making Test (TMT)	Psychologist	8 min
7	Senior Fitness Test	Psychologist/G.P	15 min
8	Reaction Time	Psychologist	10 min
9	WHOQOL_BREF	Psychologist	10 min
10	Socio-demographic data and social activity	Psychologist	10 min
11	CERAD	Psychologist	60 min
	Total Time Required		**148 min**

Additional tests to be conducted, specific to the trial group (e..g, MCI, Mild Dementia, etc.), or specific to this site, which may be used to derive additional, site-specific scientific data related to this trial site, are listed following:

Test No.	Test Group	Dementia Assessment Test Name/Description	Resources Required for Test	Time Required
		ALZHEIMER PROTOCOL		
1	Alzheimer	MMSE	Psychologist	5 min
2	Alzheimer	Psychiatric/medical history	Psychologist/G.P	5 min
3	Alzheimer	IADL	Psychologist	5 min
4	Alzheimer	ADAS	Psychologist	45 min
5	Alzheimer	Senior Fitness Test	Psychologist/G.P	15 min
6	Alzheimer	Reaction Time	Psychologist	10 min
7	Alzheimer	WHOQOL_BREF	Psychologist	10 min
8	Alzheimer	Sociodemographic data and social	Psychologist	10 min

[4] Indicates, if any, specialised knowledge, training, or equipment is required to conduct the test. For example, indicate whether a physician with a specific background/specialization is needed, or a particular medical device is required.

		activity		
		Total Time Required		**105 min**

3.3 Pilot Conduct/Procedures

3.3.1 Programme Protocol

The treatment will be held in different settings:

- **The two Memory Clinics in Valladolid and Zamora (INTRAS' own facility)**
- **The Zamora Hospital (Centre for Psychosocial Rehabilitation)**
- **The Reference Centre for Alzheimer Disease (CREA) in Salamanca**
- **The residence facility "Virgen del Canto" in Toro (Zamora)**
- **The residence facility "Mi Casa" (Valladolid)d**

The first round will take place at INTRAS Memory Clinics and Zamora Hospital involving 80 participants, the second one simultaneously at INTRAS Memory Clinics, Zamora Hospital and at the CREA with a total number of participants of 70, and the last one at the two residential facilities, with 50 elderly people.

The participants will be expected to complete 36 sessions over the course of the pilot term (1 hour per day, 3 days per week, for a period of 12 weeks). The training procedure includes both cognitive and physical exercise components:

3.3.1.1 Cognitive Exercise

Depending on the facility or the centre, the availability of the computers will range from 5 to 20 units. These computers will be equipped with headphones and touch screen to make the performance of the elderly person easier and to boost usability. The participant is expected to train his main cognitive functions, by means of the Gradior programme, following a tailored set of exercises which will be planned beforehand by his therapist.

3.3.1.2 Physical Exercise

The physical exercise programme is a systematic one that will be personalized and supervised by a personal trainer together with a doctor (geriatric specialist) in order to determine the most suitable exercises to be done for each elderly individual on the CTC selected: an exercise bicycle.

This training programme should be applied three times a week and for at least 12 weeks (36 sessions) in order to induce changes in the physical condition of the participant. The total duration of the session is 1 hour per day, 3 times per week, consisting of three parts:

- **Warm-up** (10 min). A set of exercises will be done before executing the physical training at the CTC, to prepare the elderly person, and will include:
    - Balance exercises: They are important because they prevent falls and strengthen muscles.
    - Flexibility exercise to conserve muscle flexibility. Distensions should be executed at the beginning and at the end of every training programme.

- **Main part (30 min)**
  - Use of an exercise bike
  - Control of steady speed (15 – 16 km/h)
  - Measurement of time, speed and elapsed distance.
  - The main objective of this exercise is to strengthen the cardiovascular system and muscular endurance.

- **Recovering (10 min)**
  - Stretching exercises and breathing exercises
  - The main aim is the relaxation of the subject and the resetting of the heart rate at normal levels

Independent Living Component:

The participants do not necessarily have to use the functions offered by the ILC, but the component will support them during their daily living activities by increasing the safety of the independently living user. Some of the features of ILC will also be active during cognitive and physical training and thus help in evaluating their training efforts.

3.3.2 Monitoring Procedures

- regular visits and interviews by INTRAS staff and/or fitness trainer
- user diary

3.3.3 Discontinuation Criteria

5. Participants that skip more than 20% of the sessions
6. Those who during the study no longer meet the inclusion criteria
7. Those who during the study meet the exclusion criteria.
8. Those voluntarily withdrawing their consent.
9. Hospitalization of the participant for more than 15 days

3.3.4 Data Reporting

- Personal data will be gathered following National and European laws on the treatment of personal and clinical data (see the previous section on ethics)
- Each elderly individual will be assigned an alphanumeric code, which will be the basis to store their personal and clinical data as well as the results obtained in the different tests
- A database will be created to conduct the data analysis
- The Gradior programme also generates alphanumeric codes to guarantee the privacy of the user and data protection
- All the communications maintained through e-mail or electronic means that contain personal or clinical data will be protected by a password.

3.4 Risks

Risk	Likelihood	Impact	Risk Mitigation Plan
The participants are geographically too dispersed	Medium		Assignment of a well-balanced number of professionals. A support vehicle will be available for the journeys of the treatment team (van)
The system (or any of its parts, CTC, PTC or ILC) is difficult to implement	High		Assignment of a well- balanced number of highly qualified professionals. A support vehicle will be available for the displacements of the intervention team (van)
The participant is not motivated to comply	High		Requirement of a formal consent form and letter of commitment The intervention team will deal with motivation issues from the very beginning of the pilot tests
Problems in the arrangement of the schedule of the sessions	High		Date arrangements carried out with sufficient time in advance
A participant gets injured using the LLM solution	Low		Direct supervision of the intervention team. Personalized sets of physical exercises.
The participant suffers a health problem caused directly by the use of the LLM devices.	Low		Personalized sets of physical exercises. Consent of their personal physician. Supervision of two geriatric specialists.
System failures	Medium		Trained team of professionals. Technical support provided by the LLM consortium and INTRAS
Recruitment of users too time demanding	High		Screening and recruitment tasks done with sufficient time in advance
Too much personal data gathered	High		Compliance with European and national laws on data protection Design procedures for the storage and adequate treatment of the materials

			containing personal data

4. POST-PILOT ACTIVITIES

4.1 Post-Pilot Follow-up with Participants

The pilot project results will be evaluated to provide information to proceed or not proceed (i.e. go/no-go decision) with the deployment of the technology, to improve future pilots and provide recommendations to improve the technology piloted.

4.1.1 User Survey

As a part of the post-pilot activities, a user survey will be conducted to develop insights relevant to market acceptance, usability, etc. Describe the procedures for presenting participants with the user survey, collection and collation of results.

The survey will be conducted by the treatment team in the post-pilot period that will take place after each iteration at every facility involved in the LLM test.

- At least three members of the team will be present at every participant centre.
- It is important to keep the elderly people motivated to obtain feasible data
- The survey will be presented in a written format (big letters, simple questions, etc.) but will also be read in aloud. In the event that an elderly individual does not have the skills or training to read or write, a member of the treatment team will be ready to do so for him/her.
- In order to have enough time to perform data analysis, the survey will be carried out in groups of over 20 persons
- Important or useful qualitative data obtained in the survey will be collected at the reports to improve LLM service.

4.1.2 Outcome Measures

The timing of post pilot testing and prior data analysis is indicated below in blue and the final collection of data/ data analysis in red.

2009		2010															
May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct

4.2 Data Analysis

Clinical data analysis in general and data obtained related to dementia protocol in particular will be analyzed according to the established procedures of each measure by the clinical and

treatment team. The timing of these analyses is represented in the table (above situated) in blue.

4.3 Dissemination

LLM pilot results will be disseminated by means of:

- Press releases
- LLM Spanish newsletters
- Articles in scientific journals
- Papers at international conferences
- Networking: INTRAS is a full member of relevant scientific networks in the fields of mental health, dementia and Alzheimer's.

One dissemination activity will be carried out every three months

INTRAS INFORMED CONSENT FORM

NAME: INFORMED CONSENT FORM OF USER DATA FOR RESEARCH PURPOSES

DEPARTAMENT RESPONSIBLE: R&D DEPARTMENT

PERSON RESPONSIBLE: _____

DATE: _____

ISSUE NUMBER: 00

USE OF DATA INFORMATION FOR TEACHING OR RESEARCH PURPOSES:

On XX/XX/XXXX (date) the user or patient _____ (name) has been verbally informed by the clinical professional _____ (name) of the possibility of using data obtained during the applied treatment for teaching or research purposes, always keeping the anonymity of the patient intact.

The patient gives his/her consent for the use of said data for teaching or research purposes, on the condition that his/her anonymity is assured.

YES ☐

NO ☐

Note: in the event that the patient or user does not mind his/her personal identification data being used, he/she should sign a document of authorisation.

4.4 Deployment Plan Pilot E-SENIORS (France)

1. PILOT SITE PROFILE

1.1 Organisational Background

E-seniors is a non-profit NGO aiming at fighting against e-exclusion by providing access to and training in information and communication technologies for seniors and/or disabled people.

The objectives of E-Seniors are:

- bridging and shrinking the digital gap between generations;
- caring for elders by fighting against senior isolation;
- opening new horizons for the efficient use of free time

Since its creation, five years ago, E-Seniors has provided courses on ICT usage for seniors in various public locations. Due to growing demand, E-Seniors have been constantly opening new locations all over the "Ile de France" region in order to provide a "proximity" service which takes into account the rhythm, interests and needs of our target population.

Besides teaching "basic computer skills", we have opened more thematically-oriented workshops for "advanced" students, dealing with, for example, digital images and sounds, and interactive messaging and chat. Step by step, E-Seniors have added new activities such as "writing memories", conferences and meetings dealing with the fight against e-exclusion. All this is accomplished with the concept of a "cyber seniors club" in mind, inducing socializing on an informal level. This is a quasi non-existent concept in most big cities!

Other target population is people with reduced mobility to whom adapted activities are proposed.

In addition, E-Seniors work with people in retirement homes, day-care centers (for MCI or Alzheimer patients eg.) and other specialized institutes. For this target population, E-Seniors experienced staff, with the cooperation of resident-care staff, offer cognitive and physical stimulation through interactive games, using Nintendo consoles, Wiifit balance boards and other online games. In that particular framework, E-Seniors' network of institutions taking care of the elderly makes access to a choice of pilot sites possible.

1.2 Pilot Site(s) Description

1.2.1 Site Location and Organisation

In France, the LLM pilot tests will be conducted at different types of sites:

- **Day care center (OSE)**
  OSE (acronym for "Oeuvre Sociale pour l'Enfance") is an organisation which was founded in the beginning of the 20th century. E-Seniors have been working for two years in two of the day care centres, setting up computer based activities for senior, handicapped and MCI sick people, and will continue next year to set up cognitive and physical stimulation activities in the new centre for younger Alzheimer-sick people

(from 50 years old). One, two if possible, "Day care centre" type installations of LLM are going to be installed within the three day care centres of OSE.

- **MAPI Les Amandiers Retirement/ nursing home (Paris 20)**
  MAPI Les Amandiers is a private retirement/nursing home hosting elderly residents of various conditions, from autonomous and semidepentent to ones suffering from mild dementia and cognitive deterioration. The institution has 124 beds and about 100 residents. We plan on setting one "Day care centre" LLM installation type to provide training for the entire population of the institution.

- **Network of home assistance (AGEP) At home day care service**
  East – Paris AGEP network for seniors The institution intervenes with patients in close collaboration with the treating physician and all the professional health and social sector that supports the elderly.

  The services offered are as follows:
  - Practical information reserved for patients, their families and professionals about everything related to the elderly in the East of Paris (11 th, 12 th, 19 th and 20 th districts).
  - Medical benefits and help
  - Talk groups: Informal discussion meeting with the patient and his family
  - Home visits

  The AGEP institution will facilitate the deployment of 2-3 "At Home" installations for elderly people in East Paris. Through the AGEP platform we anticipate a wide dissemination of the results of the Day Care Centres Formal Care Facilities.

- **Long term hospital (Marne La Vallée Hospital)**
  Marne La Vallée hospital has a "long stay" formal care centre.

- **Additional test sites are under negotiation, outside the Ile de France Region.**
  They include one site in the 'Département du Cantal' and a hospital with a specialised geriatric department (with geriatricians and psycho-geriatrician) in Saint Girons, 'Département de l'Ariège' (S-W of France) already using the Gradior software developed by LLM partner. Discussions are still at a preliminary state but their outcome may very well be positive, depending on the amount of resources these institutions will be able to spare for LLM.

  So far no home installation (stricto sensu) ie. including the e-Home components, has been planned, the reason being that, particularly in the "Ile de France" region and even more so within Paris, apartment space is scarce and chance may be low to find users willing to dedicate additional amounts of space for a test.

  In addition, from discussions with organisation proposing physical activities to elderly people, it is understood they prefer performing these activities in public places rather than alone at home. That elderly people an opportunity to go out in addition to the fact that they feel more secure being observed closely while performing physical sport activities.

1.2.2 Physical Description

- **OSE:**
  The LLM-prototype will be installed in a room provided for the LLM project configuration. The room will be adapted adequately.
- **MAPI**
  Nursing home:
- **AGEP**
  Day care assistance network:
- **Hospital**

1.2.3 Access to Pilot Target Population

As of end October 2009, the target pilot populations are envisaged as follows:

Institutions	Type of individuals	Comment
OSE	MCI	W. passive control group
	Mild dementia	W. passive control group
	"Early" Alzheimer	W. passive control group
MAPI	Cognitively healthy	W. passive control group
AGEP	Cognitively healthy	W. passive control group
APHP Hospital	MCI	Tbd
	Mild dementia	Tbd
	"Early" Alzheimer	Tbd
Site in 'Département du Cantal' (*)	TBD	TBD
Hôpital de Saint Girons (*)	TBD	TBD

(*) Still under discussion.

Indicate how the organisation has access to the target population (own facility, relationship with other facilities, and a profile of those facilities)

Site	Site type	Access to target population
OSE	Is a day care centre where patients go for treatment/treatment activities	Patients will be offered to participate in a test aiming at determining the degree of usability of the platform.
MAPI	Is a retirement home.	Boarders will be offered to participate in a test aiming at determining the degree of usability of the platform.
AGEP		
APHP hospital	Hôpital de Marne la Vallée is a so called "long stay hospital" hosting patient with various cognitive or physical age-linked impairments, sometimes severe.	
Hopital de Saint Girons (*)	Have specialists in geriatrics and psycho-geriatrics.	Elderly people suffering from geriatric diseases.

(*) Still under discussion.

1.2.4 LLM Configuration

Site	Hardware selected
OSE	Minimum configuration envisaged: computer based cognitive exercises (**)
MAPI	Minimum configuration envisaged: computer based cognitive exercises (**) and static bicycle.
AGEP	e-Home possibility still investigated
MLV APHP hospital	Minimum configuration envisaged: computer based cognitive exercises (**)
Site in 'Département du Cantal' (*)	
Hôpital de Saint Girons (*)	Minimum configuration envisaged: computer based cognitive exercises (**)

(*) Still under discussion
(**) Final decision on hardware configuration to be decided by MDs in charge. Another bike will be circulated among various sites.

- Service maintenance: done by E-Seniors or affiliate organisation

2. PRE-PILOT ACTIVITIES

2.1 Staffing & Training Plan

2.1.1 Preparation Phase:

- E-Seniors prepare a "train the trainers" programme
- E-Seniors: inform potential test participants, conducting recruitment tests, prepare test participants for the training phase
- Evaluator (conducting and evaluating the cognitive recruitment tests) – project partner from UKON
- Supervisor for the physical recruitment tests – generally a MD, will vary according to site:

Site	Inclusion test decision
OSE	
MAPI	
AGEP	
APHP hospital	
Site in 'Département du Cantal' (*)	
Hôpital de Saint Girons (*)	

(*) Still under discussion.

- Fitness trainer – aid in selection and contacting of participants : may in some instances be a physio-therapist.

NB: On 01November 2009, this list is neither exhaustive nor definitive (v.2.0 – 2009/10/31).

2.1.2 Installation phase:

- Installation of the LLM-Service (including internet connection if necessary) done by E-Seniors staff in conjunction with relevant local staff.

2.1.3 Training phase:

- (1) adequate full training of E-Seniors' staff
- (2) "train the trainers" programme implementation
- (3) Set-up of a back-up procedure for the sites.

2.1.4 Recruitment Plan

2.1.5 Participation Targets

This is yet to be defined with the various respective sites.

Study Groups	# of Participants per iteration
Cognitively Healthy	
Passive Control Group (cognitively healthy)	
MCI	
Mild dementia	
"early" Alzheimer	
Total…	

2.2 Recruitment Plan

2.2.1 Inclusion Criteria

- Aged 65 and older
- Speaking fluency in the language of the trial
- Ability to make time commitment
- Written consent for participating in the LLM intervention program (acquired before screening)
- Subjects should not have any significant mobility impairment (upper or lower extremity)
- Diagnose MCI by means of the selected assessment neurophysiological tests able to discriminate between MCI-demented patients and between MCI patients-healthy participants
- The MD in charge will check the hearing and vision criteria (hearing and vision criteria anticipate that both could be augmented, i.e., via eyeglasses or hearing aids)
- Do not suffer from severe depression or other emotional abnormalities according to the GDS and/or NPI test
- In case of any chronic diseases such as hypertension, diabetes, etc., there should be consultancy with the responsible doctor in order to keep their condition under control
- Personal physician's consent.

For At-Home-installations:

- living in a single-person-household (without cat/dog)
- the size of the person's apartment must not exceed 3 rooms.

NB: On 01November 2009, this list is neither exhaustive nor definitive (v.2.0 – 2009/10/31).

2.2.2 Recruitment Material

E-Seniors will produce a document for the participants, keeping in mind this is not a formal clinical trial as such, but a straightforward pilot product test. There are no "clinical trials" as such for marketing game consoles with cognitive fitness exercises.

- Information document about the project and the tasks the participant has to carry out during the trial.
- Document to be countersigned by participant.

Legal advice on whether approval of the materials by a review board is needed, will be investigated.

2.3 Pilot Programme Approvals

This question is currently (Oct/Nov 2009) being investigated.

3. PILOT ACTIVITIES

3.1 Timeline for Pilot Iterations

- The **first trial** will be conducted in a medical centre, probably OSE, for a period of three months beginning in march 2010, providing all pieces of the system have been delivered and proper training done.

- **Pilot**: There will be 3 pilot iterations depending on site with a duration of 3 months each. One month of evaluation will be taken. Service adaptations will be adjusted between every iteration.

NB: (01November 2009), these figures may vary slightly (v.2.0 – 2009/10/31).

3.2 Screening

3.2.1 Informed Consent

To be defined

3.2.2 Exclusion Criteria

Exclusion criteria to be applied as initial pre-screening for volunteers include the following:

1. Major neurological or psychiatric illness history
2. Any recent (within 6 months) history of stroke, transient ischemic attack, traumatic brain injury, ALS, MS, PD
3. Current substance abuse.

4. Acetylcholinestearase inhibitor use is not excluded, so long as use has begun 4 months prior to enrolment in study, and is stable and during course of the study remains consistent.
5. Significant communication impairments (e.g., unable to respond to questions in screening).
6. Concurrent enrollment in other studies.
7. Statin users may be excluded unless use is consistent during the course of the study, and is stable.
8. Need to check to find out if interference of Zig-bee, Blue Tooth etc. for pacemakers participants. They could be excluded.
9. for At-Home-Installations: sharing the apartment with somebody else (can even be a cat or dog)

NB: On 01November 2009, this list is neither exhaustive nor definitive (v.2.0 – 2009/10/31).

3.2.3 Screening Tests

The screening tests will be used to measure outcomes, and will serve as the key source of information to derive scientific support for the deployment and use of the LLM solution.

The total time required for screening one person should not exceed one hour (including physical and cognitive screening). Experts from project partner UKON will decide about and conduct the cognitive screening tests. The fitness trainer of the senior citizen centre will design an appropriate physical screening test.

Standard tests to be utilised for screening for all participants include the following.

Test No.	Test Name/Description	Resources Required for Test[5]	Time Required
1	t.b.d.		
	Total Time Required		20 min

Additional tests to be conducted, specific to the trial group (e..g, MCI, Mild Dementia, etc.), or specific to this site, which may be used to derive additional, site-specific scientific data related to this trial site, are listed following:

[5] Indicates, if any, specialised knowledge, training, or equipment is required to conduct the test. For example, indicate whether a physician with a specific background/specialization is needed, or a particular medical device is required.

Test No.	Test Group	Test Name/Description	Resources Required for Test	Time Required
1		n/a at pilot-site Schwechat		
		Total Time Required		0

Exceptions from standard tests, if any, include: TBD

3.3 Pilot Conduct/Procedures

3.3.1 Programme Protocol

Sites	Protocol
OSE	
MAPI	
AGEP	
APHP hospital	
Site in 'Département du Cantal' (*)	
Hôpital de Saint Girons (*)	

(*) Still under discussion.

3.3.1.1 Cognitive Exercise

The cognitive training procedure is expected to utilize one LLM-computer equipped with headphones per trial site. The participant is expected to do the training one hour per day, three times a week, whereas it is possible to split this time into a couple of shorter sessions per day.

3.3.1.2 Physical Exercise

The physical exercise program is a systematic one, which contains four basic types of exercise:

- Endurance
- Strength
- Balance (static and/or dynamic) and
- Flexibility

The types of exercises considered for incorporation into the programme include:

- Exercises such as gait, slow jogging and cycling target to the improvement of the cardiorespiratory system.
- Muscle strength exercises are related to weightlifting.
- Balance targeted exercises are important because they prevent falls. They could be incorporated into the program of muscle strengthening

- Flexibility exercises (distensions) conserve muscle flexibility and protect from injuries. Distensions should be executed in the beginning and at the end of every training program.

It is supposed that most of the participants can be categorized as beginners. To avoid that the program is too challenging for them, the training program should be applied two times a week and for at least three months. The design of the training session for this pilot, as evaluated, is:

Duration is 30 minutes per day, 2 times per week, consisting of three portions:

- Warm up (10 min)
  - Use of ergometer bikes, treadmills
  - Control of steady speed (15 – 16 km/h)
  - Measurement of time, speed and elapsed distance

- Main part (15 min)
  - In early stages each exercise shall be executed in 2 sets of 8 repetitions with 1 minute interval
  - Maximum number of sets: 3
  - Maximum number of repetitions: 15
  - Equipment to be used: gymnastics tires, weights of one kilo each, rhythmic gymnastics ball (16 cm diameter), gymnastics bars (1 meter)

- Recovering (5 min)
  - Stretching exercises and breathing exercises
  - Main target is the relaxation of the subject and reset of heart rate at normal levels

The program must include CTC 3 times per week, and PTC 2 times per week, but the sequence and mix does not matter.

Independent Living Component:

TBD

Pre-pilot-trial in senior citizen centre (multi-user-situation):

3.3.2 Monitoring Procedures

- Regular visits and interviews by E-Seniors staff.
- User log.
- Local team report

3.3.3 Discontinuation Criteria

To be fine-tuned with medical advice from the sites.

3.3.4 Data Reporting

Users will be "anonymised" and identified with and ID, probably composed of two parts: centre number and individual number.

3.4 Risks

Risk	Likelihood	Impact	Risk Mitigation Plan
PTC-training program is too demanding	Medium	High	Reduce physical effort Reduce time effort
CTC-training program is too demanding	High	High	Distribute it over time, follow advise of partners with expertise in CTC
Participant gets injured conducting the physical training program	Low	High	None Approval by General Practitioner (GP) before starting test, inform about risk before test
System failure to log usage data occurs	Low	Medium	Run Lab Test Define quality criteria to be met before starting pilot Use pre-pilot to gather experiences
Users indicate to not see the benefit of the trial	Medium	High	Try to find the reason for this opinion. Maybe the training program is not demanding enough
User needs additional on site motivation	Medium	Medium	Visit and / or talk to the participants regularly
Recruitment of users too time demanding	Low	Low	Start recruitment phase as early as possible
Delayed availability of system components for pre-pilot trials	Low	Medium	Reschedule test Prepare initial time schedule with buffer time Reserve buffer time in technical work packages
Logged data not sufficient for recognition of system usage / user activities	Low	High	confirm sufficient data quality during lab tests and pre pilot integrate regular supervision of logged data during pilot to discover potential problems quickly (limit the amount of missing / not sufficient data)

NB: On 01November 2009, this list is neither exhaustive nor definitive (v.2.0 – 2009/10/31).

4. POST-PILOT ACTIVITIES

4.1 Post-Pilot Follow-up with Participants

The pilot project results will be evaluated to provide information to proceed or not proceed (i.e. go/no-go decision) with the deployment of the technology, to improve future pilots and provide recommendations to improve the technology piloted.

4.1.1 User Survey

As a part of the post-pilot activities, a user survey will be conducted to develop insights relevant to market acceptance, usability, etc. Describe the procedures for presenting participants with the user survey, collection and collation of results.

After each iteration the participants will be interviewed individually about their perceptions about the LLM-installation in the framework of a mixed directive and non-directive exchange.
Whenever possible, a group discussion with participating seniors, experts and site managers will take place, during the tests and at the end of the tests. Mid way discussions might possibly reveal information concerning adaptation time to the system, early difficulties met, and other pertinent issues. In fact feedback loops, originating from the field, should be planned.

Key factors that will be tested and verified are:
- User acceptance
- Usability
- perceived usefulness
- pleasure taken or discontent in using the system objectively or subjectively
- Accessibility of the solution

4.1.2 Outcome Measures

Post-pilot testing, utilising the screening tests will be performed.

After the trial-period the same tests as in the screening sessions will be performed with each participant.

4.2 Data Analysis

It is assumed that guidelines and/or recommendations will be proposed by UKON regarding data analysis methods and tools.

4.3 Dissemination

This will be dealt within the Dissemination Plan.

4.4 Pilot Debriefing

4.5 Deployment Plan Pilot MILTON KEYNES (UK)

1. PILOT SITE PROFILE

1.1 Organisational Background

Milton Keynes often abbreviated MK, is a large town in Buckinghamshire, in the south east of England, about 60 miles (97 km) north-west of London. It was formally designated as a new town on 23 January 1967. Its 89 km2 (34 sq mi) area incorporated the existing towns of Bletchley, Wolverton and Stony Stratford along with another fifteen villages and farmland in between. At the 2001 census the population of the Milton Keynes urban area, including the adjacent town of Newport Pagnell, was 184,506, and that of the wider borough, which has been a unitary authority independent of Buckinghamshire County Council since 1997, was 207,063. The Borough's population is currently estimated to be over 230,000.

1.2 Pilot Site(s) Description

1.2.1 Site Location and Organisation

Milton Keynes and neighbouring counties have a number of privately owned residential homes for the elderly. This is where citizens who are assessed as too frail to live independently are given care within such homes. We aim to find a significant proportion of our pilot subjects within these homes. It is also envisaged that there may be a number of dwellings within sheltered accommodation. This type of care bridges the gap between independent living and residential care, where the citizen is provided with an apartment within a block where they are frequently visited by a warden. There may also be a number of home settings of people who may be more independent than the two aforementioned situations.

1.2.2 Physical Description

As a general layout residential care homes normally have a communal lounge area which may include a television, board games and other entertainment activities. Each resident will be allocated his or her own bedroom which will be tailored to individual needs. There may also be a separate dining area.

Sheltered accommodation is where a number of apartments are housed within a complex and facilitates semi-independent living. The complex is patrolled by a warden, who makes regular checks on the residents and is available to answer distress calls trigger by residents. Usually the apartment would comprise of a living area, bathroom, kitchen area and a bedroom. There are distress alarms situated around the apartment or are in the shape of a pendant worn around the neck. If the resident finds themselves in difficulty they pull a chord or push a button to alert the warden.

As with most residential units in the UK space is at a premium and within the two above environments the equipment footprint must be kept to a minimum. It would be impractical to install bulky equipment within residential care homes and sheltered accommodation. Residential care homes frequently rearrange communal areas for different recreational

activities; therefore static equipment may impinge the flexibility of such rooms. From our pilot planning enquiries with some settings/homes we have noted they have raised health and safety concerns relating to the equipment if it left unattended.

1.2.3 Access to Pilot Target Population

It is envisaged that connections will be made either through direct marketing via Milton Keynes Council or through the Adult Social Care department within the Council.

1.2.4 LLM Configuration

- Acquisition of equipment – Late December and early January 2010.
- Equipment installation January and early February 2010
- Initial Users tests late February 2010
- Initial active use in a planned pilot phase - March 2010

(Draft -To be confirmed)

2. PRE-PILOT ACTIVITIES

2.1 Staffing & Training Plan

Medical Professional (New Temporary Appointment)

A medical professional will be appointed to assess the eligibility of citizens for the tests and for the ethics submission and associated medical work that is required. Along with consultations with the participant's regular general practitioner, basic health tests will be performed in order to ascertain whether the participant is a suitable candidate. They will require training to familiarise themselves with the LLM solution.

Manager/Warden (New Temporary Appointment)

8To oversee the participants when performing the LLM test will fall to the manager of the residential care home or warden of the sheltered accommodation where required. It may be that after an initial period of familiarising themselves with the software and exercises the participants will be able to perform these independently. LLM solution training will be required.

Project Manger (Milton Keynes Council Staff)
Will oversee the progress of the pilot and make day to day decisions. The Project Manager will also record the data with regards to the test participant and will be responsible for reporting back to the LLM board. Will need training in LLM record keeping, reporting and technical support.

2.1.2 Recruitment Plan

2.1.2.1 Participation Targets

Currently a consultation meeting has been carried out with two residential care homes. This has yielded a possible 50 subjects within the groups MCI and mild dementia. This is expected to grow exponentially once the publicity materials start to be distributed.

Study Groups	# of Participants per iteration
MCI	
Mild dementia	
Cognitively Healthy	
Active Control Group (define relationship to other study groups -- i.e., MCI, Mild Dementia, Healthy)	
Passive Control Group (define relationship to other study groups – i.e., MCI, Mild Dementia, Healthy	
Total…	

2.2 Recruitment Methodology

2.2.1 Inclusion Criteria

- Aged 65 and older
- Speaking fluency in the language of the trial
- Ability to make time commitment
- Written consent for participating in the LLM intervention program (acquired before screening)
- Participants should not have any significant mobility impairment (upper or lower extremity)
- Diagnose MCI by means of the selected assessment neurophysiological tests able to discriminate between MCI-demented patients and between MCI patients-healthy participants
- Fulfill the hearing and vision criteria set by a specialized physician (hearing and vision criteria anticipate that both could be augmented, i.e., via eyeglasses or hearing aids)
- Do not suffer from severe depression or other emotional abnormalities according to the GDS and/or NPI test
- In case of any chronic diseases such as hypertension, diabetes, etc., there should be consultancy with the responsible doctor in order to keep their condition under control
- Personal physician's consent.

2.2.3 Recruitment Material

To be confirmed

2.3 Pilot Programme Approvals

To be confirmed with Doctor
Currently our medical professional is reviewing our ethics submission.

3. PILOT ACTIVITIES

3.1 Timeline for Pilot Iterations

SJ to confirm

3.2 Screening

3.2.1 Informed Consent

Informed consent will be in the form of a participant's approval (or via power of attorney) to participate and the participant's medical Doctors approval.

3.2.2 Exclusion Criteria

Exclusion criteria to be applied as initial pre-screening for volunteers include the following:

1. Major neurological or psychiatric illness history
2. Any recent (within 6 months) history of stroke, transient ischemic attack, traumatic brain injury, ALS, MS, PD
3. Current substance abuse.
4. Acetylcholinestearase inhibitor use is not excluded, so long as use has begun 4 months prior to enrolment in study, and is stable and during course of the study remains consistent.
5. Significant communication impairments (e.g., unable to respond to questions in screening).
6. Concurrent enrollment in other studies.
7. Statin users may be excluded unless use is consistent during the course of the study, and is stable.
8. Need to check to find out if interference of Zig-bee, Blue Tooth etc. for pacemakers participants. They could be excluded.

3.2.3 Screening Tests

To be confirmed with Doctor

The screening tests will be used to measure outcomes, and will serve as the key source of information to derive scientific support for the deployment and use of the LLM solution.

Standard tests to be utilised for screening for all participants include the following.

Test No.	Test Name/Description	Resources Required for Test[6]	Time Required
1	t.b.d.		
	Total Time Required		20 min

[6] Indicates, if any, specialised knowledge, training, or equipment is required to conduct the test. For example, indicate whether a physician with a specific background/specialization is needed, or a particular medical device is required.

Additional tests to be conducted, specific to the trial group (e..g, MCI, Mild Dementia, etc.), or specific to this site, which may be used to derive additional, site-specific scientific data related to this trial site, are listed following:

Test No.	Test Group	Test Name/Description	Resources Required for Test	Time Required
1		n/a at pilot-site Schwechat		
		Total Time Required		0

Exceptions from standard tests, if any, include: TBD

3.3 Pilot Conduct/Procedures

3.3.1 Programme Protocol

The intervention will be held in residential care homes or in sheltered accommodation, ranging in size of about 20+ people per establishment. It is envisaged that there will be multiple units deployed in homes in order for there to be sufficient time for all participants to complete their sessions within the day. It is also envisaged that there will be multiple establishments hosting LLM concurrently. Participants will be expected to complete 40 sessions over the course of the pilot term (1 hour per day, 5 days per week, for a period of 12 weeks). The training procedure includes both cognitive and physical exercise components:

3.3.1.1 Cognitive Exercise

The cognitive training procedure is expected to utilize PCs (the number which will be dependent on the size of the establishment) equipped with headphones. During each training session, the participant is expected to work with four of the six exercises for 15 minutes per exercise.

3.3.1.2 Physical Exercise

Each residential home has its own program of physical exercise. This includes Pilates, Tai Chi and Movement to Music programs. Where possible these programs will be incorporated into the LLM Intervention.

This has three benefits:

1. The regime is tailored to the residents abilities and will not add additional training burden to the residential homes.
2. There will be no additional heath and safety issues from the placement of equipment
3. There will be no evaluation procedures for fitness ability (as this has already been done)

Within the other two installations (sheltered accommodation and home installations) there will be the installation of equipment, these are dependant on room and space available. This will be on a best fit basis.

3.3.2 Monitoring Procedures

Once trained the staff at the relevant establishment will monitor the participants and give progress reports directly to the manager/warden. Managers/wardens will submit data to the project manager on a weekly basis and any concerns about participants immediately.

3.3.3 Discontinuation Criteria

1. Participants that skip more than 20% of the sessions. Discontinuation on this criteria would be evaluated beginning after 12 weeks of the intervention.
2. Those who during the study no longer met the inclusion criteria.
3. Those who during the study met the exclusion criteria.
4. Those voluntarily withdrawing their consent.

3.3.4 Data Reporting

Data will be recorded in three phases:

- Pre-LLM assessment
- Post-LLM assessment
- Assessment 3 months after the completion of tests

3.4 Risks

Risk	Likelihood	Impact	Risk Mitigation Plan
Trips or falls from equipment		High	Adequate training and supervision for participants
Physical exercises too demanding		Low	Assessment prior to acceptance
Poor medical advice		Low	Medical professional is vetted and registered with the GMC
Undetected medical illness leading to complications		Low	Pre-assessment and consultation with the participants GP

4. POST-PILOT ACTIVITIES

4.1 Post-Pilot Follow-up with Participants

The pilot project results will be evaluated to provide information to proceed or not proceed (i.e. go/no-go decision) with the deployment of the technology, to improve future pilots and provide recommendations to improve the technology piloted.

Once the LLM intervention is complete participants will be re-assessed after a three month period has lapsed after the intervention.

4.1.1 User Survey

As a part of the post-pilot activities, a user survey will be conducted to develop insights relevant to market acceptance, usability, etc. This will be in the form of a short survey and will be offered to participants on completion of the 12 week trial.

4.1.2 Outcome Measures

Post-pilot testing, utilising the screening tests will be performed.

4.2 Data Analysis

Data from the trials will be recorded in a central database and this data will be used as the source for analysis of the projects' outcomes. Any localised analysis of results (e.g., if additional outcomes, beyond the standard set) particular to the pilot site is to be completed, describe that analysis procedure here.

4.3 Dissemination

This will be dealt within the Dissemination Plan.

4.4 Pilot Debriefing

5. Training and Documentation

5.1 Training

Training Plans for preparing and conducting training for the purpose of training all stakeholders on the use of the product/service.

To achieve LLM training objective, the Consortium will work closely together with the respective aspects work packages involved in setting up a training plan that determine the training requirements.

LLM training will provide the trainees with knowledge and skills required to perform their duties. Training Plans are dealt with, partially in WP3?? and also in D4.2 "Training and Quality Assurance"

The target population of the training is:

Pilot partners and/or Pilot partners collaborators:

- Health and social care professionals, domiciliary care staff, residential care home managers and staff, and support workers,including the voluntary sector.

End-users will be trained by them. It is recomended to select a small elders group and to train them thoruoghly to be they the ones to teach their peers.

Training will have two levels:
One with more technical implications addressed to those in charge of setting the pilots and customising them according to end-users requirements.

The second level of the training will be addressed to end-users and thus will have to be necessarily simplier.
Pilots partners in charge of the running of the pilots are the final responsible of training end-users and/or alternatively those they designated to work into the project, accompanying and supporting end-users along the course of the pilot.

5.2 Documentation

5.2.1 Documents

Identification and description of the documents that will be produced for the purpose of aiding in installation, support, or use of the product/service.

The Training documents are comprise of

Training Course and Schedule detailing the type of training: on-site; on-line, …

- Quick Reference Guide
- LLM Guidance document
- Training videos

5.2.2 Documentation Activities

- Setting up a brief document describing LLM guidelines for the training materials.
- Use record presentations as a basis for a training video??
- Production of training videos
- Production of quick start guides
- ....

6. Risk Planning

In LLM we have defined risk as any event which **is likely to** adversely affect the ability of the project to achieve the defined objectives.

Pilot project risks may affect project goals and pilot goals.

During production of the DoW main pilot project risks were identified and assocciated to each task (see the following table)

Task Nº	Task	Risk Nº	Risk	Mitigation Plan	Risk Cleared Milestone
T2.1	Initial creation of network of interest	R2.1.1	Lack of interest from Public Administrations	Greater involvement of practitioners in the field Second wave of **LLM** partners ready to join the deployment	M1, M4
		R2.1.2	Lack of interest from Users Private Networks	Involving closely all consortium partners to bring together the relevant stakeholders	M1, M4
T2.2	Web site construction	R2.2	Contribution Content and translation from consortium partners Low visibility and poor audience for the Internet portal	Continuous review of these activities to prevent failure Web site promotional strategies (link exchange directory, …)	M9
T2.4	Workshops Activities	R2.4	Insufficient power call Failing to establish the goals and messages	Greater involvement of practitioners in the field	M12
T3.1	Requirements and Configuration	R3.1	Failure to elicit all the necessary requirements by the Consortium members	Repeated iterations of the requirements catalogue to external Living Labs also	M3
T3.2	Technical Setup	R3.2	Limited programming time for adaptation	The project's coordinator can draw personnel from a pool of 1,000 employees. For specialised and urgent need subcontractors can be used	M6
T3.3	Testing and Validation	R3.3	Narrow scope and time for debugging	Technical coordinator will continue debugging and improving the service for the whole project's duration	M8
T4.1	Deployment Planning	R4.1.1	Previous infrastructure for deploying services is not ready	Second wave of **LLM** partners ready to join the deployment	M8
		R4.1.2	The consortium fails in getting involved Public Administrations and social systems	Join forces with current administration providers? Second wave of **LLM** partners ready to join the deployment	M8
		R4.1.3	The consortium fails in getting involved private networks of users and final users itself	Second wave of **LLM** partners ready to join the deployment	M8
T4.2	Quality of service assurance	R4.2	Partners not prepare or unwilling to take the testing	Continuous review of these activities to prevent failure	M6
T4.3	Technical support and training	R4.3	The people responsible for organizing the pilots are not sufficiently trained before the pilots start	Technical support provision directly by the consortium experts to alleviate initially and disappear the problem	M11
T4.6	Post-implementation Review	R4.6.1	Insufficient evidence of a fully developed validation cycle	Further adaptations of the pilots according the different requirements	M20

Task Nº	Task	Risk Nº	Risk	Mitigation Plan	Risk Cleared Milestone
		R4.6.2	Difficulty to maintain the service due to: Technical difficulties Too much efforts Too much cost	Technical partner and subcontractors providers total commitment with the project, the technological innovation to be always ahead of competitor	M20
T5.2	Business Strategy & Development	R5.2	Country-level differences Markets too differentiated for following a common strategy A poor market perspective is found for **LLM** service across European MS	An accurate mapping of the situation will enable the Consortium to adjust its strategy according the requirements of the different investors and countries situation	M10
T5.3	Public initiative for financing	R5.3	Not to raise enough interest for getting public support or involving public administrations as prescriptors of the service People making decisions change frequently according to political pressures (need to start from the beginning once and again) City councils budgetary dependence from autonomous governments and/or national government	Establish a network of interest and discuss Memoranda of Understanding and terms since Day One of the project. Also special attention has been paid to this issue by marking 3 out of the 5 tasks of WP5 for the establishment of partnerships.	M20
T5.3	Private initiative for financing	R5.3.1	Partners do not find private investors willing to invest in the project	Redefine cooperation strategies and lowering expectations	M20
		R5.3.2	Failure to involve all the Consortium members in the new venture	All partners are already committed to the project follow-up in terms of service implementation	M20
T5.4	Commercial Alliances	R5.4	Not concluding commercial agreement with the different intermediaries that will be selling the services	Strategies refocus	M20
T6.1	Ethical issues guidelines	R6.1	Problematic cooperation with the external Independent Ethical Board or discrepancies within that board	More active involvement of the Project Coordinator to alleviate the situation Addition of new members to the Board or usage of EU policy guidelines as impartial criteria to resolve arguments	M5
T6.2	Legal issues	R6.2	Failure of the service or the pilots to comply with national legislation	Adaptation of the service or provision of "Terms of agreement" document to actively inform and receive the direct consent of the service's users	M6

Besides these risks identified at the project global level, pilot partners, have identified specific risks associated with the deployment and running of the pilots trials (see chapter3, point 3.4 for each pilot)

6.1 Risks/barriers preventing pilots deployment

We have quantified the **likelihood** of each risk's prioritizing each of them according to the **likelihood** and **impact** rating.

LIKELIHOOD

Title	Score	Description
Very Low	20	Highly unlikely to occur; however, still needs to be monitored as certain circumstances could result in this risk becoming more likely to occur during the project
Low	40	Unlikely to occur, based on current information, as the circumstances likely to trigger the risk are also unlikely to occur
Medium	60	Likely to occur as it is clear that the risk will probably eventuate
High	80	Very likely to occur, based on the circumstances of the project
Very High	100	Highly likely to occur as the circumstances which will cause this risk to eventuate are also very likely to be created

IMPACT

Title	Score	Description
Very Low	20	Insignificant impact on the project. It is not possible to measure the impact on the project as it is minimal
Low	40	Minor impact on the project, e.g. < 5% deviation in scope, scheduled end-date or project budget
Medium	60	Measurable impact on the project, e.g. 5-10% deviation in scope, scheduled end-date or project budget
High	80	Significant impact on the project, e.g. 10-25% deviation in scope, scheduled end-date or project budget
Very High	100	Major impact on the project, e.g. >25%% deviation in scope, scheduled end-date or project budget

By prioritizing likelihood and impact we have obtained the score of the risk, calculated as follows: *Priority = (Likelihood + Impact) / 2*

Priority Score	Priority Rating	Colour
0-20	Very low	Blue
21-40	Low	Green
41-60	Medium	Yellow
61-80	High	Orange
81-100	Very High	Red

By applying the scores of risks we have obtained the following results (applies only to pilots risks)

RISK	Likelihood	Impact	Priority Score	Rating
PTC-training program is too demanding	Medium	High	70	High
CTC-training program is too demanding	High	High	80	High
Two participants want to use the "public" LLM installation at the Senior Citizen Centre at the same time	Low	Low	40	Low
Participant gets injured conducting the physical training program	Low	High	60	Medium
System failure to log usage data occurs	Low	Medium	50	Medium
Users indicate to not see the benefit of the trial	Medium	High	70	High
User needs additional on site motivation	Medium	Medium	60	Medium
Recruitment of users too time demanding	Low	Low	40	Low
Delayed availability of system components for pre-pilot trials	Low	Medium	50	Medium
Logged data not sufficient for recognition of system usage / user activities	Low	High	60	Medium

6.2 Contingency Planning

!ATTENTION! ALL the pilots SHOULD BE SUMMARISE HERE IN ONE UNIQUE TABLE. I HAVE TAKEN CEIT table as the most complete -and given that E-SENIORS have use it also the same. MILTON is slightly different and shorter. For the rest of partners I do not know yet.

For any other risk outside the pilots side, please, refer to table… in page ….

Typical main categories of risk can be summarised as:

- **Physical:** loss of, or damage to, information, equipment or buildings as a result of an accident, fire or natural disaster
- **Technical:** systems that do not work or do not work well enough to deliver the anticipated benefits
- **Labour:** key people unable to contribute to the project because of, for example, illness, career change or industrial action
- **Political/social:** for example, withdrawal of support for the project as a result of change of government, a policy change by senior management, or protests from the community, the media, patients, service users or staff

- **Liability:** legal action or the threat of it because some aspect of the project is considered to be illegal or because there may be compensation claims if something goes wrong.

LLM Risk Contingency Plan, contain the suggestions –what to do- that we have considered relevant for each of the identified risk (assocciated to each task) and that must be known and assumed by all the partners, in order to prevent them to happen and if they do, know what to do to mitigate/counter fight them.

Contingencies for pilots sites can be seen in the next table:

Risk	Risk Mitigation Plan
PTC-training program is too demanding	Reduce physical effort Reduce time effort
CTC-training program is too demanding	Distribute it over time, follow advise of partners with expertise in CTC
Two participants want to use the "public" LLM installation at the Senior Citizen Centre at the same time	Every participant gets its own time slots for using the public installation; A procedure is defined how the users can modify their slot on request
Participant gets injured conducting the physical training program	None Approval by General Practitioner (GP) before starting test, inform about risk before test
System failure to log usage data occurs	Run Lab Test Define quality criteria to be met before starting pilot Use pre-pilot to gather experiences
Users indicate to not see the benefit of the trial	Try to find the reason for this opinion. Maybe the training program is not demanding enough
User needs additional on site motivation	Visit and / or talk to the participants regularly
Recruitment of users too time demanding	Start recruitment phase as early as possible
Delayed availability of system components for pre-pilot trials	Reschedule test Prepare initial time schedule with buffer time Reserve buffer time in technical work packages
Logged data not sufficient for recognition of system usage / user activities	confirm sufficient data quality during lab tests and pre pilot integrate regular supervision of logged data during pilot to discover potential problems quickly (limit the amount of missing / not sufficient data)

Besides pilots sites, for overall project risks, Contingency Plan is detailed in tables of chapter 6.

7. Glossary

Definition of all terms and acronyms required to interpret the Deployment Plan properly.

ALS	Amyotrophic lateral sclerosis
CMS	Central Management System
CTC	Cognitive Training Component
EHOME or HCU	Home Control Unit
ICT	Information and Communication Technologies
GDS	Global Deterioration Scale
ILC	Independent Living Component
LLM	Long Lasting Memories
LUI	Local Interface Unit
MCI	Mild Cognitive Impairment
MS	Multiple Sclerosis
NPI Test	Neuropsychiatric Inventory
PD	Parkinson's Disease
PTC	Physical Training Component

8. Annexes