Deliverable 3.3.2 Specification of tests and test groups

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ISISEMD

Intelligent System for Independent living and SElfcare of seniors with cognitive problems or Mild Dementia

WP3 – Specification of tests and test groups

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Short Abstract

One of the main goals of the ISISEMD project is to offer innovative ICT services to improve the quality of life of elderly persons with cognitive problems or mild dementia and their informal and formal caregivers who provide every day care for them. This will be done via integrating intelligent scalable ICT services which will be tested for a period of 12 months under realistic conditions. Offering the services could not be complete without evaluating quality of life improvement, user acceptance and user satisfaction with a representative group of the target user groups. This document is devoted to describing important aspects of services evaluation such as: who the test participants will be, inclusion and exclusion criterion, selection standards, how the test participants will be recruited, ethical considerations, etc. Test methodology, test objectives, evaluation parameters, work plan for the tests, test tasks and test scenarios are further presented.

Key Words

profiles of target user groups, planning of tests, test groups, test methodology, data collection methods, measurable indicators, rating scales, tests for cognitive decline, tests for measuring quality of life

Approvals

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Coordinator	*Kjeld B. Olesen*	*ND*	*31 Jan 2010*
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Table of Content

Section 1 - Executive summary

1.1 Description of the deliverable purpose and content

One of the main goals of the ISISEMD project is to offer innovative ICT services to improve the quality of life of elderly persons with cognitive problems or mild dementia and their caregivers who provide the daily care for them. This will be done via integrating intelligent scalable ICT services to be tested for a period of 12 months under realistic conditions with a total of 80 test volunteers in four countries in Europe – Denmark, Greece, Finland, and North Ireland. The primary user group of these services will be the elderly person with mild cognitive impairments or mild dementia who actually will be using the services, a single individual; "the well-being person". This group directly benefits from ISISEMD innovative services by increased quality of life. The secondary users will be persons or organisations being in direct contact with the primary end user, such as formal and informal care persons, family members, care organisations and their representatives. This group benefits from the scalable ISISEMD services directly, when using the services (at a primary end user's home or remotely) and indirectly, when the care needs of primary end users are reduced.

To work with a representative sample of the primary end-users, the recruitment of ISISEMD trial participants for the pilot services will follow strongly defined inclusion and exclusion criteria. The World Health Organization (2007) International Classification of Diseases (ICD-10) will be used to classify dementia type and level with the aid of the Montreal Cognitive Assessment (MoCA) to determine cognitive decline. The main inclusion criterion for the primary users is the stage of disease (level of with cognitive decline). More specifically, **adults over 60 years of age diagnosed with stage two (Age Associated Memory Impairment) to four (Mild Dementia), according to The Global Deterioration Scale (GDS), developed by Dr. Barry Reisberg.**

ISISEMD services will be offered in three-level service bundles, which are demand-driven and user-oriented. They will offer daily technological support to seniors with mild dementia in a way which increases their quality of life by allowing them to live safely and independently in their homes and decreasing social isolation. Offering the services could not be complete without their evaluation and validation. The evaluation parameters concerning the users' side are assessing cognitive functioning, quality of life improvement, user acceptance, ease of use and user satisfaction with a representative group of the three target user groups.

Test objectives will be to evaluate the effects and the efficiency of ISISEMD services, find out how success/failure is correlated with a certain group of the users, identify the most successful and most preferable service, find out which parameters are most important for user satisfaction/acceptance, and find out what should be improved in the services for future application and research.

ISISEMD will utilize the Quality of Life – Alzheimer's disease, or QOL-AD, [Logsdon, 2002] measurement tool to assess QOL improvement for primary end-users. The QOL-AD is a 13-item questionnaire designed to elicit patient and caregiver reports of patient QOL, specific to a home care situation.

Considering that informal caregivers are heavily involved in the daily care of elderly citizens with dementia, they experience substantial stress from the care giving tasks they perform. Improving QOL of informal caregivers will be measured using Glozman rating scale - Scale of Quality of Life of Care-Givers (SQLC) [Glozman, 1998]. SQLC evaluates both qualitatively and quantitatively the principal levels of the subject's activities: (a) professional activity of the care-giver, (b) social and leisure activities, (c) responsibilities of the care-giver to help the patient in everyday living. Zarit Burden Interview (ZBI) for evaluation of the care burden and Caregiver Activity Survey (CAS) for evaluation of the time spent by relative for caring for adult with mild dementia will be also used.

User acceptance, satisfaction and ease of use will be assessed utilizing a proposed method called "**Triangulation of the three methods**". The test methodology will include questionnaires, participation observations, qualitative and quantitative interviews use case description and analysis. To

assess the user acceptance and satisfaction with the use assistive technology, specifically designed ISISEMD questionnaire will be administered. It is inspired by QUEST 2.0 and ETUQ instruments, which has specific focus on daily use of assistive technology and for adults with mild dementia [Demers, 2002], [Nygård, 2002], [Rosenberg, 2009].

Validation of the services will be carried out in two stages – small-scale and large-scale validation. The services will be first tested in a smaller scale, with a few end-users at each site for 2 months, in order to identify if major problems exist before the large scale testing with all users during the rest of the testing period until end of the pilot phase of the project. To allow for iterative evaluation, there will be initial, mid-term and final assessment. The work plans for the pilots describe exactly which tests will be administered to which group of target users and at what time. Based on assessing QOL improvement from the final evaluation, cost-utility analysis for these tele-care services will be carried out.

This report is organised as follows:
Section 2 describes the profiles of the target test groups – the seniors with cognitive problems or mild dementia, the formal and informal care-givers. Section 3 presents inclusion and exclusion criteria for the test participants from the three target user groups. Section 4 describes ISISEMD services, service scenarios and the equipment to be used. Section 5 provides substantial information about conducting the tests – test methodology, test objectives, preparation of the test environment, how support to the users will be provided, written material to be presented to the test participants, interview guides for collecting user feedback, etc. The report is concluded in Section 6. In the Appendix Section, supporting materials for the trial protocol are presented.

1.2 Deviation from objectives

There is no deviation from objectives. However, the following must be noted:
The preliminary version of the document was submitted in M06 because at that stage of the project (M06) the services to be integrated in the ISISEMD system were only selected. The system was not yet integrated and installed at the pilot sites. Therefore, complete planning for the testing and preparation of the testing material could not be done in M06.
This is the final version of this report. In this final version detailed test planning was be described, such as which services will be tested in each region, tasks to be tested, test scenarios, and necessary written test material was be presented.

Specifically, the following updates were done:
Added 3.1.5.2 – information about demo rooms
In 5.3.5 – added information about CAS instrument – Caregiver Activity Survey (CAS)
Added section in 5.4.4 – information about parameters for CAS instrument
Table 6 was updated, Table 8 was updated
Added Figure 1- with indicative floor plan of equipment
Table 9 was updated, Table 13 was updated
Sect. 5.2 was updated with list of trial hypothesis
Added Sect. 3.1.8 - Forming of test and control groups by random selection
Sect. 5.9 – updated text and figure
Sect. 5.10 – new input, Sect. 5.11 – new input, Sect. 5.12 – new input, Sect. 5.13 – new input
Section 6 – conclusions was updated
New appendixes were added with testing instruments, examples of test scenarios, screen shots from user guides, Separate consent form for Outdoor Guard service was added in the appendix section.

1.3 If relevant: corrective actions

N/A

Section 2 - Description of Target User Groups

The goal of this section is to define who the target user groups of ISISEMD services are, to describe the profile of the three user groups - their everyday needs, their limitations, and to provide information about the stages of dementia for which ISISEMD services will be focused.

Home care is labour-intensive and depends on an assortment of sources to provide a variety of clinical, psychological and social services in the home setting. These providers are a combination of professional and non-professional personnel, such as volunteers, spouses, dieticians, physicians, social workers, therapists, nurses and home care assistants. Historically, home care across all European countries has relied heavily on informal care giving. The central networks of family and kin remain a uniform theme in all European welfare systems [WHO Europe, 2008]. When services and care are brought to the person so that they can continue to live in one place safely, comfortably and independently regardless of ability level, it is referred to as Aging in Place (National Aging in Place Council, 2008).

In ISISEMD project, we distinguish the following end-user groups:

- Primary end-user - the old person who actually is using service, a single individual, "the well-being person". This group directly benefits from the project by increased quality of life.

- Secondary end-users - persons or organisations directly being in contact with the primary end-user, such as formal and informal care persons, family members, friends, care organisations and their representatives. This group benefits from project directly when using the services (at a primary end-user's home or remote) and indirectly when the care needs of primary end users are reduced.

As for demand it combines requirements of primary and secondary end-users: old citizens (in general and the ones having mild dementia), the closest family members and the professional care-givers. In more details they are explained below:

- **Elderly People in general**: Generally they need an intelligent system that enables them to enjoy comfort, convenient and secure home environment. To prevent their social isolation and to help them to maintain their relations with friends and families.
- **Elderly People with mild dementia:** Most of these people have difficulty in their everyday life which sometimes comes due to cognitive problems and mild dementia. However, these people want to be independent from their relatives, to be social and generally enjoy their own life. This can be fulfilled by the smart home that facilitates their life and makes them feel secure and safe. Additionally, to stop the regression or keeping the brain status at the same level, cognitive training could help to delay their situation to become worse.
- **Closest family members (informal care-givers)** – very often the closest family members are the direct care-givers and supporters in the daily care for the clients. They would like to take care of their loved ones in a more efficient way, helping them to reduce their own burden and their own stress. They would also like to enjoy their life and maintain their social network.
- **Professional care-givers**: They want at any time to have overview of their client's conditions. To be able to send them simple instructions, reminders and alarms.

Based on these main user groups, the test groups with which the functionality of the scalable services will be evaluated and validated are divided in test groups.
The test groups will be

- Test group EP - of primary end users – elderly people with cognitive problems or mild dementia, as well as normal elderly people
- Test group ICG - of secondary end users – informal care givers. This includes closes family members who take care of the senior

- Test group FCG - of secondary end users – formal care givers. This test group includes home care personnel and specialised dementia care giver personnel

2.1 What is dementia?

In ISISEMD Del 1.1.1 "User & System Requirements" and Del 1.1.2 "User & System Requirements updated version", detailed definition for dementia is presented. The main stages of dementia for which ISISEMD services will be offered, have been described. In this section, for the sake of completeness, we briefly revisit them again.

Dementia is not a specific disorder or disease. It is a syndrome (group of symptoms) associated with a progressive loss of memory and other intellectual functions that is serious enough to interfere with performing the tasks of daily life. Dementia can occur to anyone at any age from an injury or from oxygen deprivation, although it is most commonly associated with aging. It is the leading cause of institutionalization of older adults. Dementia is an overall decline in intellectual function, including difficulties with language, simple calculations, planning and judgment, and motor (muscular movement) skills as well as loss of memory.

According to the World Health Organization's International Classification of Diseases (http://apps.who.int/classifications/apps/icd/icd10online/), ICD-10, DEMENTIA is evidence of each of the following, each of them characterised with a number of stages:

(1) G1 - **A decline in memory**, which is most evident in the learning of new information, although in more severe cases, the recall of previously learned information may be also affected. The impairment applies to both verbal and non-verbal material.
(2) G2 - **A decline in other cognitive abilities** characterized by deterioration in judgement and thinking, such as planning and organizing, and in the general processing of information
(3) G3. A decline in emotional control or motivation, or a change in social behaviour, manifest as at least one of the following:
    (1) emotional ability;
    (2) irritability;
    (3) apathy;
    (4) coarsening of social behaviour.
(1) G4. For a confident clinical diagnosis, G1 should have been present for at least six months; if the period since the manifest onset is shorter, the diagnosis can only be tentative.

Dementia can be caused by nearly forty different diseases and conditions, ranging from dietary deficiencies and metabolic disorders to head injuries and inherited diseases.
One of the categorisations of dementia is Primary dementia. These dementias are characterized by damage to or wasting away of the brain tissue itself. They include Alzheimer's disease (AD), frontal lobe dementia (FLD), and Pick's disease.

The information for dementia is found in http://www.who.int/classifications/icd/en/GRNBOOK.pdf. Dementia definition starts on page 45 of document, below is pasted from document.

Very general, the severity of the decline is defined as follows:

G1. Evidence of each of the following:

(1) **A decline in memory,** which is most evident in the learning of new information, although in more severe cases, the recall of previously learned information may be also affected. The impairment applies to both verbal and non-verbal material. The decline should be objectively verified by obtaining a reliable history from an informant, supplemented, if possible, by neuropsychological tests or

quantified cognitive assessments. The severity of the decline, with mild impairment as the threshold for diagnosis, should be assessed as follows:

Mild: a degree of memory loss sufficient to interfere with everyday activities, though not so severe as to be incompatible with independent living (see comment on cultural aspects of "independent living" on page 24). The main function affected is the learning of new material. For example, the individual has difficulty in registering, storing and recalling elements in daily living, such as where belongings have been put, social arrangements, or information recently imparted by family members.
Moderate: A degree of memory loss which represents a serious handicap to independent living. Only highly learned or very familiar material is retained. New information is retained only occasionally and very briefly. The individual is unable to recall basic information about where he lives, what he has recently been doing, or the names of familiar persons.
Severe: a degree of memory loss characterized by the complete inability to retain new information. Only fragments of previously learned information remain. The subject fails to recognize even close relatives.

(2) A **decline in other cognitive abilities** characterized by deterioration in judgement and thinking, such as planning and organizing, and in the general processing of information. Evidence for this should be obtained when possible from interviewing an informant, supplemented, if possible, by neuropsychological tests or quantified objective assessments. Deterioration from a previously higher level of performance should be established. The severity of the decline, with mild impairment as the threshold for diagnosis, should be assessed as follows:

Mild. The decline in cognitive abilities causes impaired performance in daily living, but not to a degree making the individual dependent on others. More complicated daily tasks or recreational activities cannot be undertaken.
Moderate. The decline in cognitive abilities makes the individual unable to function without the assistance of another in daily living, including shopping and handling money. Within the home, only simple chores are preserved. Activities are increasingly restricted and poorly sustained.
Severe. The decline is characterized by an absence, or virtual absence, of intelligible ideation.
The overall severity of the dementia is best expressed as the level of decline in memory or other cognitive abilities, whichever is the more severe (e.g. mild decline in memory and moderate decline in cognitive abilities indicate a dementia of moderate severity).

Dementia is specified here as having a minimum duration of six months to avoid confusion with reversible states with identical behavioural syndromes, such as traumatic subdural haemorrhage (S06.5), normal pressure hydrocephalus (G91.2) and diffuse or focal brain injury (S06.2 and S06.3).

In ICD-10, dementia is classified under
F00-F09 - Organic, including symptomatic, mental disorders

There are many different types of dementia, presented below:
F00 Dementia in Alzheimer's disease
F01Vascular dementia
F02Dementia in other diseases classified elsewhere
F03Unspecified dementia
F04Organic amnesic syndrome, not induced by alcohol and other psychoactive substances
F05Delirium, not induced by alcohol and other psychoactive substances
F06Other mental disorders due to brain damage and dysfunction and to physical disease
F07Personality and behavioural disorders due to brain disease, damage and dysfunction
F09Unspecified organic or symptomatic mental disorder

Additionally,
F06.7Mild cognitive disorder

The main feature is a decline in cognitive performance. This may include memory impairment, learning or concentration difficulties. Objective tests usually indicate abnormality. The symptoms are such that a diagnosis of dementia (F00-F03), organic amnesic syndrome (F04) or delirium (F05.-) **cannot be made**.

One important thing to be kept in mind for the services offered by ISISEMD to elderly with mild dementia is:

- Each person with dementia is a unique individual with their own individual experiences of life, their own needs and feelings, and their own likes and dislikes.
- Although some symptoms of dementia are common, dementia affects each person in different ways.

These two very important specifics of the dementia lead to very challenging work for the ISISEMD partners w.r.t. the offered services, their acceptance, testing and evaluation.

2.1.1 Symptoms of cognitive problems or mild dementia

In regard to the Primary End User Group, the major symptoms of dementia are:

- Weak memory (forget to eat, drink, take medicine, forget appointments, etc.)
- Difficulty performing well-known tasks
- Difficulty creating the structure of the day
- Confusion
- Difficulty concentrating
- Reduced speaking ability
- Disorientation for time and place
- Problems with abstract thinking
- Reduced or poor ability to judge
- Reduced ability to understand numbers and to calculate
- Reduced ability to understand senses and feelings
- Change in mood and behaviour
- Changed personality and feelings
- Reduced own initiative

2.1.2 Difficulties experienced by persons with cognitive problems or mild dementia in daily living

The following is based on input from the [Dementia North, 2008]. Problems/ difficulties which elderly with cognitive problems or mild dementia experience very often depending on the stage of the illness:

- Increasingly unstable short-term memory
- Forget to take medicine (which prescription, amount and time schedule)
- Forget appointments
- Forget the names of well-known people
- Forget what they are looking for
- Forget wallet when going shopping
- Forget what to purchase
- Difficulty maintaining tasks and structure of the day
- Disorientation for time (day, month, time of the day)
- Disorientation for place
- Inability to prepare meals and remember when to eat
- Decreased personal hygiene
- Difficulties to unlock the door when returning home
- Difficulties dressing in clothes (how to dress as well as appropriateness)
- Difficulties reading and judging time

- Difficulties using a normal telephone Mismanagement of finances
- Forget kitchen equipment switched on
- Forget past events, details, birthdays
- Difficulties for orientation in unknown places
- Socially isolated because of their illness
- Forget keys for the home before going out
- Difficulties managing appointments on their own
- Difficulty reading and comprehending

In the following subsections, more details for the profile of the user groups are presented.

2.2 Profile of Primary end user group

Some preliminary ideas for the profile of the user groups have been drafted in Description of Work. They are presented in the Table 1 below:

Table 1: General user profiles for the three test groups

Range of User Profile	Group end-users (EP)	Group of informal caregivers (ICG)	Group of formal caregivers (FCG)
Gender	Both genders; preferably 50% females	Both genders; statistically female	Statistically female
Age	60-90 years old	Adults over 18 years old. However, two main age groups: • 60-90 years old (if partner) • 18-45 years old (if children or grand children)	No limitation, usually 20 – 50 years old
Cognitive decline	Dementia stage 2-4	No	No
Health needs	Very often have another chronic disease	Some of them may also have health needs	N/A
Care needs	- General older adult needs - elderly subjects with mild dementia The care needs – - self-care - medication self-management - meals self-management - activity reminders - needs to feel safety at home - social needs	Some of them may also have care needs	N/A
Needed type of service/ technology	- Self-care - Home safety - Cognitive training (reminders) - Medication self-management - Communication with care-givers - Social interaction	-unobtrusive monitoring - 2 way Notification service - 2 way Communication service - location notification service - emergency notification service	- unobtrusive monitoring - 2 way Notification service; - 2 way Communication service - emergency notification service - location notification service (if permission

			is given by the elderly) - re-planning of tasks service
Use of technology	In most of the cases - Not very used with everyday communication via internet and , - No computer literacy - Not very used with mobile phones - Primary means of communication is a fixed line telephone	Depending on the age – - Either like EP - Or like FCG	Everyday use of - Desktop Computer - Internet - Mobile phones - PDA

2.3 Profile of Secondary user group – informal caregivers ICG

Informal care giving by family and friends serves as the backbone for long-term care. For individuals whose conditions have resulted in chronic illness or disability, access to help with daily activities such as meal preparation, bathing or transportation involves a considerable amount of time, devotion, perseverance and patience. ICG are usually female, family members between the ages of 45 and 65, without gainful employment (or with part-time employment) and lower educational and socioeconomic levels [Carretero, 2008]. The most common ICG is a middle-aged daughter caring for an aging parent; second most common is elderly wives providing assistance to husbands [WHO Europe, 2008].
Care giving is normally delivered in the residence of the dependent person on a continual, intense, daily basis ranging from personal safety to psychological support. Total hours of care giving per week can easily exceed national standards for full-time employment. Assistance is generally provided by a single caregiver and responsibility often lasts for years, with approximate average at 5 years [Family Caregiver, 2001].
The majority of informal care burdens fall upon these persons who do not possess any formal training about care and who do not receive any economic retribution for these tasks. As individuals or as a society, we cannot afford to pay the costs that informal care giving relieves from paid, formal personnel. Socially speaking, ICG often go unnoticed except by those who depend on their care; the recipients of informal care giving understand how important their caregiver's efforts are to their well-being and that these contributions are invaluable. Due to the chronic nature and indeterminate end point that care giving entails, it has been linked to negative trends in physical, psychological and social well-being of the ICG [Carretero, 2008]. Considering this, informal care has been conceptualized as a critical stress factor, now referred to as **caregiver burden**.

In the Table 1 above, the group of informal caregivers has been described as both genders, age – from 40-75 years, some of them might also have specific health needs or care needs.
Here we extend the description of the informal care-givers since we expect that there will be a substantial difference towards ISISEMD services depending on the generation shift and the ability to use new technology. This is reflected in the Table 2 below.

ICG could be characterised as two subgroups –

- **ICG-partners** - the group of the elderly partner who lives with the patient and is not very accustomed to use technology and usually provides care for ADLs
- **ICG-children** - the group of the middle-aged children or young grandchildren who also provide care to the patient but with different types of tasks, usually related to IADLs

Table 2: Profile of informal caregivers (ICG)

Range of User Profile	Group of informal caregivers
Gender	Both genders;
Age of ICG-partners	60 - 80 years old
Age of ICG-children - middle-aged children or grandchildren	20-60 years old
Health needs of ICG-partners	Some of them may also have health needs or some long-term conditions as hearing, seeing impairments or have chronicle illness
Care needs of ICG-partners	Some of them may also have care needs
Use of technology – ICG-partners	It is not very common to have knowledge about use of computers. It is expected that some of them have and use a mobile phone on daily basis. It is to be expected that all of them are very familiar with use of a stationary telephone.
Use of technology - ICG-children	It is very common to have knowledge about use of computers and use of internet portals, social internet networks, etc. It is expected that most of them have and use a mobile phone on daily basis. It is to be expected that all of them are very familiar with use of a stationary telephone.
Needed type of service (in a very general aspect)	- unobtrusive monitoring of the EP - 2 way notification service - 2 way communication service - location notification service - emergency notification service

2.4 Profile of Secondary user group – formal caregivers FCG

Throughout Europe, many resources are available to support families caring for an older adult, one being the availability of formal caregivers. These are paid individuals who are employed full-time or part-time, through an agency or hired privately and can provide physical assistance and care to older, dependent adults. Formal caregivers are statistically female, middle aged and have a formal education. They have experience in working with dementia or general with elderly clients, work well independently and can prioritize tasks efficiently, are open, interested and responsible for their work, set interdisciplinary cooperation and responsibilities high and enjoy direct patient contact.

There are different types of formal caregivers, depending on the level of services needed. Examples of formal caregivers for in home care are:

House workers – perform basic household duties such as cleaning, cooking, household management, some personal care and medication reminding.

Home Health Aides, Certified Nurse Assistants (CNA) and Nurses Aides – often referred to as *Home Health Care Workers*; provide a broad range of services consisting of assisting with therapy, personal care, hygiene, transferring, physical exercise, medication administration and many aides have additional special training and qualifications. These FCG will typically visit the patient more frequently than others.

Registered Nurses (RN), Licensed Practical Nurses (LPN) and Therapists – often referred to as *Skilled Nursing Care*; nurses represent the largest group of professional caregivers (WHO Europe, 2008). Nurses evaluate patients, develop care plans, provide skilled nursing care, determine whether services are functional and perform duties that cannot be safely performed by other (nonprofessional) care

personnel such as wide-ranging medical care (IV injections, tube feeding and cleaning and dressing memoir wounds. Physical (PT), occupational (OT) or speech therapists (SP) evaluate therapy needs, develop care and rehabilitation plans, assess the home and environment and monitor domain status.

Social Workers and Geriatric Case Managers – often grouped together as *Social Care Workers*; support patients, families and caregivers in finding and receiving access to assistance, navigating bureaucracy and financial difficulties, utilizing community and social care programs and providing further recommendations for care.

Their daily tasks of more specialised FCG staff usually involve:

- Participation in searches, determination and diagnosis of patients
- Guide for patients and caregivers on dementia diseases, treatment and psychosocial support
- Follow-up of patients in dementia clinic after diagnosis
- Provide communication to municipality dementia coordinators
- Contribute to a healthy, coherent patient
- Participate in dementia clinic other clinical work (e.g. assist in lumbar puncture)
- Participate in training to relatives of diagnosed patients

Conclusion for Section 2

This section was devoted to describing the specifics of dementia as illness and the general profile of the main end-user groups of ISISEMD services – the elderly persons (EP), the informal caregivers (ICG) and the formal caregivers (FCG). Due to dementia, EP have decline in memory or in other cognitive ability. Depending on the stage progressing of the illness, they have difficulties to live independently or cannot live independently. It is expected that they have very limited knowledge about using new technology and it will be difficult for them to learn to use it if the illness has progressed. ICG are split in two subgroups- the ICG-partners and ICG-children. ICG-partners are statically females and do not have very good knowledge for the new technology either and which burden t o care for their ill partner causes a lot of stress and social isolation. ICG-children are usually middle-aged and statistically females too, who is expected to use technology on a daily basis.
FCG are generally females with formal education in care for seniors or in care for dementia patient. It is expected that they use PC, mobile phone, etc in their professional tasks.

Section 3 - Criteria for recruiting the test participants

This section describes how the test participants will be approached and found, which inclusion/exclusion criteria will be used to find the trial participants for the three user groups. Classification standard for dementia will be presented together with rating scales for assessment of cognitive decline. The process of selection of test participants will be described and description of the test samples will be presented.

Since the study is designed to examine technology as a non-pharmaceutical intervention within the home, the ISISEMD consortium agrees that participant samples will include only people who live in their home and who have mild cognitive impairments (MCI) to moderate cognitive decline. Detailed below are conditions regarding all user groups, inclusion and exclusion criteria and selection standards.

3.1 For Primary User Group (EP)

The ISISEMD project is to offer and test services for elderly with cognitive problems or mild dementia with a goal of increasing quality of life. The World Health Organization (2007) International Classification of Diseases (ICD-10) will be used to classify dementia type and level with the aid of the Montreal Cognitive Assessment (MoCA) to determine cognitive decline (*see Section 3.1.2 for description*). Within this framework, the stages correspond to the widely used concepts of mild, moderate, moderately severe and severe dementia. It also gives information as to which stages fall within the more general divisions of early-stage, mid-stage and late-stage categories.

3.1.1 Classification standard for stages of dementia

This subsections presents which classification standard is taken into account for the stages of dementia.

According to The World Health Organization (2007) International Classification of Diseases (ICD-10), dementia is a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgment. Consciousness is not clouded. Impairments of cognitive function are commonly accompanied, and occasionally preceded, by deterioration in emotional control, social behaviour, or motivation. This syndrome occurs in Alzheimer's disease, in cerebrovascular disease, and in other conditions primarily or secondarily affecting the brain.

Dementia produces an appreciable decline in intellectual functioning, and usually some interference with personal activities of daily living, such as washing, dressing, eating, personal hygiene, excretory and toilet activities. How such a decline manifests itself will depend largely on the social and cultural setting in which the patient lives. Changes in role performance, such as lowered ability to keep or find a job, should not be used as criteria of dementia because of the large cross-cultural differences that exist in what is appropriate, and because there may be frequent, externally imposed changes in the availability of work within a particular culture.

The primary requirement for diagnosis is demonstration of a decline in both memory and thinking, sufficient enough to impair personal activities of daily living (ADLs). The impairment of memory typically affects the registration, storage, and retrieval of new information and previously learned and familiar material may also be lost, particularly in the later stages. Dementia is also impairment of thinking and of reasoning capacity, and a reduction in the flow of ideas. The processing of incoming information is marred, and the individual finds it increasingly difficult to focus on more than one stimulus at a time (ICD-10).

A characteristic of normal cognitive aging is the large inter-individual variance in performance [Bäckman, 2003]. Although one participant may have a clinical diagnosis of mild dementia, it is entirely possible that their functioning status is lower than that of another participant measured at moderate. Despite cognitive deficits being observed years before a clinical diagnosis, empirical evidence is unclear regarding the distinctive point from which cognitive impairments become a syndrome or disease.

Stages of Dementia

The Global Deterioration Scale (GDS), developed by Dr. Barry Reisberg, who is Clinical Director of the New York University School of Medicine's Silberstein Aging and Dementia Research Center, provides caregivers an overview of the stages of cognitive function for those suffering from a primary degenerative dementia such as Alzheimer's disease. It is broken down into 7 different stages. **Stages 1-3 are the pre-dementia stages. Stages 4-7 are the dementia stages. Beginning in stage 5, an individual can no longer survive without assistance.** Within the GDS, each stage is numbered (1-7), given a short title (i.e., Forgetfulness, Early Confusional, etc followed by a brief listing of the characteristics for that stage. Caregivers can get a rough idea of where an individual is at in the disease process by observing that individual's behavioural characteristics and comparing them to the GDS. (From geriatric- resources)

The GDS for Assessment of Primary Degenerative Dementia:

Level 1 - NO COGNATIVE DECLINE: No subjective complaints of memory deficit. No memory deficit evident on clinical interview.

Level 2 - VERY MILD COGNATIVE DECLINE (Age Associated Memory Impairment): Subjective complaints of memory deficit, most frequently in following areas: (a) forgetting where one has placed familiar objects; (b) forgetting names one formerly knew well. No objective evidence of memory deficit on clinical interview. No objective deficits in employment or social situations. Appropriate concern with respect to symptopathology.

Level 3 - MILD COGNATIVE DECLINE (Mild Cognitive Impairment): Earliest clear-cut deficits. Manifestations in more than one of the following areas: (a) patient may have gotten lost when travelling to an unfamiliar location; (b) co-workers become aware of patient's relatively poor performance; (c) word and name finding deficit becomes evident to intimates; (d) patient may read a passage or a book and retain relatively little material; (e) patient may demonstrate decreased facility in remembering names upon introduction to new people; (f) patient may have lost or misplaced an object of value; (g) concentration deficit may be evident on clinical testing. Objective evidence of memory deficit obtained only with an intensive interview. Decreased performance in demanding employment and social settings. Denial begins to become manifest in patient. Mild to moderate anxiety accompanies symptoms.

Level 4 - MODERATE COGNITIVE DECLINE (Mild Dementia): Clear-cut deficit on careful clinical interview. Deficit manifest in following areas: (a) decreased knowledge of current and recent events; (b) may exhibit some deficit in memory of one's personal history; (c) concentration deficit elicited on serial subtractions; (d) decreased ability to travel, handle finances, etc. Frequently no deficit in following areas: (a) orientation to time and place; (b) recognition of familiar persons and faces; (c) ability to travel to familiar locations. Inability to perform complex tasks. Denial is dominant defence mechanism. Flattening of affect and withdrawal from challenging situations frequently occur.

Level 5 - MODERATELY SEVERE COGNITIVE DECLINE (Moderate Dementia): Patient can no longer survive without some assistance. Patient is unable during interview to recall a major relevant aspect of their current lives, e.g., an address or telephone number of many years, the names of close family members (such as grandchildren), the name of the high school or college from which they

graduated. Frequently some disorientation to time (date, day of week, season, etc.) or to place. An educated person may have difficulty counting back from 40 by 4s or from 20 by 2s. Persons at this stage retain knowledge of many major facts regarding themselves and others. They invariably know their own names and generally know their spouses' and children's names. They require no assistance with toileting and eating, but may have some difficulty choosing the proper clothing to wear.

Level 6 - SEVERE COGNITIVE DECLINE (Moderately Severe Dementia): May occasionally forget the name of the spouse upon whom they are entirely dependent for survival. Will be largely unaware of all recent events and experiences in their lives. Retain some knowledge of their past lives but this is very sketchy. Generally unaware of their surroundings, the year, the season, etc. May have difficulty counting from 10, both backward and, sometimes, forward. Will require some assistance with activities of daily living, e.g., may become incontinent, will require travel assistance but occasionally will be able to travel to familiar locations. Diurnal rhythm frequently disturbed. Almost always recall their own name. Frequently continue to be able to distinguish familiar from unfamiliar persons in their environment. Personality and emotional changes occur. These are quite variable and include: (a) delusional behaviour, e.g., patients may accuse their spouse of being an impostor, may talk to imaginary figures in the environment, or to their own reflection in the mirror; (b) obsessive symptoms, e.g., person may continually repeat simple cleaning activities; (c) anxiety symptoms, agitation, and even previously nonexistent violent behaviour may occur; (d) cognitive abulla, i.e., loss of willpower because an individual cannot carry a thought long enough to determine a purposeful course of action.

Level 7 - VERY SEVERE COGNITIVE DECLINE (Severe Dementia): All verbal abilities are lost over the course of this stage. Frequently there is no speech at all -only unintelligible utterances and rare emergence of seemingly forgotten words and phrases. Incontinent of urine, requires assistance toileting and feeding. Basic psychomotor skills, e.g., ability to walk, are lost with the progression of this stage. The brain appears to no longer be able to tell the body what to do. Generalized rigidity and developmental neurologic reflexes are frequently present.

The target primary end-user group of ISISEMD services will be elderly persons with dementia 2-4 stage and partially 5 stage, since some of 4 stage subjects, in 12-month duration of the test project periods, might progress to stage 5. The trial participants will be classified according to the above presented standard for stages of dementia.

Functional Assessment

Since dementia is related to functional decline, below a simplified checklist version of the seven dementia stages is presented in the **Functional Assessment Staging Test (FAST).**

Note that stages 6 and 7 are broken down into smaller steps.

1 No difficulties, either subjectively or objectively
2 Complains of forgetting location of objects; subjective word finding difficulties only.
3 Decreased job functioning evident to co-workers; difficulty in travelling to new locations.
4 Decreased ability to perform complex tasks (e.g., planning dinner for guests; handling finances; marketing).
5 Requires assistance in choosing proper clothing for the season or occasion.
6a Difficulty putting clothing on properly without assistance.
6b Unable to bathe properly; may develop fear of bathing. Will usually require assistance adjusting bath water temperature.
6c Inability to handle mechanics of toileting (i.e., forgets to flush; doesn't wipe properly).
6d Urinary incontinence, occasional or more frequent.
6e Faecal incontinence, occasional or more frequent.
7a Ability to speak limited to about half a dozen words in an average day.
7b intelligible vocabulary limited to a single word in an average day.
7c Nonambulatory (unable to walk without assistance).

7d Unable to sit up independently.
7e Unable to smile.
7f Unable to hold head up.

Since very often when dementia is diagnosed, it is from type of Alzheimer disease, to avoid misunderstanding, below we present the mapping between the dementia stages and the Alzheimer stages. More information could be obtained from the website of the Alzheimer organization http://www.alz.org/alzheimers_disease_stages_of_alzheimers.asp.

Table 3: Mapping between the dementia stages and the Alzheimer stages

Stage	Cognitive decline	Dementia	Alzheimer's disease
Stage 1:	No impairment (normal function)		
Stage 2:	Very mild cognitive decline	Age Associated Memory Impairment	May be normal age-related changes or earliest signs of Alzheimer's disease
Stage 3:	Mild cognitive decline	Mild Cognitive Impairment (MCI)	Early-stage Alzheimer's can be diagnosed in some, but not all, individuals with these symptoms
Stage 4:	Moderate cognitive decline	Mild Dementia	Mild or early-stage Alzheimer's disease
Stage 5:	Moderately severe cognitive decline	Moderate Dementia	Moderate or mid-stage Alzheimer's disease
Stage 6:	Severe cognitive decline	Moderately Severe Dementia	Moderately severe or mid-stage Alzheimer's disease
Stage 7:	Very severe cognitive decline	Severe Dementia	Severe or late-stage Alzheimer's disease

Disabilities to be covered by the project as described in the WHO ICF Classification

Since ISISEMD services are is closely related to ADL and IADL, which on their side are linked to some disabilities. The objectives of ISISEMD can be explained in *the context of improving functional status and improving the impact of the environment on the person's functioning (improving the social aspects of disability)* as outlined in The International Classification of Functioning, Disability and Health (ICF).

The International Classification of Functioning, Disability and Health (ICF), known more commonly as ICF, are a classification of health and health-related domains. These domains are classified from body, individual and societal perspectives by means of two lists: a list of body functions and structure, and a list of domains of activity and participation. Since an individual's functioning and disability occurs in a context, the ICF also includes a list of environmental factors.
The ICF is WHO's framework for measuring health and disability at both individual and population levels. (http://www.who.int/classifications/icf/en/)

d ACTIVITIES AND PARTICIPATION
d199 Learning and applying knowledge, unspecified
d598 Self-care, other specified
d599 Self-care, unspecified

d630-d649 Household tasks
d699 Domestic life, unspecified

e1 PRODUCTS AND TECHNOLOGY
e115 Products and technology for personal use in daily living
e125 Products and technology for communication

e3 SUPPORT AND RELATIONSHIPS
e310 Immediate family
e355 Health professionals

e5 SERVICES, SYSTEMS AND POLICIES
e5750 general social support services
e580 Health services, systems and policies

3.1.2 Tools for cognitive assessment

This subsection will present two standard tools for cognitive assessment (MoCA and MMSE) and their comparison.
IMMSE and MoCA stands for Mini Mental State Exam and Montreal Cognitive Assessment respectively. These are standard rating scales questionnaires for assessing stage of cognitive decline. MMSE has been created in 1975. It is 30-pt questionnaire and is administered for 15 Minutes. MoCA has been created in 2005. It is 12-section interactive questionnaire/interview (patients not only answer questions, but have to draw, recall, think abstractly and draw and is administered in about 10 minutes.
The specific is that they must be administered by specially trained staff from the care-provider organisation for this type of questionnaires. The general training is to ensure that during the interview, the interviewer reduces interviewer influence and do not influence the patients' answers with body language, voice, etc.
The main difference is that MoCA is useful for the mild stages of the cognitive impairment spectrum (including MCI and mild AD), and the MMSE is superior for more-advanced stages (AD patients with more significant functional impairment). There are currently no other screening tools to quickly and reliably distinguish MCI from normal controls.

3.1.2.1 Mini Mental State Exam (MMSE)

The MMSE [http://www.minimental.com/], or Folstein test, [Folstein, 1975] is a 30-point questionnaire used to screen for cognitive impairment with lower scores suggestive of greater impairment. MMSE is owned by Psychological Assessment Resources (PAR) and official versions must be ordered through PAR, although many free versions are available on the Internet. Taking less than 15 minutes, MMSE assess functions including arithmetic, memory, repeating lists of words, language, comprehension, basic motor skills and orientation. The maximum score on the Mini Mental State Exam is 30.

As it is written in MMSE guidelines, in general, scores fall into four categories:
24 – 30: "normal" range
20 – 23: mild cognitive impairment or possible early-stage/mild Alzheimer's disease
10 – 19: middle-stage/moderate Alzheimer's disease
0 – 9: late-stage/severe Alzheimer's disease

After 1975 trials and studies have adjusted scores from the initial mapping, MMSE is not as sensitive as the developers first thought it was in 1975. The updated mapping is the following:
27-30: no impairment
20-26: mild cognitive impairment

10-19: moderate to severe impairment
0-10: severe impairment

MMSE is currently a widely used as assessment tool by all end-user partners in Denmark, Greece, North Ireland and Finland. Due to its high acceptability but low sensitivity (18%) and specificity, MMSE will be used as a secondary cognitive assessment tool.
For the next version of this report the partners will take decision which mapping will be used in ISISEMD.

3.1.2.2 Montreal Cognitive Assessment (MoCA)

The Montreal Cognitive Assessment, or MoCA, [Nasreddine, 2005] was designed as a short screening instrument for mild cognitive impairments where participants not only answer questions, but have to draw, recall and think abstractly. It assesses 8 different cognitive domains, including attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. The time to administer MoCA is approximately 10 minutes with a total possible score is 30 points. A score of 26 or above is considered normal, so ISISEMD will be using a cut-off point of $\geq$25. MoCA has been evaluated as being easy to use (by both interviewers and interviewees) for any health/social care professional to administer [Olson, 2008]. The measurement consists of interactive tasks such as copying figures, naming objects, repeating words and drawing a clock. The test can be used free of charge and is standardized in 26 languages (www.mocatest.org).

MoCA is useful for assessing milder stages of cognitive impairment, including MCI and mild Alzheimer Disease (AD) where there are currently no other screening tools as quick and accurate to distinguish Mild Cognitive Impairments from healthy controls (90% sensitivity). Due to its high specificity and sensitivity in detecting MCI, MoCA will be used as the primary cognitive assessment tool in determining level of cognitive functioning and changes over the course of the clinical trials.

3.1.2.3 Comparison among MMSE and MoCA rating scales

The MMSE is the most commonly used cognitive screening, but is not most accepted for its sensitivity. MMSE is best suited for distinguishing gross cognitive impairment, but not for detecting damage to abstract reasoning, executive functioning, and visual perception, which MoCA is. MoCA has been shown to have a lesser completion time (by 5 minutes) and 50% more sensitivity towards cognitive impairments. Conclusions are that it is well tolerated, accurate, and provides additional information over the MMSE [Olson, 2008]. Additionally, MoCA is available in over 25 languages via free internet download, without restrictions, and can be administered by any member of the care team. Currently MoCA is translated into the four languages of the end-user partners (English, Danish, Greek, and Finish).
Measuring the level of cognitive impairment in dementia is essential to clinical trials testing assistance and interventions. In order to produce the most accurate results, as well as gain valuable scientific data, a combination of both tests could be used. MoCA scores will be the primary assessment (for determining cognitive functioning to provide services) but both tests will provide useful information. Where available, MMSE could be administered as well. Administration suggestion to those reasons is that tests are randomly administered within the same interview (second test is administered within a few hours of the first, but can be in either order and randomized to end users).

3.1.2.4 Need for Standardisation

For assessment tools to be validated and widely applicable, they need to be translated and standardized depending on the country of use. This entails not only translating the language used in the tool, but adjusting the wording used to create the same level of meaning. Additionally, interviewers (the person administering the assessment) can influence results and should be trained (or at least familiarized) as

to how their choice of words, body language, tone of voice, patience, and other non-verbals can influence the person answering questions. This is especially true in longer assessments. Fortunately, the care personnel from the regional partners that already have access to and use MMSE will have already been trained. As MoCA is shorter and easier to administer (designed to be administered by any member of the care team) and most interviewers have had training with MMSE, there are no foreseeable difficulties in using. Since at the time when ISISEMS partners started discussion about the cognitive assessment tools, translation in Finish was not available, the partners contacted the developer of MoCA, Dr Z. Nasreddine. Per our request, the developer published finish version of MoCA and recommendations/guidelines for translation and standardization.

In the discussion process for the identification of suitable classification standards and standard screening tools for cognitive assessment and quality of life questionnaires, ISISEMD partners consulted national experts and initiated close fruitful cooperation with representatives from their national Alzheimer Associations. The list of contacts is presented below:

Denmark
Kasper Jørgensen
Neuropsykologisk fagkonsulent
Nationalt Videnscenter for Demens Rigshospitalet,
afsnit 7661
Blegdamsvej 9,
2100 København Ø
www.videnscenterfordemens.dk

For the Ethical application itself for the pilot trial in Denmark, the following expert has been associated as a scientific responsible for the trial:
Anne Stubbe Arndal
Doctor, National leader for Alzheimer association in Denmark

North Ireland
Dr David Craig and Dr Ben Knapp
from Memory Clinic based at the Belfast City Hospital (BCH)
The clinic is led by the consultants in elderly care who hold Senior Lectureships at the Queen's University of Belfast.
Dr David Craig and Dr Ben Knapp are also involved in other European projects such as COGKNOW (STREP project with focus on mild dementia persons), Netwell (under INTERREG programme), CAPSIL (Support Action project).

Finland
Professor Olli-Pekka Ryynänen
University of Kuopio
Leading researcher of QOL testing in Finland.

Greece
Ms Sakka and Ms Areti Efthymiou who is Chairwoman of Athens Association of Alzheimer's Disease. They will become external scientific advisors of the partner from Trikala for the project.

3.1.3 Main inclusion/exclusion criteria for primary end-user group (EP)

Inclusion criteria:

- Age – above 60 years
- Diagnosed with dementia - diagnose system ICD-10 will be used. Para-clinical data which will be used to make the diagnosis is cognitive screening tests.

- Dementia stages 2 to stage 4 according to GDS (Dr. Barry Reisberg scale), corresponding to MoCA or MMSE scores 19-26.
- Lives in own home; could be supported by home care
- The dementia diagnoses and stage is defined by a specialist (neurologist, geriatric specialist, etc.)
- Can self understand and give consent to participate in the project trial
- Have a close relative which is willing to help for the participation to the project trials
- Open to use new technology in the everyday life

Elderly participants with the following conditions will be excluded from the test group:

Exclusion criteria:

- Malignant illness
- Psychological conditions with symptoms which could be wrongly assumed to be dementia, especially depression and delirium
- Present misuse of alcohol or medicine – patients with heavy behaviour disorders and psychotically symptoms – for them participation to the project trial will be difficult
- Participants with dementia which is in the frontal part of the brain since the persons with this type of dementia develop sometimes paranoid symptoms and could be aggressive
- Participants with stage of dementia higher than 5 (moderate and severe dementia) classified according to GDS
- Dementia secondary to head trauma
- Participants whose dementia is reversible (nutrition deficiencies)
- Participants with psychological long-term conditions, for example schizophrenia or depression
- Participants under active treatment (chemotherapy, radiation therapy) for cancer or other terminal diagnosis
- Bedbound (confined to a bed or chair for 20 hours a day for 4 out of 7 days)
- More than three acute medical hospitalizations in the past year (other than dementia related admission)
- Planned long term care admission in 6 months

These main inclusion/exclusion criteria have been consulted with Bodil Gramkow, chief physician at Department of Psychological and Gerontology in Brønderslev, Denmark and Kasper Jørgensen from National Knowledge Center for Dementia in Denmark.

3.1.4 Secondary inclusion/exclusion criteria

The project aims to introduce ICT services to senior citizens and at the same time it is observed very often some kind of conservatism and resistance to new technology among them. Therefore a secondary inclusion criterion for the EP could be that the person is accustomed to use modern communication such as mobile phone, eventually computer. Even having a PC at home would be an additional advantage.

Because of some cultural differences, both elderly living alone and with a partner will be involved. The aim is to have 50% representation of both groups. Also, both genders will be represented. It is a general trend that in almost all European countries women live longer. Therefore, when recruiting the test subjects, the goal will be to involve at least 50% women.

Due to matters related to budget limitations and costs per pilot, secondary exclusion criteria for the persons from the test group will be

- Participants living in big homes (due to the limitation to buy and install many sensors in their homes)
- Participants who do not have Internet access or for whom there is no possibly to provide such

3.1.5 Selection process

3.1.5.1 Channels to find potential test participants

Potential participants will be recruited with the help of general and nurse practitioners, aging and cognition specialists, memory and dementia clinics and national and local organizations for aging programs and services. Fliers will be posted in their buildings; presentations will take place at caregiver education and support groups, and staff communication with potential participants and information in local news media that describe the project. In this dissemination material, the contact details of the responsible person for the trials in each region will be provided. In this way potential participants can call research team members first to express interest. Potential participants will then be contacted via telephone by a member of the project research team who will explain the project, answer any questions the potential participants have and identify the primary caregiver (the person who is most responsible for assisting on a daily basis). During this contact, primary caregivers will complete a screening tool to document the characteristics of the caregiver (e.g. occupational status, current use of technology, general health status), the individual with dementia (e.g. need for assistance with ADLs/IADLs, any challenging behaviours) and the care giving situation (e.g. length of time in role as caregiver, hours per day spent care giving, formal assistance received).

From the interviews with informal caregivers during the process of collection of user requirements, it became clear that they could play very important role when recruiting the primary end-users. With their help it would be easier to find test participants. So another approach to be used by ISISEMD partners is to contact the support groups of informal caregivers. The advantage of this approach is that when the close relative or partner is positive for the services offered by ISISEMD project, he/she could easier convince the primary end-user to take part in the trials.

More specifically for each region, the test participants will be approached using the following activities:

Trikala
1st step - The choice for the patients will be made by the current advisor psychiatrist Mr. Stoforos from ISISMED Project in Trikala
2nd step - The Choice of patients will be made by the rest Psychiatrists in Trikala through our own awareness
3rd step - Announcement in local newspapers in order to search for volunteer patients

Belfast
To allow for a final group of 20 clients, 20 informal caregivers and 10 formal caregivers to be selected and tested in the pilot group, initially a group of 40 potential participants and accompanying informal caregivers will be identified by staff from the Community Mental Health teams of the Belfast Trust. This will occur at Diagnostic outpatient clinics held in premises of the Belfast Trust. These clinics are already held in Belfast for the particular client group addressed by the ISISEMD project. They are led by consultants, other professional and Community Mental Health staff, are also in attendance at these clinics. The outpatient attendance of the clients at the clinics in Belfast is made by both new referral clients and review caseloads. Staff at these clinics presently undertakes the MMSE diagnostic tests with clients. Nurse led Memory clinics held in Belfast and attended by those with prior diagnosis, will also participate in this initial identification of the potential client group. The clients' scores will be recorded at this point.

Lappeenranta
The main channel to disseminate the information for testing ISISEMD services will be to use memory clinic. All 20 end user, relative and 10 caregivers will be from City of Lappeenranta.

Frederikshavn

The main channel to disseminate the information for testing ISISEMD services and to announce for the trial activities will be to use the dementia group from Frederikshavn Elderly Care Department. Additionally, very good awareness for the project has been already created with the press coverage from the kick-off meeting (articles, radio and TV interviews).

3.1.5.2 Process of selection of test participants

As describe in the previous section, participants will need a clinical evaluation by a specialist (neurologist, geriatric specialist, etc.) and a rating of cognitive decline. **Test participants will be seniors over 60 years of age with stage of dementia 2 to 4 and a MoCA or MMSE score 19-26.**

Following the evaluation based on the telephone screening, eligible participants will receive a home visit by two or more of the research members. It is ideal to have half of the participants living alone in their home and half living with a spouse or caregiver. Both genders will be represented as equally as possible. The home will be evaluated by an occupational therapist (OT) to determine functionality, feasibility and receive professional recommendations. This visit will serve to present both oral and written information regarding the research and clinical trial as well as:

- Obtain informed consent of participants
- Measure the level of cognitive impairment with MoCA
- Measure quality of life with QOL-AD
- Conduct an assessment of each room used by the individual with dementia, documenting challenging behaviours that present safety concerns and identifying potential equipment (e.g. camera and sensor) placement
- Ascertain caregivers' familiarity with computer and cell phone
- Document caregivers' feelings of obligation, competence, role satisfaction, etc.
- Caregivers complete a self-report time budget in which they report length of time spent in which care giving activities in the previous 24-hour period

In the next month of the project, the professional staff will identify potential clients which will attempt to fulfil mandatory requirements (it must be underlined that they will be only identified, and not recruited for the trials before approval from ethical committees is obtained). If there are a large group of potential clients to choose from, consideration will also be taken into account of technical access i.e. those that have PCs in home and internet access, with a carer/relative willing to participate and willing to use technology. The delimitations described in Sections 3.1.3 and 3.1.4 will also be taken into account. In general, around 20-23 EP per region will be aimed at. However, some of the regions (for example Belfast) would aim to identifying 40 persons with mild dementia. In this case, the 40 primary end-user group will be those with dementia stages 2- 4 with the aim to target clients with the relevant MMSE/MoCA scores for early stage dementia to allow for deterioration. At this stage care will be taken not to raise user expectations, any mention of the project pilot to clients will be made in a general sense. The reason for this is to have a broader sample of persons, thus allowing later to select the exact needed persons based also on some secondary criteria.

As another activity which could help to recruit test subjects, the end-user partners from the ISISEMD consortium has decided to organise a demo room in each region during M12-M13. This will be a ready ISISEMD platform, installed in a suitable room in the premises of the care-giver partners. The purpose of this is four-fold:

- Demonstration of the systems to potential test participants and their relatives – they will be able to see, and experience the system before deciding to join the controlled study and be convinced that it is very user friendly and also aesthetically acceptable
- In this demo rooms, the formal caregivers will be able to try in reality the system and provide final feedback to technical partners for usability and functionality and suggestions for improvement
- Introduction seminars and training could be provided to end-users

- Personnel from care-giver organisations will gain hands-on experience from installation of the system before the pilot installations

The final 20 clients and caregivers chosen will not be recruited before approval from the ethical committee is granted. The final group chosen will consist of 10 in a control group i.e. no services provided and 3 different groups in the 3 stages of dementia (i.e. stage 2- 4) of 3-4 clients (all in all 10 test subjects). They will be chosen according to the criteria previously described, with appropriate housing requirements/suitability to accommodate the technology inclusion criteria and with a carer/relative willing to participate and willing to use technology. Again the delimitations described in Sections 3.1.3 and 3.1.4 will also be taken into account. This group will be tested with the relevant dementia test (MMSE/MOCA) one month before the pilot is due to begin. A quality of Life assessment will also be conducted for the client/informal caregiver groups.
The eligible participants will have received a home visit to evaluate suitability by the professional member of staff and equipment necessary for the pilot. Informal caregivers will also be visited. Consent forms and Information leaflets will have been prepared and provided. The consent forms will stipulate that the carer is responsible outside normal working hours and contingency arrangements will be described.

3.1.6 Number of participants for the evaluation

The targeted number of participants in each user group has been defined in Description of Work. The following table summarizes the user involvement per group and per region.

Table 4: Target end-user involvement per group and per region

Test groups	Denmark	Greece	Finland	UK
EP - elderly with cognitive problems from MCI to mild dementia	20	20	20	20
ICG - informal caregivers	20	20	20	20
FCG - formal caregivers	10	10	10	10

As could be seen from the above table, the goal is to involve 20 primary participants in each region. However, it could be expected a small number of some drop outs due to various reasons. Therefore, additional 2-3 primary participants per region will be identified and kept as a back-up solution. The exact number of the involved ICG will depend on the status of the EP – if he is alone or has a close family member living with him/her or close to the home. The exact number of FCG will depend on the EP sample too – if most of the EP lives in one area of the city there could be less FCG caring for more EP. The number of FCG will depend also on the organisational structure in each region and in general on the ratio between the number of carers vs. number of clients.
Out of the number of 20 primary end users (as back up 22-23 persons), the test group itself will consist of half of them. The test group will be offered the ISISEMD services and the system will be installed in their homes.

The following Table 5 presents the target characteristics of the sample of EP:

Table 5: Target characteristics of the test sample of EP

Characteristics of the sample of EP	Comments
Country of origin	Denmark, Finland, North Ireland, Greece
Geographical distribution	From North, South and Western Europe
Race	Any race
Number of test subjects EP	80
Gender - Female	50%
Gender - Male	50%

Living alone	50%
Living with a partner	50%
Stage of dementia	stage dementia 2 to 4
Duration of dementia, y	Minimum ½ year
Age, y	>60 y
Educational level, y	No specific
Type of home	Flat or house

The sample of EP subjects in ISISEMD will be community type, living in a city.

3.1.7 Control group of primary end-users (EP)

The control EP group will be as characteristically similar to EP group as possible. They will be community dwelling, half living alone, with a clinical evaluation by a specialist (neurologist, geriatric specialist, etc.) and a rating of MCI to stage 4 moderate cognitive decline following ICD-10 and a MoCA score below 26. Participants will also be recruited with the aid of general and nurse practitioners, memory and dementia clinics, and regional organizations working with dementia populations.
The control group will consists of approx. 10 subjects from primary end-user group to allow for a good comparison. They are going to be involved as the test participants from the beginning months of the test period and relevant test will be applied to them too. Control group will also be administered all tests for the test group except test user acceptance and user satisfaction because they will not be given any technological intervention. For the type of tests to be administered to test and control groups, please refer to Section 5.9 and Figure 1.

3.1.8 Statistical considerations and forming of test and control groups by random selection

The overall hypothesis for ISISEMD project is that ICT services can improve QoL among elderly with cognitive problems or mild dementia. The end-user partners are not aware of previous research to document such a hypothesis with a controlled study. Only references have been found that only indicate that there is a relation. According to Logsdon [Logsdon, 2002], it could be expected an average score of QoL-AD at approx. 39.5 points (spreading 5,3) among a test group. In ISISEMD project, we will try the ICT service for N=97, and MMSE score 17-29.
We are aiming to be able to measure increased QoL with 6%, spreading 5,3 and p-value of 5% is calculated that N=37 persons to be used in the control and test group, in order to prove the hypothesis with significance. Because of this reason, the number of test persons will be N=40, meaning 10 persons in the test group and 10 persons in the control group for each region.
Additionally, in order to have statically valid test results, the test and control groups of the elderly will be randomly selected. This will be done by a small lottery. Some more details are provided in Section 3.1.5.2.

3.2 For Secondary User Group – informal caregivers (ICG)

ICG will be recruited based on EP recruitment as it is desired to have fifty percent of EP participants living with a partner.

3.2.1 Inclusion/Exclusion Criteria for ICG

Inclusion Criteria:

a. 18 years or older
b. actively involved caregiver for the care recipient
c. Must live with the care recipient and/or live separately but provide on average of a couple of hours of supervision or direct assistance per day

d. Must plan to remain in the area for the duration of the intervention and follow-up
e. Caregiver role for more than 6 months

Exclusion Criteria:

a. Active treatment (chemotherapy, radiation therapy) for cancer
b. Imminent placement of care recipient into a nursing home or with another caregiver (within 6 months)
c. Has some stage of dementia

3.3 For Secondary User Group – formal caregivers (FCG)

FCG will be recruited by informing local aging and memory organizations, clinics and support and activity groups about the research project. If willing to cooperate, these organizations and groups will be asked to identify potential participants and professional caregivers familiar with the potential family. Once the potential FCG are identified, they will be contacted via telephone by one of the researchers who will further explain the project and answer any questions they may have. Formal caregivers will also be asked to identify the care giving situation from their (professional) point of view regarding ICG status, EP status and care giving situation. FCG will complete a screening tool to determine their occupational status, current use of technology and role in the care team. Formal caregivers are encouraged to participate in the home visit of EP to assess the situation, setting and possible solutions.

In determining which kinds of equipment they use, we found that nearly all use a PC, also used are PDA, cell phone, fax, internet and some video conferencing. Formal caregivers are also familiar with standardized medical equipment (such as IV, respirators, catheter, etc.). Formal caregivers come from a variety of professional backgrounds, including:

- Doctors (general, neurological, psychiatric), nurses, and other health care professionals
- Gerontologists, Psychologists, Social Workers and other non-medical care professionals
- Long-Term Care, Care managers, business and administration

3.3.1 Important points to be considered

We would like to mention here that a number of studies have indicated that the formal caregivers are quite happy with the good possibilities which use of PDAs gives them. However, we are also aware that a recent study among professional care personnel in Denmark using PDAs in their work tasks and who are members of FOA (Fag or Arbejde) has shown that only 4 out of 10 caregivers are satisfied with the use of PDAs. The study identifies that this is due to technical problems. For example - there are often problems with failure, and the person needs to log-in again, small keyboard, slow internet connection, the battery cannot hold long, etc. This leads to the perception that PDA uses some of the time which they need to spend with the client. Our assumption is that this puts additional stress on the professional caregivers [PDA, 2009]. Therefore, it is of utmost importance that the ISISEMD systems and services must work properly from the very beginning and this will be taken care of by the technical partners. Special attention will be paid during the user acceptability evaluations to also assess this aspect of introducing new technology.

Conclusions for Section 3

This section presented the list of main and secondary inclusion and excision criteria for finding the trial participants. As the main inclusion criteria for EP participants is to have mild dementia, first the classification standard for dementia stages was presented – namely, the Global Deterioration Scale (GDS), developed by Dr. Barry Reisberg. Then the tools for assessing cognitive declined were presented – MMSE and MoCA. It was also explained which channels will be used to approach the trial participants and how the users will be selected and how many they will be.
Further, the inclusion and excision criteria for the care-giver groups (formal and informal) were listed.

Section 4 - Description of the ISISEMD services and the equipment

This section presents short overview of the ISISEMD services which will be offered by ISISEMD platform and the necessary equipment. List of considerations for the primary end-users is listed to highlight some important aspects when introducing the ISISMED system in the people's homes. It further describes how user guides will be prepared and how the support for the end-users will be ensured during the 12-month trial period.

4.1 Short Description of the ISISEMD services

The needed services to be provided by ISISEMD platform have been described in Del 1.1.2 "User& System Requirements – updated version" in M06. However, during the customisation and adaptation work of the integrated services, some deviations happened since M09 from the initially defined services to be implemented. The following table 6 is updated based on this outcome.

In Table 6, the "User friendly" names for the services or sub-functions are also presented. The names that are marked with the yellow colour indicate where the name is different from the original service matrix name from the initial phase of user requirements collection.

Remark: It must be noted, that even though the overall goal of the ISISEMD trial will be to evaluate with all end users all the integrated services, some differences are expected among the four trial sites. This is due to the fact that for each dyad patient-relative, there will be individual evaluation which services to be offered to them based on their individual care needs and dementia level of the primary user. It will be also difficult to guarantee for a particular patient that the set of services needed in the beginning of the trial period will be the same as in the end of the trial period (after one year). Even though the best evaluation will be to have all services tested with all users for the whole test period, the test participants cannot be forced to use all of them if they do not like them and moreover, if many services are introduced to the primary end-user at once, this might lead to confusion and drop-out from the trial.
All these specifics will be reported in the evaluation report for the services.

Table 6: Table of the integrated ISISEMD services for the pilot

User friendly names	Service Matrix ID	Service Matrix name	Level of Implementation
SERVICES BUNDLE A			
Cooking monitor	A1 (A1F1)	Home safety\Cooking monitor	Full
Smoke detector – Fire alarm	A1 (A1F2)	Home safety\Smoke detector – Fire alarm	Full
Kitchen water reminder and Bathroom water reminder	A1 (A1F3, A1F4)	Home safety\ Kitchen water reminder and Bathroom water reminder	Full
Remember your keys	A1 (A1F5)	Home safety\Remember your keys	Demo only, no implementation
Smart Lock	A1 (A1F6)	Home safety\Smart lock	Full
Fridge door alarm	A1 (A1F7)	Home safety\Fridge door alarm	Full
To-do list, Calendar, Season and clothing	A2 (A2F1-A2F4)	Reminders	Full
Locater of personal belongings	A3 (A3F1)	Locater of personal belongings	No implementation
Brain Games	A4 (A4F1)	Cognitive stimulation	Full
SERVICES BUNDLE B			
Wake up sensor	B1 (B1F1)	Sleeping activity\In bed for how long time	Full
Leaving bed during night for long time	B1 (B1F2)	Sleeping activity\Leaving bed during night for long time	Full
Intelligent front door	B2 (B2F1, B2F2)	Intelligent front door	Full
Videophone	B3 (3F1)	Videophone	Full
Memory Lane	B4 (B4F1)	Reminiscence	Full
Med Manager	B5 (B5F1)	Medication Manager	No implementation
SERVICES BUNDLE C			
Outdoor positioning	C1 (C1F1)	Portable Guard\Outdoor positioning	Full
Panic button with tracker	C1 (C1F2)	Portable Guard\Panic button with tracker	Full
Fall alarm	C1 (C1F3)	Portable Guard\Fall alarm	Full
Remote Doctor	C2 (C2F1)	Remote Medical Consultation	Full
Everyday Activity Pattern	C3 (C3F1)	Lifestyle Pattern Recognition	To be implemented during the start of the 12 month pilot.

ISISEMD scenarios have been described in details in Del 1.1.2 “User & System requirements updated version”.

4.2 Short description of the equipment to be used

A number of devices can be used to provide ISISEMD services. First of all, a classification of the devices is required; two categories can be identified: **interactive devices and non-interactive devices.**

- The interactive devices are those which exchange contents when decided by the user and under user's control. Examples of interactive devices are mobile phone, PC, etc.
- The non-interactive devices are those that control some functions but, once programmed, do not need any user control. Examples of non interactive devices are home automation controllers (flood, fire sensors/actuators).

Non-interactive devices will be chosen by WP2 based on technical and economical criteria and will not be a direct subject of evaluation for user satisfaction; it is more the services which they offer will be the subject of evaluation. The main focus of the tests with users will be what these devices do, not the devices themselves. More technical evaluation, for example number of fault alarms, time if they do not function properly, reliability, etc, will be evaluated in the end, as a part of the overall assessment of ISISEMD platform.

The possible interactive devices which allow to access and use ISISEMD services are:

Table 7: Generic list of devices to access and use ISISEMD services

Device Name	Device description	Services involved in
PC	Any general purpose computer which is intended to be operated directly by an end user. PCs usually have ready-to-use standard software installed. ISISEMD PC should be equipped with Web Browser and internet connection, features usually available on almost all PCs	A2, A4, B1, B2, B3, B4, B5, B6, C2, C3
PDA	Personal Digital Assistant is a handheld computer. ISISEMD PDA should be equipped with Web Browser and internet connection	A2, A4, B1, B2, B3, B4, B5, C3
Phone/mobile phone	Standard telephone or GSM/UMTS device that allow vocal communication between two users located remotely and can receive SMS notification	A2, B1, B2, B3, B4, C3
Videophone	Telephone like previous one, but equipped with display to allow video call	B5
TV	Television is a medium for receiving and transmitting moving images	A2, A4, B6
Medical devices	Devices that are allowed to be used by persons in order to measure the value of life parameters like blood pressure, Oxygen saturation, etc.	C2, C3
Digital Photo frame	A display that is a photo and video clip container that allow photo slideshow and moving	B6
Black Boxes	Ad hoc solutions to implement specific functions (e.g. Outdoor localisation including panic button)	A3, C1

The list of equipment (BoM) to be used by the different user groups is presented in the following Table 8. This list was also included in the set of material for the Ethical Committee applications in

order to demonstrate that all equipments are with CE label and that ISISEMD platform is not a medical device.

Table 8: ISISEMD list of equipment (Bill of material)

Item No.	Product	Type	Must be exactly the same[1]	Quantity
1	Cooper M12	Smoke/fire detector	NO	1
2	Bosch Blue Line P1	Motion detector	NO	2
3	CSA Cooper Safety 1450	Flood detector	NO	2
4	Sunwave SD-8561W	El-magnetic contact for door, window	NO	3
5	RAMOS Mini C	Sensor control module	YES	3
6	Asus PL-X31	Power line Ethernet	YES	4
7	Mat Sensor **or** bed sensor	Mat Sensor **or** Bed sensor	NO	1
8	HP TouchSmart 300-1000 Desktop PC (20'' screen) **Or** HP TouchSmart 600-1000 Desktop PC (23'' screen)	PC with touch screen	YES[2]	1
9	Lommy GPS	The devise for the GPS tracking	YES	1

Note2: Because of some considerations for confidentiality, it might be necessary the sections 4.1 and 4.2 be omitted in the public version of this report which will be uploaded on the project website.

The following Figure 1 presents indicative layout of equipment within a house.

[1] "NO" means that another alternative equipment with the same functionality can be used. "YES" means that only the specific product type can be used.
[2] It must be chosen one of the two models. The most relevant difference for the ISISEMD platform is in the screen size.

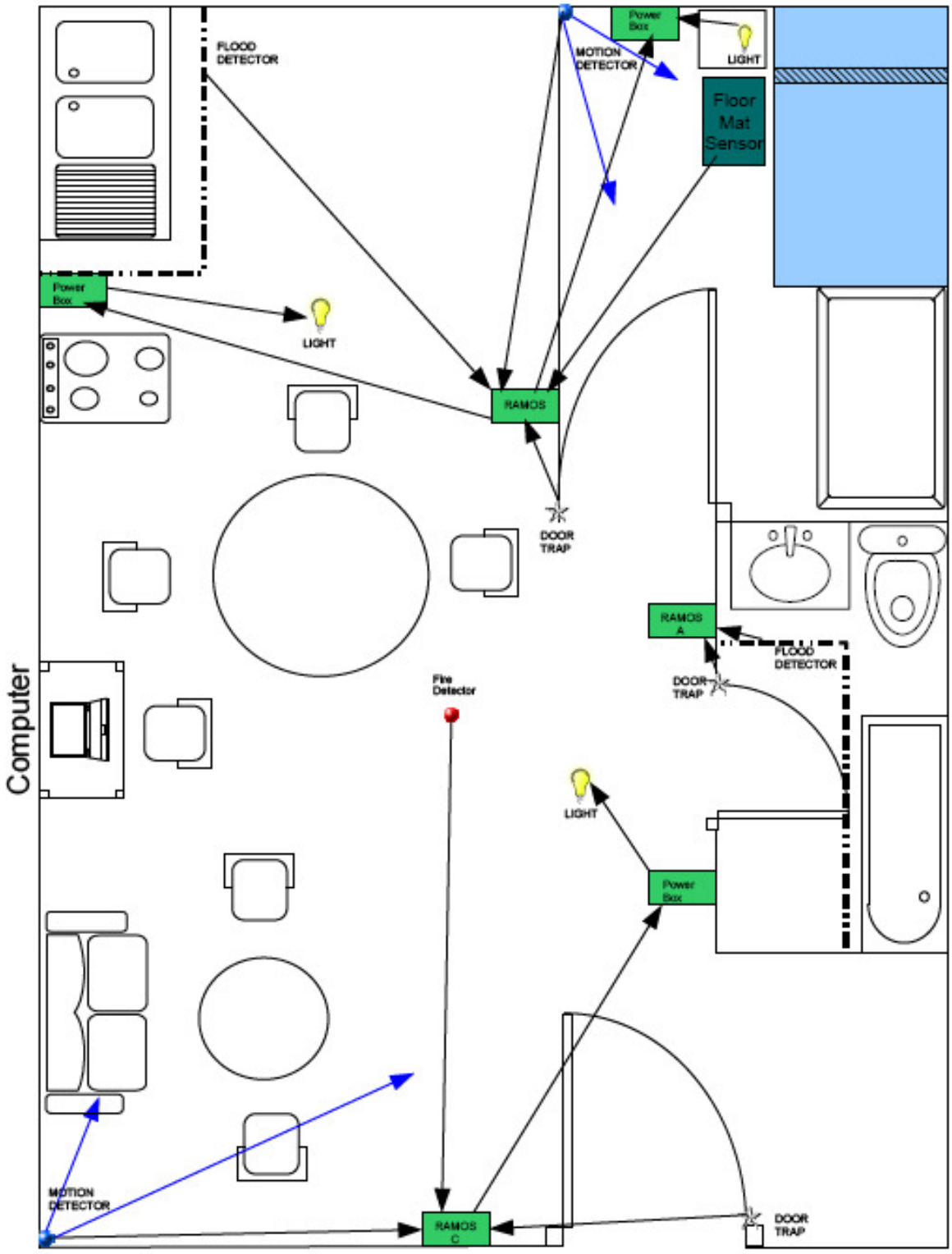


Figure 1: Indicative layout of equipment within a house

4.3 Important considerations for introducing ISISEMD system to primary end-user

Since the ISISEMD system will be offered to elderly persons who are not very used to operate with modern technical devices and in addition, have memory problems and problems to learn new things, these limitations for the elderly with mild dementia must be considered when installing the system in their homes:

- Elderly with dementia might be even more confused if they are supposed to live interactive with relatives via videophone – for the communication service
- Only one technical help device should be introduced to the elderly at a time
- The technical device must be placed in place where it is easy to see and known for the person
- Technical service/device/intervention for only one of their problems/needs do not help so much, meaning that a number of technical services/devices should be introduced in order for them to feel safe and live independently
- Sometimes difficult for them even to watch TV because they are not able to turn it on due to the impairment that cannot read small print or are confused by buttons
- Cannot see small print or cannot here very well (typical for elderly persons)
- May become confused or startled if there are "Speaking" technical devices in their rooms
- Necessary for them to have enough time to learn how to use technical help devices
- Help from others (relatives, care persons) is needed to program, adjust, and update information in the technical devices
- Technical help devices must be introduced to them in the early stage of the dementia when they still can learn how to use them and foster a feeling of safety and control over their life and surroundings

4.4 How the end-user support will be ensured

The end-user support will be provided through the best practices of the IT Infrastructure Library paradigm (ITIL) and especially through the IT Service Support action. This action implies the distinction of service support into different layers with concrete responsibilities and roles.

In general, there are at least two roles: **the first level support and the second level support**.

- The first level support is provided by personnel who are trained and responsible to receive the requests from the end-users (whether these requests are questions, complaints, incident reporting, etc) and try to resolve them directly through their knowledge, experience, or documentation they have available. In case that this cannot be solved, then the request will be forwarded to an agent of the second level support who actually has experience and expertise on the specific topic. The procedure of forwarding the "ticket" of the request has to be defined into detail so as to keep track of its progress and avoid any long workflows that delay the whole process.
- The second level of support will be either technical (on how to upgrade specific versions of the software installed, etc) to professional care-giving services as these are going to be offered in ISISEMD. For this reason, the Service Support in ISISEMD will be assisted by an IT infrastructure, but needs the involvement of all roles that belong to its service chain.

For the purpose of the ISISEMD project, the web portal that will be developed will contain a "**Help desk**" area for supporting the services. This area will contain a form with which the end-user will be able to write down the support he would like to receive, along with a classification of the incident. The backend of the portal will allow a processing of these incidents in terms of assigning, replying, archiving and so on. The help desk will be assisted by **a hot line** as well to allow a phone communication channel. During the project lifetime, the language for this communication will be in

English because this is international project. Localisation issues will be handled accordingly by some of the technical partners- there will be a person allocated to be involved in the help desk procedures and undertake the communication role with people that speak the same language. In general, the Help desk of the ISISEMD project will be staffed with personnel from all partners, as all partners are involved not only in various technical issues but also in care-giving issues. The role definition and responsibilities will be finalized before the start of the pilots.
The support will be subject to a given Service Level Agreement (SLA), especially as far as it concerns the overall time until resolving an issue. The terms of this SLA will be defined however, at the time when the Help desk will be setup and based on the various topics that it will cover. In general, the response time will be divided into two zones: namely the normal working hours and the non-working hours (e.g. Sundays, nights, etc) so that there is a distinction and dimensioning of the Help desk itself.
The first level support will be provided by a staff from the regional care-provider. Since support is needed also out of normal working hours, it is up to the regional care-provider how to organise the persons involved. This will depend on the internal organisational model of the service providers (the regions).
It is foreseen that the first level support will be a person who will be trained to have the knowledge as **a super-user** of the ISISEMD system in the respective region – both w.r.t. the web-portal and general knowledge about the installations in the clients' homes. The super-user(s) in the respective region will be trained by the technical partners well in advance such as after the installations, he/she will be able to provide support. Therefore, the super-user(s) will be able to provide support on local language.

On the other hand, it is foreseen training activities to be carried out in all pilot sites. These training activities will target all end-user groups in the form of organisation of workshop and training calendar. For this reason, the regions will try to select EP and ICG who live in the same area so it will be easier and cheaper for them to travel for this training workshop. There will be demo for ISISEMD platform and information for the project. A good period of time for notice would need to be given beforehand to coordinate time slots for this.
Another training workshop will be organised for the FCG too, most probably with more hours for training, because they will be using the ISISEMD platform to perform their everyday working tasks and will have higher responsibilities.

4.5 Preparation of user guides

For the ISISEMD users, documentation will be provided for all services and equipment as part of the deliverables in WP2 for Prototype Integration and Customization. This includes also a user guide and description of the specific system/functionality. The documentations and user guides will be used in the user training as part of the preparation of each pilot site before start of WP3 – Pilot operation.

The user guides will be provided in local language where this is considered to be necessary – at least for the User Guides for functions where the elderly people need to interact.

The ISISEMD platform and portal will be as little interactive as possible (except for example cognitive training) for the elderly people with dementia which reduces the risk for difficulties by using the system, reading and understand user guides etc. But where interaction and use of devices are needed, an instruction will be provided visualising and describing the functionality in a clear and easy understandable version. These user guides will be prepared in cooperation with professional caregivers or professional educated personal in dementia.

Additionally, short user guides were necessary to be included in the set of materials to be sent together with the applications to the Ethical Committees in some of the regions (Frederikshavn for example). First versions of the user guides for the ISISEMD portal and the CareBox have been already prepared in English. The next step will be to translate them in the other three languages.

Some screen shots from the user guides are provided in the Appendix G as a simple example for user guides.

Conclusion for Section 4

This section 4 shortly presented overview of the ISISEMD services to be integrated in a common platform and the expected list of equipments, also specifying the list for each user group. Fist and second level support will be provided. It further explained how the user support will be ensured and what activities are necessary to be organized in order to provide training to all groups. The activities foreseen are training of super-users in each region and educational and training workshops in each region. User guides will be also prepared, as part of WP2 activities.

Section 5 - Description of the tests

One of the most important aspects of testing ISISEMD services with end-users will be pilot trails in the four regions and evaluation of the services. This section describes the ethical consideration for carrying out the tests with human participants and the applicable international and national laws and acts which will be fulfilled with ISISEMD platform and during the testing. Short information is then presented for the applications to the Ethical committees in each country that will be sent before the tests start. Further, test objectives and test methodology will be outlined followed by list of parameters to be evaluated and quantifiable susses indicators for the pilot sites. In the end of the section, work plan for the pilot sites is presented.

5.1 Ethical considerations and applicable laws and acts

As ISISEMD pilot will involve human subjects, a number of ethical and legal considerations will be considered. They are briefly summarised below:

- *The right to be informed*: any participant in the ISISEMD pilot has the right to know the purpose of the activity he or she is involved in, the expected duration, procedures, use of information collected, the participant's right as a part of the study and any risks, discomfort, or adverse effects. This information should be conveyed during the recruitment process and then reiterated at the beginning of the activity when the **informed consent** form is distributed and signed by the participant. The participant signs this form to acknowledge being informed of these things and agreeing to participate.
- *Permission to Record*: before recording the voice or image of any individual permission will be obtained. This will be accomplished with the consent form.
- *Anonymity*: Participants have a right to anonymity. Their information will be kept confidential and participants name will never associate with his/her data or other personally identifiable information. Instead a participants ID will always be used.
- *The right to withdraw*: Participants should feel free to withdraw from any activity without penalty.
- *Valid and reliable data*: In every activity, we will ensure that the data we collect are free from bias, accurate, valid and reliable. We will inform stakeholders about the limitations of the collected data.
- *Data retention and documentation*: collected original data will be retained only for as long as it is relevant for the project.

Very important prerequisite for testing ICT services with human subjects is to have approval from national and regional Ethical Committees. This is necessary in order to ensure that all ethical rights of the citizens will be respected and that the test will be carried out according to the national regulations and the privacy of the trial participants and all data related to this, will be ensured. In the following paragraphs information is provided for the applications to the Ethical Committees which will be sent by each regional partner. Table 9 provides brief overview of the time plan for these applications and from which authority's approval will be sought.

Table 9: Calendar of Applications to Ethical Committees (update on 27 January 2010)

Pilot-site (Country /Region)	**Activity**	**Need approval?; Name of authority**	**Start date of activity**	**Period in advance if approval need**	**Supporting Info Needed?**
Denmark	Testing of ISISEMD services in user's home	Approval is needed from Committees for data protection and from Regional Ethical Committee	M12 March 2010	**Approval from Committees for data protection has been already granted on 6th of July 2009.** The journal number is: j.nr. 2009-54-0750. An extension of the application on the 16th of December 2009 was made, where Alcatel was included as host for the data. Application to Regional Ethical Committee was sent on 12 Jan 2010 **Provisional approval received on 27 Jan**. Final approval is expected beginning of Febr 2010.	For Committees for data protection – the names of the persons who will have access to information about test participants and who will conduct ISISEMD controlled study Detailed application was prepared with a number of sections based on a template with 14 sections and a lot of additional explanation material in 12 Appendixes. Declaration form that ISISEMD platform is not a medical device. Agreement has been signed by Frederikshavn Kommune and Alcatel that the personal user data will be stored in Alcatel premises according to the European rules.
UK	Testing of ISISEMD services in user's home	Approval will have to be sought from both the Research Governance Dept of the BHSCT and the Northern Ireland Regional Ethics Committee http://www.orecni.org.uk/display/home. A preliminary meeting has taken place with ORECNI on 27th April 2009 to establish necessary steps.	M12 March 2010	Approval for both Trust and Regional depts. could take approx 4 months. For the ORECNI approval alone, before the pilot can begin approval will take approx 38 calendar days Ethical applications were sent by 1 Oct 2009 with any accompanying documentation e.g. copies of Client Consent forms, Protocol etc. Jill Harpur was invited to a meeting to answer questions by 13 members of Ethics Committee on 17 Dec 09. After that, BHSCT **received provisional approval** (opinion) and request for further clarifications to be submitted by end of	Any preliminary interviews (if necessary) before the main pilot which will involve NHS staff or clients will also involve ethical approval Detailed application was prepared with approx. 80 questions and a lot of supporting material in Appendixes. Additional supporting information on request was submitted by mid Jan 2010. Declaration form that ISISEMD platform is not a medical device.

				Jan 2010. BHSCT was asked to fill in declaration that ISISEMD platform is not a medical device – for MHRA. Final answer is expected mid Febr 2010.	
Finland	Testing of ISISEMD services in user's home	Approval is needed from Regional Ethical Committee	M12 March 2010	Application to Regional Ethical Committee was sent by end of Nov 2009. **Approval for the pilot in Finland has been granted on 18 Dec 2009.** Ref.: Decision making: Lappeenranta, Social and Health Services, Ethics Committee 3/12/2009, Case No. 3.	Detailed application was prepared with a number of sections with relevant information based on material prepared in this report – - How the data is encrypted - where data is stored - how long data is stored - Description of the ISISEMD service - Agreement with end-users. - interview forms
Greece	Testing of ISISEMD services in user's home	Approval is needed only from Hellenic Data Protection Authority (HDTP).	M12 March 2010	The notification to the Data Protection Authority (DTP) will be submitted in the beginning of Febr 2010 immediately after the employment of the two psychologists that will run the telecare center that will monitor the 10 houses.	Just a simple notification is required to the DTP, since Trikala will employ psychologists as formal care givers in the telecare center.

5.1.1 Ethical and Legal Framework

The information necessary to be provided in the applications to the Ethical Committees to get approval to conduct ISISEMD pilot testing material includes different aspects. A number of details must be described, such as short overview of the project and its goal, description of services to be tested, duration of the trials, responsible person, involved equipment and its certification, user guides for use of the equipment, what type of personal data will be collected, for how long after the trial end it will be kept, who will destroy it after that, examples of interview guides and questionnaires, etc. A set of written material for the test participants partially describing all these aspects must be prepared, consent forms, etc. All this necessary material will be step by step prepared by ISISEMD partners immediately after submission of due reports in M06 because in some of the regions it takes some months the applications to be processed. In the following subsections the most important parts of these applications are presented, namely trial protocol, written material for the trial participants. Some more details and different forms are presented in Appendix A and B.

5.1.1.1 Trial protocol

A trial protocol is a document describing the objective, design, methodology, planning, statistical considerations, research-ethical considerations, finances, publication and information for participants in connection with research project, etc.

The most important documents which must be enclosed with the trial protocol [DK Trial]:

- Written information for participants
- Description of procedures for communicating oral information to participants
- Declaration of consent
- Advertising material for recruitment of participants
- Questionnaires
- Other relevant material like procedures for ensuring security and privacy during and after the trials

In the following paragraphs some more information for the necessary information is provided:

1. The purpose of the project, including problem and hypothesis, also supplemented by a short review of literature or an actual bibliography. The goal of the description is to enable the committee to decide whether there are sufficient grounds for implementing the project, and whether the hypothesis of the project is justified; to decide whether the project may be justified by the expected therapeutic and public health benefits.
2. Trial method, including design and planning. Use of control group, randomisation, etc. The goal of this information is to enable the committee to assess the research standard of the project and ensure that the project contributes to providing new valuable knowledge. Selection of a control group shall be accounted for too. It must be also stated who is the monitor on the trial.
3. Information for the data collection - what type of data will be stored and who can have access to the data; for how long the data will be stored, etc.
4. Description of Statistical considerations. They must be sufficient for an evaluation as to whether the project can provide answers to the questions made.
5. Trial subjects, including criteria for inclusion and exclusion. The inclusion and exclusion criteria shall be stated. The gender and age of the trial subjects shall be given, including whether the subjects included are patients and/or healthy trial subjects. A statistical reason for the planned number of trial subjects shall be given.
6. Side effects, risks and inconveniences for the trial subjects. The description shall cover predictable risks, side effects, including known long-term side effects, complications and

inconveniences involved in participation in the trial. The trial protocol shall describe any safety measures.

7. Respect for the physical and mental integrity of the trial subjects and for their right of privacy. Statement shall be given that data concerning the trial subject are protected under all valid Acts on Processing of Personal Data and the Acts on the Health Act.
8. Where a researcher wishes to use information from patients' records in the research project, this shall appear from the protocol. What information is to be used and the intended use hereof shall also be stated. The information must be relevant and necessary for the research project. Any subsequent contact to the patients concerned shall take place only if the health person who has treated the patient allows this

In the trial protocols will be stated that the project is implemented in accordance with the rules of the respective Acts on Processing of Personal Data in each of the four countries where the pilot sites are established (Denmark, North Ireland, Finland and Greece).

9. Recruitment of participants. A description shall be made of where and how trial subjects are recruited. The wording shall be without value-laden expressions and shall not arouse unrealistic expectations in the target group of the advertisement.
10. Availability of information for trial subjects. Indication shall be provided as to how the trial subject is guaranteed access to further information on the project, such as reference to a health professional who may act as a contact person.
11. Publication of trial results. The project must publish negative as well as positive trial results. If the results cannot be published in a journal, publication must be made in another way. A statement shall be provided as to how publication will be made.
12. Statement of research ethics. The protocol shall include a statement concerning the ethical issues raised by the research project, including an argumentation that the project is sound in terms of research ethics.

The statement shall include a thorough risk/benefit assessment of the trial. The risk assessment shall comprise an evaluation of side effects and risks calculated in absolute figures and in terms of relative risk without regard for any other benefits. This shall be followed by an assessment of the project in relation to predictable benefits for the trial subjects, for others and for research.

During the trials, of big importance will be the oral information provided to the participants. The following paragraphs present the guidelines for oral information for the trial participants.

5.1.1.2 Guidelines for oral information for the trial participants

Guidelines for communication of oral information to participants will be attached to the trial protocol. The guidelines will apply to the person who provides the information in practice, i.e. the health professional who communicates the information. Basically, the guidelines will describe how to plan the information process, but also what is to be included in the information.

As a minimum the guidelines shall consider:

- Who provides the oral information?
- How is the first contact to the trial subject made?
- Through posting or a personal contact?
- When is the oral information given (e.g. before or after the written information)?
- How to make sure that the information interview is undisturbed?
- How to make sure that the trial subject is given the option to have an observer present at the information interview?
- How much time for reflection should be given between the oral/written information and the subsequent signature on the declaration of consent?
- When to ask for consent?

One of the most important points of the tests will be the interviews with the trial participants from the three end-user groups. There are also guidelines what to be considered during the information interview. They are presented below.

5.1.1.3 Guidelines for information interview

During the information interview, the following important points must be considered:

- The interview will be planned so that the trial subjects have sufficient time to read the written information, listen to the oral information and ask questions.
- The interview will contain an understandable presentation of the research project without using technical or value-laden terms and communicated considerately adjusted to the individual in terms of age, maturity, experience, etc.
- The information will include details on any predictable risks, side effects, complications and inconveniences and state that participation in a biomedical research project may involve unpredictable risks and harm.
- The information will include details on circumstances about which the trial participant is believed to be unaware, but which are important to the trial participant's decision.

After the information interview:

- The trial participant will be informed if, during the implementation of the trial, new information becomes available concerning effect, risks, side effects, complications or inconveniences.
- The trial participant who is still actively involved in the trial will be informed if the trial design of the research project is significantly altered in relation to the safety of the trial subject.
- The trial participant will be informed if, during the implementation of the research project, significant information becomes available on the trial subject's state of health; unless the trial subject has expressly stated that he or she does not want this.
- If it is feasible and the trial participant so wishes, the chief investigator or the health professional in charge of information shall, when reporting the research project, inform the trial participant of the results achieved and of any consequences for the individual subject.

5.1.1.4 Written information for participants

The trial protocol will also include written information for participants, submitted in paper form or electronically.

The most important written information for participants shall include the following:

- Request regarding participation in a scientific trial at the beginning of the information.
- Purpose and method and the importance, nature and scope of the research project, including the practical arrangement of the project and any clinical trials.
- Any predictable risks, side effects, including known long-term side effects, complications and inconveniences by participating in the research project, and that participation in a research project may involve unpredictable risks and harm.
- How the security and privacy of the collected and communicated data will be ensured. What will happen to the communicated and collected data after the termination of the project, will it be passed on others outside the respective country? For how long will the data be stored? For instance, will it be destroyed after the termination of the project?
- The possible benefits of the research project. A distinction shall be made between benefits for the individual trial subject, for others and for scientific progress.

- Circumstances which may result in the involuntary exclusion of the subject concerned from the research project as well as circumstances under which the project as a whole may be discontinued.
- Where the trial subject may obtain further information on the research project (e.g. from the contact person).

During the trials, **declaration of consent** will be signed by the trial participants who will be legally competent trial participant or be a legally competent representative.
In a biomedical research project, an informed consent is a decision to participate in a research project which has been made upon satisfactory information on the nature, significance, implications and risks of the project and receipt of suitable documentation. The decision is made voluntarily by a person who is capable of giving his or her consent. The consent shall be in writing, dated and signed or provided using an electronic signature.

The trial protocol will be accompanied by a copy of the declaration of consent.
Original declarations of consent will be stored by the chief investigator, and the trial participant is entitled to have a copy of the declaration of consent. ISISEMD Informed consent form for the ISISEMD platform is provided in Appendix B1.
Additionally, declaration of consent for the Outdoor Guard (GPS) service was prepared by the partners separately in order to ensure that also this service will be approved by the Ethical Committees in all regions. See Appendix B2.

5.1.2 Applicable laws and acts

All tests with all user groups in all regions from the consortium partners will comply with the applicable European and national laws. As described in Del 1.3.1 "Privacy & Security Analysis Report", building and deploying ISISEMD system and the services will fulfil the national and European regulations, rules and laws for collecting and accessing the user's data and appropriate security and privacy protections mechanisms will be implemented.

Below is just a short summary of the applicable laws [Del 1.3.1, 2009]:
To tackle all the potential ethical issues deriving from the collection and processing of personal data, the project partners have agreed in taking concrete action to the thorough examination of the European and international regulatory framework on the protection of personal data, respecting the relevant legislation, the established case law, the legal doctrine and the opinions and recommendations of the Data Protection Working Party of Article 29 of Directive 95/46/EC.
The aforementioned legislation is the result of various international legislative initiatives which reflect the established morals and ethics regarding the protection of privacy and personal data. It follows that in order to ensure that all potential ethical concerns with regard to the processing of personal data are covered, it is necessary, first and foremost, to ensure that the relevant legislation is respected. More specifically, every activity undertaken within the ISISEMD project will be fully compliant to the international and European and national privacy and data protection laws. The process of collecting the users' data will be legitimate, in the context of article 7 of Directive 95/46/EC. Additionally, in respect with the trans-border transfer: the personal data collected will not be transferred to any third county that does not offer adequate protection. In cases where the project results or data regarding the evaluation and pilot phase of the project are communicated to the public, they will not include the names or other personal data of the users who have been the subject of the activity.

With regard to the willingness of the users (and their informal caregivers) to participate in ISISEMD, we underline that every user will be notified in advance and asked to consent specifically for the collection and processing of their personal data for the purposes of the project. In addition, their consent will be based on thorough and intelligible information *on how their personal data will be collected and processed*, what will be *the benefits of such processing* and that *they can withdraw their*

consent anytime, after the start of the pilot activities. In the contest form it will also be explained some other relevant aspects, such as among others - liability. For example it will be mentioned, that the solutions offered by the project aim to enhance the quality of life and not to substitute professional medical assistance for the project/trial period. Details about this type of written material for the test participants are presented in the Section 5.1.1.4 above and some documents are provided in Appendix A and B.

Specific fact about ISISEMD services are that they will support the everyday life of persons with cognitive decline or mild dementia who in some cases are not able to take legal decision by themselves. Therefore, in these cases they have a legal representative. Because of these circumstances, the applicable national laws will be fully respected. The principles of the Mental Capacity Act of 2005 include supporting people to make decisions for themselves wherever possible, and making decisions in the best interests of people who cannot decide for themselves. The Code of Practice which accompanies the Act outlines how health professionals should support the person and/or include carers in the decision making process. The social services department of the local authority has a duty of care for vulnerable adults living in its area. It has to assess the needs of these adults and provide services and/or equipment to meet any assessed needs. Social services also employ Occupational Therapists (OT), who are specialists in assessing the living environment.
The Data Protection Act of 1998 covers medical records, and medical professionals often quote it when families ask to see a person's medical notes or ask to be kept informed about their care. However, it could be argued that it is in the patient's best interests for the information to be made available so that the people who are involved in their care are well informed and able to act in the person's best interests.

5.1.3 National acts

Frederikshavn

In order to carry out the ISISEMD pilot in Denmark, the project will be certified by the Local Scientific Ethnics Committee for North Jutland Region and will follow the rules set by the National Scientific Committee (and the Helsinki declaration):
http://www.cvk.sum.dk/CVK/Home/English.aspx and
http://www.efgcp.be/Downloads/EFGCPReportFiles/Flow%20Chart%20Denmark%20(revised)%2008-03-01.pdf.
The project has already been approved by the Bureau for Control of Personal Data, July 2009 and data will be administrated by their rules: http://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/
Other applicable law in Denmark is “Magtanvendelseloven” (law for preventing use of force). This law will be respected when ISISEMD services are being integrated, deployed and used.

Some more relevant information is summarised from the book “Håndbog om demens. Til myndighedsniveau: ledere, politikere og forvaltningsmedarbejdere” published by Servicestyrelsen in Denmark:

The legal right of the dementia persons
Use of force over persons with dementia is only something, with some exceptions, that can be applied as a last resort; after all possible means are tried and failed. The use of force is considered an “attack” over the personal freedom of the person. Applying these rules is, to a high degree, to strengthen the legal right of the person with dementia so that unnecessary interventions do not take place and to ensure openness and reflection about the situation of the person with dementia

Personal rights
The Danish society is a democratic society and the human rights are written in Grundloven. Two of these fundamental rights are the right to self-decision and integrity. Self-decision means that the single

person has the right to decide over their own life both in personal and economical respect. Integrity means actual and real wholeness or inviolableness: however, one can go further and define integrity as respect for the single person in physiological, physical or personal aspects. Integrity is therefore further understanding of self-decision. Interference in one person's self-decision can only take place with a law and only when the person himself, other people or the society behaves for this.

Use of alarms, technical care systems, door openers

If the person with dementia leaves their home and poses a risk for damage to themselves or others, the care personnel can search for permission to use personal alarms or technical care systems. It must be documented that the person with dementia leaves the home and cannot care for themselves and the personnel has utilized different social, pedagogical approaches without success to avoid the person leaving the home. Only after this situation should the use of alarms or technical care systems be considered.

If all other approaches have been tried without success and there is high risk for personal damages if the person leaves their home, an exception could be given for the use of special door-openers in a limited period.

Decision for use of personal alarms, special door-openers or technical care systems is taken by the care personnel in the municipality in a limited period.

More information for the topic "use of force" and the use of technical means for care for dementia can be found in:

- Guide for alarm- and care systems for persons with dementia, Styrelsen for Specialrådgivning og Social Service, 2007
- Vejledning om magtanvendelses m.v. efter lov om social service nr. 16 af 31/03/2008.

In general, more information about patients with dementia, their relatives, and conditions for all aspects of everyday care can be obtained from Servicestyrelsen website www.servicestyrelsen.dk/demens.

Lappeenranta

There are two acts concerning the ISISEMD application:

- Personal Data Act 22.4.1999/523: http://www.finlex.fi/fi/laki/kaannokset/1999/en19990523.pdf
- Act on the Protection of Privacy in Electronic Communications 516/2004:

http://www.finlex.fi/fi/laki/kaannokset/2004/en20040516.pdf

This Act entered into force on 1 September, 2004.

Trikala

The collection, processing and management of sensitive personal data holds threats to the patients who have the legal right to be protected according to the 9th Article of the Greek Constitution. In Greece, these people's rights are safeguarded by the Independent Authority of Personal Data Protection.

European and Greek Legal Context

The legal context of personal data protection determines:

1) The Greek Law 2472/1997 which constitutes a full legal system to protect the subject from the processing of personal data.
2) The Greek Law 3471/2006 which mainly concerns the protection of personal data and privacy in the field of telecommunications. With this law there have been major amendments to the aforementioned law and Greece complied with the 2002/58/EK of the European Union, incorporating amendments that the Authority of Personal Data Protection suggested as an outcome of its experience, abolishing law 2774/1999, in which the already applying directive 97/66EK had been incorporated.

3) The Greek Law 3625/2007 through which the field of application and jurisdiction of the Authority of Personal Protection Data is determined.
4) The Directive 95/46/EK which is still applying concerning the protection of natural subjects against the processing of personal data and the free circulation of these data.
5) The Directive 2002/58/EK which is still applying about the processing of personal data and the protection of privacy in the field of telecommunications.
6) Article 9 of the Greek Constitution
7) Article 8 of the European Agreement on Human Rights
8) The Greek Law 2071/1992 about the National Health System, article 47
9) Bearing in mind the arrangements of article 22 of the Greek Law 2472/1997, as it was amended, it is currently applying and the arrangements of the Penal Code about trespassing of confidential data, articles 370 and the following ones, specifically article 371 of the Penal Code concerning professional confidentiality and the arrangements concerning crimes against the subject's value (articles 361 and the following of the Penal Code) which determine the penal repercussions of the offenders.
10) Different arrangements of the Greek Civil Code, especially those which concern the rights of the self, article 57 of the Greek Civil Code, and the arrangements 914,919 and 932 of the Greek Civil Code, which determine the civil outcomes.
11) The regulatory acts, directives and decisions of the Authority of Personal Data Protection, which constitute the result of this institution's function until the present day and the in concrete application of the relative legislation.
11) The decisions of the Greek Courts of Law, Administrative, Civil, Penal.
12) The relative European Legislation, Regulation (European Union), no 460/2004 of the European Parliament and the 10th of March Commission about the creation of the European Organization about the Network and Information Security (F375KB), Security of Networks and Information: European policy proposition, Index (com/2001/0298), 18th February 2003 Commission's Resolution about the European perspective concerning the networks' and data security, 28th January 2002 Commission's Resolution about a joint approach and special actions in the field of data and network protection(2002/C43/02)

Belfast

Two pieces of legislation are of particular relevance to people with dementia and housing, the Mental Capacity Act (MCA) of 2005 and the Disability Discrimination Acts (DDA) of 1995 and 2005. The MCA clarifies the legal position of those providing help or services to people who may lack the capacity to take certain actions or decisions for themselves. The DDA prohibits discrimination against a disabled person. People with dementia would fall into this category, along with those with a learning disability or mental illness. The Mental Capacity Act 2005 provides a statutory framework to strengthen the position of - yet also protect - adults who may lack capacity to make some decisions for themselves. It enables capacitated people to plan for a time when they may lack capacity and clarifies who can take decisions, in what situations and how to go about it. The Act is relevant to everyone who supports or cares for – whether formally or informally – people who may lack capacity to make decisions for themselves.

The UK laws that will concern the ISISEMD application will also involve the Data Protection Act of 1998 and the protection of Personal Information.

5.2 Trial Objectives

This section presents overview of the main objectives which ISISEMD partners aim to achieve with testing ISISEMD services with end-users.

One of the main objectives of ISISEMD project is to trial the integrated services in a real life, for 12 months, involving all relevant main end-user groups.

A major potential for big impact in improving quality of life for elderly with mild dementia in Europe is that on first place, some type of technology assistive services **in their homes** will be offered to them and their closest relatives. Currently such type of "home" services does not at all exist in the care-provider organisations of the regional partners for **these specific groups of clients**.

On the second place, with the help of the ISISEMD platform and demand-driven services, the senior citizens will be able to live independently in their homes safely and longer, their quality of life will be improved and the burden of taking care for them which their closest relatives feel will be reduced.
Of course, after the end of the 12-month trial period, technical assessment of the ISISEMD services will be done. The outcomes of it will be presented in D-3.3.4 "Report on validated common functional specifications building on the pilot experience". On the other hand, it is of a crucial importance to assess to what extent the ISISEMD services fulfil the user expectations, what the user acceptance and satisfaction is after the 12-month trial. These are aspects related to the human factor and in many situations directly linked with subjective evaluation and perceived individual quality.
The main topic of this report is exactly this – to discuss the acceptance from the point of view of the human subjects. This report could also serve as a handbook for caring out the trial. Therefore, as a starting point, the trials objectives must be clearly defined. They are mapped to the overall project objectives.
Table 10 below is based partially on a table from Description of Work presenting the project objectives and their respective Quantifiable Success Indicators. It must be noted, that only the project objectives relevant to the testing with human subjects, are discussed in this table.

Table 10: Mapping of Project Objective and Trial Objectives

Project objective	Quantifiable Success Indicators for each Project objective	Trial objectives
O1 - Improve care of elderly with cognitive problems by offering them ICT services for self-care	Satisfaction of elderly using ISISEMD services	• Measure improvements in quality of life of elderly • Measure acceptability of the services by elderly • Measure satisfaction from the use of the services by the elderly
O2 - Improve care of elderly with cognitive problems by offering the care-givers ICT services	Satisfaction of the care-givers using ISISEMD services	• Measure acceptability of the services by informal and formal caregivers • Measure satisfaction from the use of the services by the informal and formal caregivers • Measure improvements in quality of life of informal caregivers and reduction in their burden • Measure efficiency of ISISEMD services for the formal caregivers
O4 - Evaluate the pilot set of scalable ISISEMD services under realistic conditions and for adequate time period	Run the pilot service for a certain period (12 months)	• Carry out the trials in the clients homes for 12 months
O6 - ISISEMD services to be demand-driven	Involve all main stakeholders in the pilot service	• Carry out the trials with the three main user groups

As seen from the table above, the key words for the trial objectives are **User Acceptance, Satisfaction, QoL and Efficiency**.

More specifically, the trials will try to give answers to a number of hypotheses which ISISEMD partners have formulated, based on the objectives of ISISEMD project.
In the following lines, the hypothesis and the research questions are presented.

Main hypothesis:

- - ICT services will have a positive effect on Quality of Life for the elderly with mild dementia and their caregivers

- Supporting Hypotheses:
  - Quality of Life
    - ICT services will increase QOL for 50% of EPs in the test group
    - ICT services will increase QOL for 70% of ICGs in the test group
  - Burden of care for the informal caregivers
    - ICT services will reduce the burden of care by 60%
  - Feeling of Safety
    - Test group EPs and ICGs will report a higher feeling of safety (30% higher) in their daily life than the control group.
  - Social Benefits (Effectiveness and Economic Impact/Costs)
    - ICT services will allow for the transfer of care giving tasks from FCGs to ICGs (more efficient for FCG daily tasks, time, and travel)
    - Test group ICGs can remain employed outside the home longer due to reduced need in time spent in the care giving role
  - Accessibility (to care/services offered by the care provider)
    - There will be a 25% increase in access to care offered to the public in test group participants
  - Acceptability/Satisfaction
    - Test group participants will report 75% higher acceptance of ICT systems for home care than the control group
    - 75% of participants in the test group will use the ICT services regularly
    - 75% of ICGs in the test group will report acceptance of ICT services as support in their care for EP (desire to continue utilizing ICT services)
    - 75% of test group participants will report satisfaction of ICT services

Answers will be sought to the following SCIENTIFIC (RESEARCH) QUESTIONS

- What effect will ICT-services have on the quality of life of the end-users?
- How is the user accept and satisfaction with use of ICT-services?

- Could ICT-services help EP to live longer in their home?

- The need for care will be stable (will not increase) for EP who uses ICT-services while there is increasing need for a lot of care with the progressing of the disease with elderly who do not use ICT-services.

- How is user satisfaction correlated with a certain user group characteristics?
  - Age
  - Gender
  - Living alone or with an informal caregiver
  - Dementia stage

- Which of the ICT services have maximum/minimum accept by the test persons?

- Which of the ICT services is maximum/minimum satisfactory for the test persons?

- Which parameters of the ICT-services are the most important for the user-satisfaction and accept?
    - That ICT-services are easy to use?
    - The look of the service
    - The functionality of the service
    - Support/Training for the users and maintenance of the service

5.3 Test Methodology

Shortly speaking, in the evaluation process, the selection of appropriate evaluation method to be used is very important in order to avoid subjective evaluation, be most suitable for the client and the care staff. This section describes test methodologies to be used in the evaluation process, namely which methods will be used in assessing Quality of Life (QOL), user acceptance, user satisfaction and cognitive functioning.

For assessing for Quality of Life (QOL), some standard questionnaires will be used, which have been explained in Section 5.3.4. It is important to underline though that in order to make accurate and objective comparisons, the first round of evaluations (such as functioning status, user acceptance and QOL) will be conducted before intervention implementation. Another round of evaluations will be administered before the clinical trials are completed and again after the interventions have concluded. In this way we hope to have as clear picture of the status as possible in the very begging of the 12-month trial period. After that, the initial results will be compared with the results in the end of the evaluation period.

For assessing user acceptance and user satisfaction, ISISEMD partners will use their own **explorative approach,** presented in the next subsection.

Additionally, initial assessment of cognitive functioning of the primary end-users will be carried out, but this is considered as part of the selection process and selection criteria. The rating scales for assessment of cognitive functioning have been described in Section 3.1.2. For this reason they will not be presented here again. Assessment of cognitive functioning is seen as a secondary testing during the pilot trials since the main objective of the ISISEMD services is to improve the quality of life. However, since small number of the ISISEMD services is targeting cognitive stimulation, they might have a positive effect on the speed of cognitive decline in terms of delaying the time when the person has severe dementia. Such positive influence could be caught by administering MoCA/MMSE questioners and comparing the tests scores of the test group and the control group before and after end of the trial period.

Note: The instruments, rating scales and questionnaires that are described in this report are presented in the Appendix section.

5.3.1 Triangulation of the three methods

Due to the specifics of dementia, many of the primary users do not see themselves as impaired; either they do not see their difficulties in their daily life or they are embarrassed and try to hide them. Having dementia, and the difficulties derived from that condition are often tabooed, so getting into the issue can be difficult both to the demented person but also to the data collector. Due to different understandings and views on one's own condition, one method will have different applicability on different demented persons. Therefore, it is necessary to approach the trial participants from different angles to gain the best understanding of the actual situation. The philosophy is that each of the methods will reveal different aspects of the same reality. Thus, by applying them all to the same participant, they will piece together an image closer to the objective reality.

At the same time, the selection of appropriate evaluation methods to be used is important in order to avoid invalid measurements. Considering the pathology (cognitive impairments), intervention (technological), care setting (community dwelling) and desired outcomes (user acceptance and increased QOL), evaluations need to be situation appropriate for the end users and caregivers. We consider the following methods for evaluation and validation to be appropriate:

- Questionnaires for EP, FCG and ICG
- Participation observations
- Qualitative and quantitative interviews

To answer the above mentioned challenge, in the project we will use an **explorative approach** in the evaluation of user acceptance, satisfaction and quality of life – before, during and after the pilot trail for the EP. Besides questionnaires, we will apply **two quantitative methodologies** in the analytical work for the EP: semi-structured interviews and participation observations. Finally, we will use **a triangulation of the three methods** to approach the EP of the system from different angles. This is similar to the method we used in collection of user requirements – the method of **triangulation of data collection techniques**.

In the pre-analysis phase, when determining the user requirements, the two qualitative methodologies were taken into use. By applying the two methods simultaneously on the same user, they were found to supply each other well. The Table 11 below lists some of the strengths and weaknesses seen from that approach to the users.

Table 11: Comparison of the data-collection methods

Method	Participation observation	Semi-structured interviews
Strengths	• Visualizes the physical problems in daily life (for example decor of the house) • Easily reveals difficulties in the daily day life upon the acts of the observed person	• Fast to conduct • A structured way of getting the interesting information
Weaknesses	• Time consuming • Demands that the observed person is acting • Demands that the observant is a natural part of the situation	• It is easy for the interviewed person to hide difficulties that he don't want to talk about

In the first phase of the project ISISEMD partners were seeking to identify difficulties and insecure situations from the daily life of the persons with dementia. **Difficulties and insecure situations** were the two key-words in the interviews and observations to help us gain knowledge of how technology could give the users an easier life with less dependency to ICG and FCG and feel safer. In the same manner, we will find keywords for User Acceptance, User Satisfaction and Quality of Life and create interview and observation guides to be carried out on these topics.

5.3.2 User Acceptance

In the evaluation of the ISISEMD services we will discuss user acceptance from all three main end-user groups point of view – EP, ICG and FCG.

User Acceptance by elderly subjects and their relatives
Acceptance of remote support and monitoring by elderly and their relatives is by far one of the most important parameters in ISISEMD evaluation. If clients and their relatives are not comfortable with the technology, or feel that they do not have control over the system, they may avoid using it, thereby precluding other benefits of self-care and remote monitoring.

User Acceptance by Professional Caregivers
Acceptance of homecare services by caregivers and other healthcare professionals is important in homecare evaluation. If care professionals are not comfortable with the technology or judge that the technology decreases their control over clients, they may avoid using it, thereby precluding other benefits of homecare. Clinical acceptance of a homecare application may depend on the degree of confidence which the caregivers and medical staff have in their work tasks from using the application as well as the caregiver's satisfaction with the encounter in the absence of proximate interaction with the client.

We distinguish by user acceptance from a technology perspective and from a human perspective.

User Acceptance from a technology perspective
Dillon and Morris [Dillon, 1996] define **user acceptance** *in trials such as this as "the demonstratable willingness within a user group to employ information technology for the tasks it is designed to support."*
Innovation diffusion theory is a paramount theoretical perspective on technology acceptance and it aims to provide a description of the mode in which technological innovation moves from invention to pervasive utilization. It applies five characteristics of innovations that affect their diffusion:

1. Relative advantage (the extent to which a technology offers improvements over currently available tools)
2. Compatibility (its consistency with social practices and norms among its users)
3. Complexity (its ease of use and learning)
4. Trialability (the the opportunity to try an innovation before committing to use it)
5. Observability (the extent to which the technology's outputs and gains are clear to see)

User Acceptance from a human perspective
Acceptance has also been conceptualized as an outcome variable in psychological processes that users go through in making decisions about technology [Dillon, 1996]. Theory of Planned Behaviour, or TPB, [Ajzen, 1991] holds that attitudes, subjective standards and perceived behavioural control are immediate determinants of objectives, which in turn influence behaviour. The Technology Acceptance Model (TAM), developed by Davis [Davis, 1989] predicts user acceptance of technology is influenced by perceived value and perceived ease of use. Theoretical work in social and cognitive psychology and sociology also study user acceptance, and this is particularly applicable for ISISEMD use where acceptance will be subjectively evaluated and empirically measured. Relationships between beliefs, attitudes, norms, intentions and behaviour shape subjective norms, and all are of great significance in shaping human behaviour in exercising choice. The field of human-computer interaction (HCI) and Man-Machine-Interaction (MMI) calls for user-cantered technology and current textbooks cover basic psychology and social impact, associating social science and engineering research to develop more useable and acceptable systems.

Training to increase User Acceptance/Satisfaction
In order to facilitate the best possible conditions for user acceptance, a reasonable amount of time must be spent on training. The amount of time and type of training caregivers and primary participants require for them to feel competent and confident with using the technologies, will be different for each situation. Face-to-face training at the time of installation and extensive print material with specific instructions and demonstrative pictures (such as how to provide a feedback to a prompt for example or set up an appointment) will be vital in influencing user acceptance. More technologically experienced relatives and caregivers will require more advanced materials to allow them to modify the initial system settings to meet their personal needs, such as disabling door sensor alarms during high volume use.
Training for the three main user groups is foreseen and will be carried out by technical partners before the start of the trials. More details about the training activities are presented in Section 4 of this report and will be provided in the upcoming deliverable from WP 2 D-2.2.2 "Service adaptation and customisation".

Method for assessing user acceptance for the ISISEMD services
Acceptance and use of the technological intervention by elderly and their caregivers is an important parameter in ISISEMD evaluation. Clinical acceptance of a home care intervention will depend on, at least, the degree of confidence which the ICG and FCG have in their work tasks using the application and performance satisfaction. If trial participants are not comfortable with the technology, or if the service does not work as they expect from the very first times, they are more likely to avoid using it. Additional risk factor for user acceptance from EP aspect is that sometimes they might forget which the purpose of the special box installed in their home is and thus feel confused about its presence. Another risk factor is that in the early stages of the illness, the patients sometimes does not confess their cognitive or memory decline and thus may resist (in general) that they need ICT support for their independent daily living.

User acceptance can be assessed by utilizing **Choice Modelling methodology**. Choice modelling is held to be the most accurate and general purpose tool currently available for making probabilistic predictions about human decision making behaviour in a particular situation. As opposed to utilizing a poll or survey, Choice Modelling predictions are applicable over large numbers of scenarios within a context and it is considered the most appropriate method for assessing consumer willingness to pay for quality enhancements in multiple dimensions.

For assessing user acceptance, we will make questionnaires and interviews with the users to determine their acceptance with the ISISEMD-services. Care givers (CGs) can be asked to determine how much they would be willing to sacrifice, pay or exchange to use a particular service/intervention. For example, an ICG may be asked to estimate how much they are willing to pay for an intervention or a FCG may be asked how much work time they would exchange for a service.

5.3.3 User Satisfaction

As the primary user group of elderly demented people shows a general resistance to technology, User Satisfaction is considered as one of the central measurements of the ISISEMD success. If the user is comfortable with a service, its aiding abilities are higher.

In the ISISEMD project, ***user satisfaction*** *can be defined as a user's critical evaluation of several aspects of the service.*
This evaluation is believed to be influenced by the user's expectations, perceptions, attitudes and personal values. Accordingly, **satisfaction is considered as a multidimensional concept** where different aspects should be considered and tuned to fulfil the user expectations and needs and thereby heighten the impact of the service. Therefore, user satisfaction will also be a central parameter in the improvement of the services during the pilot trail.

Method for assessing user satisfaction from the use of ISISEMD services

Similarly to assessing user acceptance, we will make questionnaires, interviews and perform observations with the users to determine their satisfaction with the ISISEMD-services. The **Quebec User Evaluation of Satisfaction with Assistive Technology** (QUEST 2.0) can be inspiring to this action [Demers 2001, Demers 2002].

QUEST is a method to assess how satisfied a person is with the use of an Assistive Technological Device (ATD) without considering how well the aid device is performing. To make a QUEST-analysis 12 items are evaluated; 8 items on the physical device or service and 4 on the service that is provided for the maintenance of the device or service. Below the 12 items are listed:

Device parameters:

Comfort	Physical and psychological well-being associated with use of ATD
Dimensions	Convenience of the device's size (height, width, length)
Simplicity of use	Ease in using the ATD
Effectiveness	Goal achievement with the ATD
Durability	Robustness and sturdiness of the ATD
Adjustments	Simplicity in setting/fixing the components of ATD
Safety	Degree to which the ATD is safe, secure and harmless
Weight	Ease in lifting and/or moving the ATD

Service parameters:

Service delivery	Ease in acquiring the ATD including length of time
Repairs and servicing	Ease in having the ATD repaired and serviced
Follow-up services	Ongoing support services for ATD
Professional services	Quality of information on ATD provided, accessibility and competence of professionals

For each of the parameters, QUEST provides evaluation questions. There are 5 possible answers for the questions.

1 – very unsatisfied
2- unsatisfied
3- somehow satisfied
4- satisfied
5 – very satisfied

Even though ISISEMD services cannot be fully considered as a single ATD, our evaluation will be based on QUEST as a method to evaluate user satisfaction. Relevant updates and additions will be made in the parameters to be evaluated. It will be further decided if the ISISEMD platform and services will be only evaluated as a whole or there will be also a separate evaluation per service or per service bundle.

Aspects of the value added services from ISISEMD platform to be assessed are:

- Easily managed, transparent and comprehensive user interaction
- Feelings of safety and security in the home
- Satisfaction in the ability to self-care and extend independence
- Enhanced social interaction
- Ability to locate EP in- and outdoors
- Ability to communicate remotely with EP
- Reduction in care burden for ICG
- Memory support

Another questionnaire that evaluates how people with dementia use technology in their everyday tasks is ETUQ - ***Everyday Technology Use Questionnaire*** [Nygård, 2002] and [Rosenberg, 2009]. The

ETUQ is developed to map out perceived relevance and competence in the use of everyday technology among older adults with MCI or mild dementia. However, it evaluates commonly used technology devices for personal care, household, data and telecommunications, shopping and transportation [Rosenberg, 2009]:

Household devices – iron, microwave
Activities in the home – TV, video/DVD player, computer
Personal care – electric toothbrush
Power tools – unspecified
Accessibility – levitator, code-operated door lock
Data and telecommunications – cell phone, email, internet
Economy and shopping – credit card, internet banking
Transportation – automated check-in at airport

It uses a four-category scale: 4= use without difficulty, 3=use independently with difficulty, 2=use with help from someone else, 1 = does not use anymore.

The ISISEMD interview guides for user satisfaction and acceptance by primary end-users and the questionnaires for the informal caregivers have been based on these two evaluations (QUEST 2.0 and ETUQ).
Interview guide for evaluation of user satisfaction from the ISISEMD platform by the primary end-user is included in Appendix D1.

Important note:
User acceptance and satisfaction are so very important in the process of introducing ICT services to elderly and also people with cognitive problems that these aspects will be two of the crucial factors which will define the susses of ISISEMD services. Therefore, in the evaluation of user acceptance and satisfaction, iterative process will be followed. The first evaluation will take place already after the first two months of the pilot trials, during the small-scale testing. There will be after that midterm and final evaluations. The drawback identified from them will be immediately provided to the technical partners to improve the services customisation.

5.3.4 Evaluation of Quality of Life of Primary End User

The World Health Organization [WHOQOL, 1995] defines **quality of life** *as one's perception about their current status in the perspective of their culture, mores and concerning their aspirations, opportunities and interests*.
It is a broad, multidimensional construct involving physical health, psychological status, environmental factors, social relationships, level of independence and individual convictions. The most common thread connecting quality of life (with dementia) assessment tools is that they are modelled after Lawton's constructs. *He stresses that QOL has temporal dimensions, including reflection on the past and expectation of the future, as well as appraisal of the present and the need for cues to reinforce identity*. Lawton identified four overarching dimensions that contribute to QOL [Lawton, 1969, 1983; 1991]:

1. Psychological Well Being (positive and negative affect)
2. Behavioural Competence (cognitive and functional abilities, weighted by third party assessment)
3. Objective Environment (caregivers and living situation)
4. Perceived QOL (paralleling behavioural competence but weighted by primary party assessment)

Going further in assessing QOL of patients with dementia, according to Scholzel-Dorenbos et al., [Scholzel-Dorenbos, 2007], the domains important for QOL according to patients with dementia are:

affect, self-esteem/self-image, social contact, attachment, physical and mental health, enjoyment of activities, sense of aesthetics, financial situation, security and privacy, self-determination and freedom, being useful/giving meaning to life and spirituality.

When assessing QOL, two perspectives come into play: the first is the subjective experience by the individual to be assessed; the second is the subjective perception by the proxy individual (usually a caregiver or physician or a closest relative). Because *quality* is a subjective term and different people perceive different levels of quality on the same subject, the problematic nature of measuring QOL becomes even more confounded when dealing with cognitive impairments. In standard rating scales for assessing QOL, it is very common that both the patient and her/his care-givers fill in the questionnaires. Very often, the scores of the care-givers or the relatives are lower than the patients themselves. This is due to the fact that they compare the current status of the patient with his/her best performance before the illness.

ISISEMD will utilize the Quality of Life – Alzheimer's disease, or QOL-AD, [Logsdon, 2002] measurement tool to assess EP QOL. It is designed for patients with mild to severe dementia, living in the home care setting. QOL-AD measures domains of: physical health, energy, mood, living situation, memory, family, marriage, friends, self as a whole, ability to do activities around the house, ability to do activities for fun, financial and a global "life as a whole" question. Comparing with Scholzel-Dorenbos domains, in the context of our study, we will focus on social contact, physical and mental health, enjoyment of activities, finances, security, self-determination and being useful.

Methods

The method to be used in assessing QOL will be a combination of approaches for the assessment of QOL in patients with dementia. These include **self-reports** by the individual with dementia, **proxy reports** by a family member or caregiver, and **participation observation** of behaviours assumed to be related to QOL. Each of these approaches has strengths and weaknesses.

Self-report directly involves the individual in the assessment, taking into account his or her subjective experiences, and places value on the perspective of the person who has the most to gain or lose from using the services. This respect for the autonomy of the individual is very important from a clinical and ethical standpoint.

Proxy reports are usually obtained from a close relative or caregiver of the affected person. They circumvent the cognitive limitations that are problematic for the person with dementia and can be used throughout the course of the disease.

Participation observation of behaviours believed to be associated with QOL has the advantage of being more "objective" in that ratings can be based on predefined behaviours and consistently rated over time. Limitations of this approach include uncertainty about whether what is being observed is what the individual considers to be important to his or her QOL. Direct observations may also be subject to many of the biases associated with proxy ratings. In addition, some raters are very alert and attuned to subtle nuances of affect and behaviour; others are not [Logsdon, 2002].

Brief presentation of QOL-AD

QOL-AD includes patient and proxy report of patient's quality of life, it is reliable and valid for individuals with MMSE greater than 10. It is 13-item questionnaire with 4-pt responses which could be completed as interview for primary user (Table 12 below). It takes usually 10 minutes. Answers are structured on a four-choice scale and items are rated according to *current* status. Patients complete the QOL-AD in an interview format and ICG complete a questionnaire, both taking less than fifteen minutes. Answers are recorded and EP response scores are doubled, added to ICG scores and the total is divided by three to give more weight to the primary subjective evaluation; higher scores indicating higher reported quality of life. Interviewers will use a set of explicit instructions in order to avoid influencing participant responses. Participants will also follow along on their own copy of the measurement and can either respond verbally or mark their own response. If an EP is unable to comprehend/respond to more than two items, the interview will be discontinued and that EP will be

considered "unable or unwilling to complete the assessment." The participant version of the instrument could be seen in Appendix C4.

It must be noted, that similar to MoCA rating scale, QOL-AD should exist in corresponding versions in Finish, Greek and Danish in order to be used by ISISEMD regional partners. QOL-AD has been already in use by AA in Athens and they have Greek version. Currently Finish version does not exist. To amend this, a leading authority in quality of life studies in Finland (Professor Olli-Pekka Ryynänen from University of Kuopio) has been contacted to help translate and adapt version of QOL-AD in Finish.

5.3.5 Evaluation of Quality of Life of Informal Caregiver (ICG)

It is well known that a chronically disabled person may often disorganize the life of the entire family and disrupt the existing balance among them. Patients in advanced stages of the disease become dependent upon family members and require permanent help from the care-givers, resulting in a declining former professional life, abilities to manage the household and to perform self-care. The need for permanent care and help to the chronically disabled person leads to a decrease in the quality of life of care-givers [Ellgring, 1993], [Gallo, 1990].
Quality of life means "the perception and evaluation by the patient (her- or himself) of the impact that the disease and its consequences have produced in her/his life" [Martínez, 1997].

It is also well documented that caregivers of persons with dementia experience substantial stress from the care giving tasks they perform. The **concept of the burden** of care was defined by Zarit [Zarit, 1980], an American gerontologist, as the discomfort encountered by the primary caregiver of an older family member, including the caregiver's health, psychological well-being, finances and social life. Since, there have been numerous studies showing the negative impact of increased caregiver stress on the person with dementia as well as caregiver overall health.

*Assessing **caregiver burden** is a measure of how straining the caregiver experiences the care giving task to be, involving objective burden (e.g. number of tasks, time per task) and care giving capacity, among others.*

To measure burden and, thusly, effects from interventions aimed at reducing burden, the Zarit Burden Interview (ZBI) full revised version [Zarit, 1985] could be used. It consists of 22 items and reporting excellent internal consistency [0.89; Zarit , 1987]. ZBI measures emotional strain, level of frustration, fulfilment, relational, caregiver uncertainty, mental, social, financial, support and physical domains of informal care-giving. It consists of a list of statements, which reflect how people sometimes feel when taking care of another person. After each statement, ICG indicates how often they feel that way - never, rarely, sometimes, quite frequently, or nearly always.
The whole rating scale could be seen in Appendix C5.

Another, more recent and advanced assessing tool for measuring QOL of informal caregivers, specifically designed for carers of patients with cognitive problems, is Glozman rating scale [Glozman, 1998]. This is the Scale of Quality of Life of Care-Givers (SQLC). It analyses the quality of life of parkinsonian patients' caregivers and additionally some factors determining their social dis-adaptation. It is a comprehensive questionnaire covering the persons' activities from different aspects: professional, family related, social and others. It evaluates both qualitatively and quantitatively the principal levels of the subject's activities: (a) professional activity of the care-giver, (b) social and leisure activities, (c) responsibilities of the care-giver to help the patient in everyday living. It is in total of 16 questions, divided in three sections.

The partners from ISISEMD consortium, based on own experience and on the consultation with specialists from the national Alzheimer Associations, find SQLC rating scale very suitable for the purpose of the project evaluation. Additionally, the formulation of the questions is neither positive nor

negative which gives a very good basis of objective evaluation. SQLC is already in use in Athens Alzheimer Association. Instructions how to administer the instrument are available in [Salec, 2004].

Another instrument which is focusing on evaluating how much time the informal caregivers spend for caring for a patient, is the Caregiver Activity survey (CAS), presented in [Davis, 1997]. The activities measured are in relation to the daily activities in the home that must be performed by the patient.
The framework of evaluation is spanning off the last 24-housrs and the instrument is self-administering by the informal caregiver and takes approx. 5 min.
This rating scale is designed to be used as a means of evaluation of the economical implications of the Alzheimer disease on the informal caregiver and also the potential effect of therapy means in the treatment and care of Alzheimer patients. It requires initial training session.
The whole CAS instrument could be seen in Appendix E2.

5.3.6 Instrumental Activities of Daily Living (IADL)

Quality of life for the ageing population is associated with the ability of the elderly people living independently and with dignity without having the need to be attached to their children, grand-children or any other person whose help would they need for their daily life and social behaviour. The dementia is one of the problems that hinder these people's ability to have such an independent life, making necessary the presence and monitoring of their daily activities by care-givers.

Activities of daily living (ADL) for old population in general are divided in Basic ADLs and Instrumental ADLs.

1. **Basic ADLs**
   The basic activities of daily living consist of these self-care tasks: Bathing, Dressing and undressing, Eating, Transferring from bed to chair, and back; Voluntarily control urinary and faecal discharge; Using the toilet, Walking (not bedridden).
2. **Instrumental ADLs (IADL)**
   Instrumental activities of daily living are not necessary for fundamental functioning, but enable the individual to live independently within a community: Light housework, Preparing meals, Taking medications, Shopping for groceries or clothes, Using the telephone, Managing money.

ISISEMD services focus on partially supporting instrumental ADLs mainly related to meals intake, Taking medications and Using the telephone tasks, safety procedures and emergency responses.

ADLs and IADLs have statistically been proven to be correlated with reported caregiver burden. In order to better equip the trial home with appropriate intervention services, an accurate account of physical functional abilities is also needed. Rather than using only observations or self-reports, ICGs will be presented list of IADLs and asked to report which they assist with and approximate time spent assisting the care receiver. In the initial home interview, an Occupational Therapist (OT) will assist ICG in answering for daily activities as OTs are specially trained in assessing patient functional abilities.

Important consideration:
Assessment of basic ADL and IADL provide the care team with an assessment of physical functional abilities. These results will serve to help ISISEMD accurately to fine-tune the services to the end users specific needs. **It should be emphasized that although both parameters of physical functioning are measured, ISISEMD is mainly providing services and solutions to aid IADLs (secondary effects may aid ADLs, but it is not the purposed goal).**

IADLs will be evaluated using Lawton and Brody's IADL Scale [Lawton, 1969]. The exact parameters which will be measured with Lawton and Brody's IADL Scale could be seen in Section 5.4.5.

As an optional choice for the regional partners who are the care providers, ADLs could also be assessed. In this case, Katz's ADL Scale [Katz, 1970] will be used. The exact parameters which will be measured with Katz's ADL Scale could be seen in Section 5.4.5.

5.3.7 Cost Utility Analysis

Finally, using data from the outcomes of QOL and IADLs assessments for the primary end-users and the informal caregivers, Cost Utility Analysis (CUA) of ISISEMD services will be done. This will be carried out after the end of trial period.

Cost-utility analysis (CUA) is a form of economic analysis used to guide procurement decisions. The most common and well-known application of this analysis is in pharmaco-economics, especially health technology assessment (HTA).
In health economics, the purpose of CUA is to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries. Hence it can be considered a special case of cost-effectiveness analysis, and the two terms are often used interchangeably.
Cost is measured in monetary units. Benefit needs to be expressed in a way that allows health states that are considered less preferable to full health to be given quantitative values. However, unlike cost-benefit analysis, the benefits do not have to be expressed in monetary terms. In HTAs it is usually expressed in **quality-adjusted life years** (QALYs).
A complete compilation of cost-utility analyses in the peer reviewed medical literature is available at the CEA Registry Website
On the plus side, CUA allows comparison across different health programs and policies by using a common unit of measure (money/QALYs gained). CUA provides a more complete analysis of total benefits than simple cost-benefit analysis does. This is because CUA takes into account the quality of life that an individual has, while CBA does not.

Health Technology Assessment (HTA) is a multi-disciplinary field of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care. [INAHTA, 2009]
It is intended to provide a bridge between the world of research and the world of decision-making [Battista, 1996]. Health technology assessment is an active field internationally and has seen continued growth fostered by the need to support management, clinical, and policy decisions. It has also been advanced by the evolution of evaluative methods in the social and applied sciences, including clinical epidemiology and health economics. Health policy decisions are becoming increasingly important as the opportunity costs from making wrong decisions continue to grow. [Menon, 1996]

Cost utility analysis will be part of the overall assessment methodology of ISISEMD services.

5.3.8 Important points to be considered

Carrying out the interviews
The intention is to carry out the interviews separately with primary subjects from relatives/partners because the care for a person with dementia puts a lot of burden and psychological stress on the informal caregiver which is documented as affecting their evaluation. It is expected that the ICG could express more sincere opinion when interviewed alone.
In addition, when EP lives with a partner, in the everyday tasks the partners compensates for the declined functions of the EP and in many cases EP does not realise that he/she a decline.

A note for the international rating scales
It must be underlined though that all these international rating scales which have been talked about in the previous sections (MMSE, MoCA, QOL-AD and SQLC, CAS) are initially published in English.

As explained in the previous sections, they need not only to be translated to the local language but also to be adapted. This is to avoid different understandings in the formulations leading to inaccurate results, coming from some cultural difference in different countries. For the tests for which translations already existed in Greek, Danish and Finish, they were obtained from MAPI Institute in France, specialised in rating scale translations. For the tests that do not have translation, the regional partners are in contact with their scientific dementia advisors who help them with the translations.
In addition to that, there could be small differences in the range of the scores in the countries. Therefore, the need for their validation and standardisation. However, validation of these tests requires running of the tests in each country with many subjects, usually more than 100 patients per country. This is a process which cannot be done in the framework of the project and usually is done by some authorised organisation.

Moreover, in order to be used for research purposes by the project partners, who are the care provider organisations, permissions for use were obtained by all the authors by each regional partner. In the same way, instructions how t carry out the tests were also obtained by the authors.

Conclusions for Section 5.3

Evaluation of ISISEMD services from human point of view is quite complex task, which has many aspects. The services will be evaluated with all three main user groups for user acceptance, user satisfaction, and quality of life improvements. With evaluation of these aspects, ISISEMD partners aim to be able to assess the introducing this new technology in the everyday life of senior citizens with mild dementia and their closest relatives from different angles and revealing different layers of factors influencing the process. In the evaluation process, some standard rating scales will be used, together with tailor made questionnaires and quantative interview.
The following Table 13 presents summary of the test methods/tools and to which group of test participants they will be applied:

Table 12: Matrix of the evaluation methods and instruments

Evaluation aspect	Assessment tool	End user involved	Time demand	Assessment method
Assessing QOL of primary end-user	**QOL-AD**	EP	3x *10 minutes*	Questionnaire with support
Assessing care burden of informal caregiver	**ZBI**	ICG	3x *15 minutes*	Questionnaire self administered
Assessing QOL of informal caregiver	**SQLC and CAS**	ICG	3x *10-15 minutes each*	Questionnaire self administered
Assessing cognitive decline for primary end-user	**MoCA**	EP	3x *10-15 minutes*	Questionnaire with professional (Certified for MoCA)
Assessing cognitive decline for primary end-user	**MMSE**	EP	3x *30 minutes*	Questionnaire with professional (Certified for MMSE)
Assessing activity of daily living	**ADL/IADL**	EP	3x *15 minutes*	Questionnaire with occupational therapist
User acceptance of assistive technology or service and User satisfaction	**User Satisfaction/ Acceptance**	EP, ICG, FCG	3x *30 minutes*	Structured interviews with ISISEMD personnel from the care providers

The next section presents overview of the parameters which will be evaluated using these methods and tools.

5.4 Parameters to be evaluated

This subsection discusses which parameters will be evaluated during the tests and the evaluation process and how they will be evaluated.

5.4.1 Parameters for Stage of Cognitive decline

The Montreal Cognitive Assessment (MoCA) assesses the cognitive domains of:

- Executive function,
- Visio-spatial function,
- New learning,
- Attention and concentration,
- Abstraction,
- Memory,
- Language,
- Conceptual thinking,
- Calculations and
- Orientation.

5.4.2 Parameters for Quality of Life of primary end-user

According to Schölzel-Dorenbos et al. [Schölzel-Dorenbos, 2007], domains of life important to persons with dementia are:

- Affect
- Self-esteem/self-image
- Social contact
- Attachment
- Physical and mental health
- Enjoyment of activities
- Sense of aesthetics
- Financial situation
- Security and privacy
- Being useful/giving meaning to life
- Spirituality

Of these, Quality of Life – Alzheimer's disease (QOL-AD) directly evaluates the person with dementia:

- social contact (family, friends)
- attachment (marriage)
- physical and mental health (physical health, energy, mood, memory)
- enjoyment of activities (leisure)
- financial situation (finances)
- being useful (ability to contribute)

QOL-AD will additionally evaluate living situation, self as a whole and life as a whole of the person with dementia.

5.4.3 Parameters for informal caregiver burden and Quality of Life

The Zarit Burden Interview (ZBI) full revised version [Zarit, 1985] measures the following domains of informal caregiver burden:

- emotional strain,

- level of frustration,
- fulfilment,
- relational,
- caregiver uncertainty,
- mental,
- social,
- financial,
- support and
- physical domains.

The Glozman rating scale (SQLC) measures the following domains for QOL for informal caregivers:

- Professional activity
- Social and leisure activities
- Responsibilities of the care-giver to help the patient in his everyday living

5.4.4 Parameters for caregiver activities survey (CAS)

Davis [Davis, 1997] use parameters for time spent for carrying for a patient with dementia (including time for reminding him) related to:

- Communicating with the person
- Using transportation
- Dressing
- Eating
- Looking after one's appearance
- Supervising the person

5.4.5 Parameters for Activities of Daily Living of primary end-users

Katz's ADL Scale [Katz, 1970] assesses:

- Bathing
- Dressing and undressing
- Eating
- Transferring from bed to chair, and back
- Voluntarily control urinary and faecal discharge
- Using the toilet
- Walking (not bedridden)

Lawton and Brody's IADL Scale [Lawton, 1969] measures:

- Light housework
- Taking medications
- Shopping for groceries or clothes
- Using the telephone
- Care of others (including selecting and supervising caregivers)
- Care of pets
- Child rearing
- Communication device use
- Community mobility
- Financial management
- Health management and maintenance
- Meal preparation and cleanup

- Safety procedures and emergency responses

5.4.6 Parameters for user acceptance and satisfaction

User acceptance will be measured for the following domains:

- Relative advantage (the extent to which a technology offers improvements over currently available tools)
- Compatibility (its consistency with social practices and norms among its users)
- Complexity (its ease of use and learning)
- Trialability (the the opportunity to try an innovation before committing to use it)
- Observability (the extent to which the technology's outputs and gains are clear to see)

User satisfaction will be measured for the following domains:

- User interaction with the platform
- Feelings of safety and security in the home
- The ability to self-care and extend independence
- Enhanced social interaction
- Ability to locate EP in- and outdoors
- Ability to communicate remotely with EP
- Reduction in care burden for ICG
- Memory support

5.4.7 Other relevant factors

Objective parameters:

- Factors related to the person with dementia (education, profession, ethnicity, diagnosis and severity, other health issues, functioning abilities, acceptance of problem, ADLs and IADLs, etc.)
- Factors related to the caregiver (relationship to the person with dementia, the nature of the care giving role, living arrangement, employment status, perceptions of EP, expected outcomes of non-pharmaceutical intervention, etc.)
- Factors related to the environment (nature and extent of services provided, EP's home environment, etc.)
- Factors related to the assistive devices (design, function, reliability, etc.)
- Factors related to the researchers (their opinions, problems the assistive device is meant to address and opinions about potential usefulness)

Subjective parameters

- If assistive technologies are useful to people with mild dementia and their caregivers.
- Potential outcomes depending on the type of problem addressed (e.g. falls at night, leaving the stove turned on, and better social interaction).
- Importance of the problem to EP, caregivers and society and how the(se) problem(s) affect them.

Also very relevant for the overall assessment of ISISEMD services are the societal benefits expected to be achieved and to be evaluated:

- Saving of personnel, time and travel for FCG, leading to reduced overall health and social care costs
- Possibility of reallocating responsibilities and tasks among FCGs in such a way that personnel with lower education levels can perform tasks when supported by ISISEMD
- Possibility to increase the number of patients one FCG is responsible for
- New business opportunities for European industries and SMEs

However, their evaluation will be part of the overall assessment methodology and will be presented in Del 3.3.1 “Assessment Methodology on ISISEMD platform” due in M13.

5.5 Success criteria for the ISISEMD platform

In the end, based on the overall evaluation of the ISISEMD platform, achievement of success criteria will be reported. The following Table 14 presents examples of evaluation questions and such success criteria (as presented in ISISEMD description of Work).

Table 13: Examples of success criteria

Parameters	Example of questions	Examples of Success Criteria
Elderly Perceptions	- Were elderly satisfied with the homecare service compared to the alternative(s)?	70-75% of the elderly feel satisfied using the system
Caregiver Perceptions	- Were attending and/or consulting caregivers satisfied with the homecare application compared to the alternative(s)?	75% of the caregivers feel satisfied using the system
Relatives perceptions	- Were relatives satisfied with the homecare service compared to the alternative(s)?	75% of the relatives feel satisfied using the system
Quality of Care and Health Outcomes	- What were the effects of the homecare application on the care process of care compared to the alternative care options? - What were the effects of the homecare application on immediate, intermediate, or long-term health outcomes compared to the alternative(s)?	70-75% of the test subjects feel positive effects
Access to Care	- Did homecare affect the use of services or the level or appropriateness of care compared to the alternative(s)? - Did the services affect the timeliness of care or the burden of obtaining care compared to the alternative(s)?	Increase of access to care with 20-30%
Home Care Costs and Cost-Effectiveness	- What were the costs of the homecare application for participating care providers or compared to the alternative(s)? - What were the costs of the homecare application for elderly and families compared to the alternative(s)? - What were the costs for society overall compared to the alternative(s)? - How did the cost of the system relate to the benefits of the homecare application compared to the alternative(s)?	10-20 % decrease in costs for elderly and families

5.6 Specific Key Performance Indicators (KPIs)

Additionally, a ***set of specific KPIs*** **(Key Performance Indicators)** related to the specific project objectives and expected impact of the project has been initially drafted. They are presented below:

Table 14: Set of specific Key Performance Indicators (KPIs)

Specific KPI	Target per region
Number of elderly people actually recruited for the Test and Control Groups	The target is 20 elderly people from each region to be involved in the evaluation of the ISISEMD services
Number of relatives actually recruited for the Test and Control Groups	The target is 20 relatives from each region to be involved in the evaluation of the ISISEMD services
Number of official care-givers actually recruited for the Test and Control Groups	The target is 10 official care-givers from each region to be involved in the evaluation of the ISISEMD services;
Number of elderly people actually recruited for the Test and Control Groups.	The target is 20
Use of the ISISEMD platform by elderly with mild dementia. During the trials the elderly will be asked to use the ISISEMD services to keep in touch with their formal and informal care-givers.	The target is that at least 90% of the members of the Test Group use the ISISEMD services till the end of the project
Use of the ISISEMD platform by relatives. During the trials the relatives will be asked to use the ISISEMD services to care for their relatives with mild dementia	The target is that at least 90% of the members of the Test Group use the ISISEMD services till the end of the project
Number of prevented risks for the health of the elderly test persons in their own home. The system is designed to prevent risks coming from improper use of home/kitchen electrical equipment.	Target is zero such risks during the trial period

Outcome and statistics for these KPIs will be done after the end of the trial period, together with the overall assessment of the ISISEMD services.

5.7 Quantifiable Success Indicators for the pilot sites

High level ISISEMD project objectives have been defined in Description of Work. Following these objectives, the consortium has defined a numbered list of operational objectives following the SMART principle (Specific, Measurable, Accurate, Realistic and Timed) in order for the consortium and for the European Commission to assess the project partial or full success. For each of these objectives, Quantifiable Success Indicators (QSI) has been also defined.
They are presented in the table below. From these objectives and QSIs, all but O3 are not related to the testing of ISISEMD services with human subjects. Outcome and statistics for these QSIs will be done after the end of the trial period, together with the overall assessment of the ISISEMD services

Table 15: Quantifiable Success Indicators for the project objectives

Project objective	Quantifiable Success Indicators for each Project objective	Measurement unit
O1 - Improve care of elderly with cognitive problems by offering them ICT services for self-care	Satisfaction of elderly using ISISEMD services	% of end-users
O2 - Improve care of elderly with cognitive problems by offering the care-givers ICT services	Satisfaction of the care-givers using ISISEMD services	% of care-givers
O3 - Integrate existing partial services and solutions from the partners	Operation of ISISEMD integrated prototype	Integrated prototype working
O4 - Evaluate the pilot set of scalable ISISEMD services under realistic conditions and for adequate time period	Run the pilot service for a certain period	Number of months
O5 - Demonstrate European acceptance of ISISEMD service	To be tested in a number of European member states	Number of regions
O6 - ISISEMD services to be demand-driven	Involve all stakeholders in the pilot service	Number of user groups
O7 - Prove cost-efficiency of the services	Reduction in the number of hours spent per end-user	% reduction of hours spent

5.8 Important point to be considered during the tests

One important point which needs the attention of the partners for the evaluation of the trials is: How to ensure that the test persons provide their honest feedback on the questionnaires and during the interviews? It sometimes happens that during trials with human subjects, they tend to answer more positively then they really feel.

This is actually a general aspect when usability evolutions are carried out. The partners will apply a number of measures to prevent this:
One measure for this is the selected approach for triangulation of methods aiming to avoid insincere answers. Other measure is that the interviews for use satisfaction and acceptance will be administered by persons from the care-giver organisations that are specially trained for the techniques for objective interviews. Also for the questionnaires for the rating scales (MoCA, MMSE, QOL-AD, SQLC, CAS, ZBI, IADL) will be administered by staff trained to perform such questionnaires.

5.9 Overall work plan for the pilot sites

The first task in WP3, namely installation of the pilots for the small scale study, will take place in M12 in all four regions. This will ensure that in the very first month of the operation of the pilot services, the systems are working properly in the users' homes.

The inclusion and exclusion criteria for the user test groups are identified in this document. With these criteria in mind, the regional partners would have been identified a group of 22-23 POTENTIAL trial participants (who will be split after that to test and control groups) in the period M11. This group of 22-23 POTENTIAL trail participants would have been found via the channels, explained in Section 3.1.5.1.

During 12 months (M13-M24), the pilots will be used by the test users under realistic conditions – older adults in their homes; the professional caregivers in their work tasks, performing their daily work to care for the elderly; the informal caregivers/family, also in their everyday activities to care for the seniors. The services will be first tested in a smaller scale, with a few end-users at each site for 2 months (M13-M14), in order to identify if some major problems exist before the large scale testing

with all users during the rest of the testing period until M24. The pilot sites will be maintained and serviced during this second phase by the technical partners.

Before the start of the test period in M13, a few persons from the care-provider organisations will be trained to use the system as expert users with the aim to provide support and guidance to the test participants during the 12-month test period. This training will take place in each pilot site, in the form of a small workshop, by the technical partner who is doing the installation. Such training workshops, if possible, will be also done for the relatives who live in the area where the pilot services will be tested. For this purpose, demo-rooms will be used as explained in Sect. 3.1.5.2.

As mentioned in Section 3.1, in some cases, the illness may progress fast; therefore the process of cognitive assessment for the stage of dementia (test MoCA/MMSE) will be done immediately before starting the test period – in M12. For the same reason, MoCA/MMSE tests will be again carried out after 6 month period. This is also necessary, because if during the first 6-month period, more cognitive problems appeared for the elderly person, they may need advanced service level. This testing of the cognitive decline in the middle of the 12-moith test period will ensure that the correct service level is provided to the client. At last, in the end of the testing period, MoCA/MMSE test will be carried out again. This will be done because part of the test participants, who have been in dementia stage 4 during the test period, may have progressed to dementia stage 5, thus making the use of some of the services inappropriate for them. A very specific example is the Outdoor Guard Service from service bundle C (C1) for providing help for the person to find the way to home in case they become lost. As soon as the dementia stage is progressed and the client is not safe to go alone in the streets because of risks for traffic accidents, this service will not be offered any longer to them since at this stage they may need to be admitted to dementia care home anyway.

Another important aspect of the work plan for the test pilots is the evaluation of the quality of life (QOL) for the primary user group and the informal care-givers. The types of QOL test was described in Section 5.3.4. QOL evaluation will be carried out in the beginning (M13) and the end (M24) of the test period using standard questionnaires. Similarly, assessing IADL will be carried out at the same time. QOL-AD will be administered for the test group of EP, while SQLC, ZBI and CAS will be administered to their relatives, in order to measure the baseline for their quality of life and care burden. These tests will be carried out also in the middle of the pilot period, in order to access the level to which EP and ICG rely on the assistive services after the initial months when they are not very used to use the services.

As described in Sections 5.3.2 and 5.3.3, to evaluate the user acceptance and satisfaction from using ISISEMD services, iterative process of periodically receiving user feedback will be applied with overall goal of constantly improving the services in the life time of the project. The first evaluation for this aspect will be carried out in the second half of M14, after the smaller scale testing with a few test participants. The main goal of this will be to identify some major flaws in the design of the services which will be avoided with the full scale testing.

Then, mid-term and final evaluation for user acceptance and satisfaction will be done in M18 and M24 respectively. Test materials are described in the Appendix section of this report.

At the end, based on feedback of this evaluation, identification of possible weaknesses in the design will be presented to the technical partners and recommendations for improvements will be given.
The following Figure 1 depicts the work plan for the pilots.

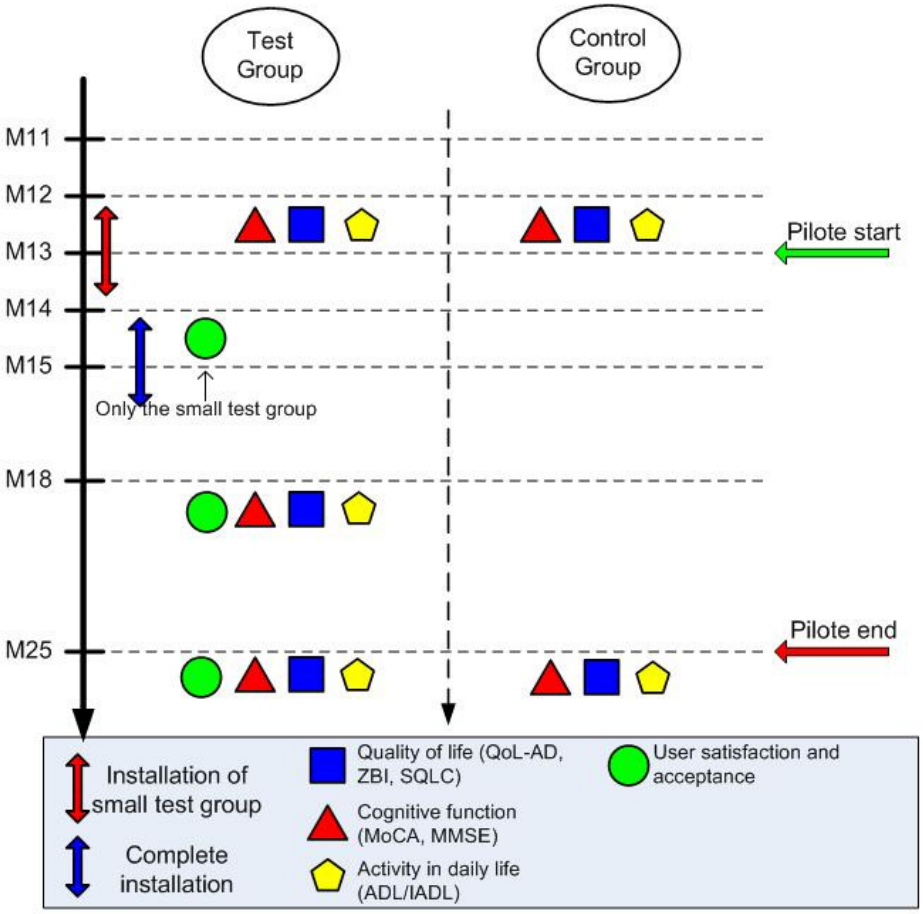


Figure 2: Work plan of the pilots and instruments to be administered

5.10 Selecting and organising tasks to test

The test tasks will aim at evaluation of the functionality of the ISISEMD platform with all the services and for validation of the usability of the assistive technology. Both the ISISEMD portal and the client CareBox will be evaluated by the respective user groups.
Below examples of the main test tasks are listed:

For ISISEMD portal:

- Task A: creation of three formal caregivers and update of information for them
- Task B: create three elderly persons and assign caregivers to them
- Task C: find EP1 information and assign home safety services and outdoor positioning service to EP1.0
- Task D: Assign the Service for daily reminders for EP2
- Task E: login as FCG1 and open the assigned services for EP1.
- Task F: login as FCG2 and find EP2 and access the service for reminders for daily activities for EP2
- Task G: find EP1 and remove service Smoke detector-Fire Alarm from his services; delete EP1

For ISISEMD CareBox (client site):

- Task A: (from the portal) - login as region, find EP1 and assign the service for daily reminders, brain games, memory lane for EP1;
- Task B: (As a care-giver) - login as CG1 and create different reminders for EP1 with the necessary settings
- Task C: (as a patient EP1 – from CareBox)
- Log-in as EP1 and see the information shown on the GUI and hear the upcoming reminders
- Task D: (As a care-giver from the portal) - Log-in as CG1 and update/remove reminders for EP1
- Repeat Task C: (as a patient EP1 – from GUI EP) – to see the changes of the settings in the reminders on the CareBox screen
- Task E: (As a care-giver from the portal) Log-in as CG1 and add/remove two more pictures for EP1 in the service "Memory Lane"
- Task F: (As a patient EP1) from CareBox – see the changes in the CareBox in the list of the pictures for "Memory Lane"
- Task G: (As a patient EP1) from CareBox – play Brain Game

Similar test tasks will be carried out for all the services.

5.11 Description of test scenarios

Based on the above listed tasks to be tested, step by step test scenarios will be prepared. Some examples of test scenarios are presented in Appendix F.

5.12 Preparing the testing environment

The test environment will be carefully prepared. Already in M12 demo rooms in the regions will be organised, with one of the aims – to help the regional partners to get hands-on experience on installing the systems in home environment.
To help in this process, the technical partners are preparing installation manual and installation video. Additionally, help line for the technicians will be established by the technical partners. In order to reduce installation costs, the list of equipment has been prepared in such a way, that it is not necessary authorised electrician to make the installations. Also, in the beginning of M12, physical meeting will be held with all partners, where installation demonstration will be done.
After making the installations in each of the homes, the floor plans of the homes will be drawn and the place of the sensors will be noted on them. These maps of the equipment of each home will then be uploaded on ISISEMD portal, to facilitate the everyday use of the home safety services.

5.13 Forming the test teams

The test teams will be formed depending on the type of the data collection methods to be administered. Overview of who will administered what type of questionnaire to which group of end user, is presented in Table 12: Matrix of the evaluation methods and instruments.

Conclusions for section 5
This section presented one of the major contributions in this report and very important aspects of measuring the success of ISISEMD services – namely, the trial objectives, parameters to be evaluated, the methods which will be used in the evaluations, etc. Additionally, all relevant ethical and legal aspects will be considered during the trials, as explained in the beginning of the section in ethical and legal framework for the ISISEMD trials. It was also explained which will be test tasks, the test scenarios, how the test teams will be formed and how the testing environments will be prepared.

Section 6 - Conclusions and Further work

The main user group of ISISEMD services will be not only old citizens but even those having mild cognitive impairments or mild dementia. This poses a number of challenges not only in the process of adaptation and customization of the services, but also in the evaluation and validation process via the trials in real-life settings.

In this respect, the goal of a controlled study will be to get from the trail participants the maximum amount of feedback about the usability, accessibility, acceptance, motivation of use, if they like or not and how do they like the services. The question is also to know the characteristic of the primary end-user in order to have the appropriate strategies in the evaluation. Since elderly people are not experts in communicating technical information, one of the most critical issues is how to define the indicators to be measured and how to measure them during the evaluation. In addition, partners and closest family play a key role in the level of independence of old people with cognitive impairments or mild dementia. Certainly, they act as informal caregivers and support elderly dependent people. A system like ISISEMD platform is complementary to the daily support provided by them and the relative itself is considered a user of the system. Their opinion for the user-friendliness of the system matters too, it must be also evaluated. All these crucial aspects for the trial planning have been discussed in this report.

Initially, the specifics of dementia as illness and the general profile of the main end-user groups of ISISEMD services were described. The main end-user groups of ISISEMD services are defined as follows: the elderly persons (EP), the informal caregivers (ICG) and the formal caregivers (FCG). Due to dementia, EP have decline in memory or in other cognitive ability. Depending on the stage progressing of the disease, they have difficulties to live independently or it is very dangerous for them to live independently. It is expected that they have very limited knowledge about using new technology and it will be difficult for them to learn to use it if the illness has progressed. ICG are further split in two subgroups - the ICG-partners and ICG-children. ICG-partners are statically females and do not have very good knowledge for the new technology either. For them, the burden to care for their ill partner causes a lot of stress and social isolation. ICG-children are usually middle-aged and statistically females too, who is expected to be able to use technology on a daily basis. FCG are generally females with formal education in care for seniors or in care for dementia patient. It is expected that they use PC, mobile phone, etc in their professional tasks.

In order to have the correct sample of users to test the ISISEMD services during the trial period, it is important to find the right trial participants. This will be based on strictly defined main and secondary inclusion and excision criteria. The main inclusion criterion will be adults over 60 years of age, diagnosed with dementia stage two (Age Associated Memory Impairment) to four (Mild Dementia). The World Health Organization (2007) International Classification of Diseases (ICD-10) will be used to classify dementia as disease. The classification standard for dementia stages which will be used is The Global Deterioration Scale (GDS), developed by Dr. Barry Reisberg. To assess the level of cognitive decline, international rating scales will be utilized.

As a primary rating scale, Montreal Cognitive Assessment (MoCA) will be used. MoCA is useful for assessing milder stages of cognitive impairment, including Mild Cognitive Impairment (MCI) and mild Alzheimer Disease (AD) where there are currently no other screening tools as quick and accurate to distinguish MCI from healthy controls. Due to its high specificity and sensitivity in detecting MCI, MoCA will be used as the primary cognitive assessment tool in determining level of cognitive functioning and changes over the course of the clinical trials. As a secondary option – Mini Mental State Exam (MMSE) is selected. The scores for inclusion will be 19-26.

The sample of trail participants from the primary group will be a total of 80 persons. There will be 20 primary end-users per region, with a back up of 2-3 persons to allow for substituting some drop out. These 20 primary end-users will be randomly split in a test and a control group, 50% division. For the caregivers - the aim is to have a trail group of 80 persons from ICG and 40 persons from the FCG in total, equally split per region and in test and control groups. However, their selection will depend on

the primary end user and will not be random. Potential participants (adults with mild dementia and their informal caregivers) will be recruited with the help of general and nurse practitioners, aging and cognition specialists, memory and dementia clinics and local organizations for aging programs and services.

During the trial period, all ethical rights of the citizens will be respected and the trial will be carried out according to the national regulations and the privacy of the trial participants and all data related to this will be ensured. All applicable national and international laws and acts will be respected too. The trial participants will be recruited only after approval from Ethical Committees is granted for each region (if such approval is required). Very important activity in preparation for the trails will be preparation of the trail protocols – a set of materials, necessary for these applications and for carrying out the trials. The protocol will include a number of short documents providing information about guidelines for oral information for the trial participants, guidelines for information interview, written information for participants, list of equipment, informed consent form, description of the services, user guides, etc. By M11, the applications to the Ethical Committees in all regions where required have been sent. For the time being, approval has been granted for the pilot site in Finland and provisionally approved in Belfast site.

Evaluation of ISISEMD services from human point of view is a quite complex task, which has many aspects. The services will be evaluated with all three main user groups for user acceptance, user satisfaction, and quality of life improvements. With evaluation of these aspects, ISISEMD partners aim to be able to assess the introducing this new assistive technology in the everyday life of senior citizens with mild dementia and their closest relatives from different angles and revealing different layers of factors influencing the process. The major trial objectives will be:

- Measure improvements in quality of life for EP and ICG
- Measure acceptability of the services by all three groups
- Measure satisfaction from the use of the services by all three groups
- Measure efficiency of ISISEMD services for the formal caregivers

For assessing user acceptance and user satisfaction, ISISEMD partners will use their own explorative approach. In the core of this approach is “Triangulation of the three methods”. The test methodology will include questionnaires, participation observations, qualitative and quantitative interviews, use case description and analysis. To assess the user acceptance and satisfaction with the use assistive technology, specially designed ISISEMD questioner will be used, inspired by QUEST 2.0 and ETUQ instruments, which have specific focus on daily use of assistive technology and for adults with mild dementia. To measure quality of life improvements in primary user group, ISISEMD will utilize Logsdon rating scale - the Quality of Life – Alzheimer’s disease (QOL-AD). It is designed for patients with mild to severe dementia, living in the home care setting. To measure quality of life improvements in ICG group, Glozman rating scale will be administered. This is the Scale of Quality of Life of Care-Givers (SQLC). To measure reducing the burden of care, Zarit Burden interview (ZBI) will be administered for relatives. Since one of the expected impacts for relatives of introducing ISISEMD system is reducing the time spent by them in the everyday care, Caregiver Activity Survey (CAS) has been found as relevant for ISISEMD trials and will be used too.

Chronologically, the trials will run in a period of 12 months (March 2010-February 2011). There will be two stages – small-scale and large-scale validation. The services will be first tested in a smaller scale, with a few end-users at each site for 2 months, in order to identify if major problems exist before the large scale testing with all users during the rest of the testing period. Evaluation and refinement from the small-scale trial will lead to second iteration of customization. Mid-term evaluation will follow in the middle of the trial period. The final assessment will be carried out after the end of the trial.

To help the users during the trials, fist and second level support will be provided. The first level support will be provided by personnel who are trained and responsible to receive the requests from the end-users. The second level of support will be more technical to professional care-giving services - on

how to upgrade specific versions of the software installed, for example. There will be also help desk assisted by a hot line to allow for a phone communication channel. Training to all user groups is foreseen too. The activities will involve training of super-users in each region and educational and training workshops in each region. User guides have been also prepared.

This final version of the report provided information for aspects which could not be explained in M06 when the initial version of the report was submitted. Namely, final integrated set of services, selection of the services to be tested, list of equipment, definition of test tasks and test scenarios, supporting material for the trial protocol, etc.

Appendix A1 - Propose to Written Material for Trail Participants

This proposal of structure to the written material for trial participants is an edit of the appendix of "Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics"
[http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx]
This material must been only as an example what type of generic material was prepared and sent as application to Ethical Committees. Each region prepared their own version based on the more specific national templates and on their language.

The written material should respect Section 5.1.1.4 – "Written information for participants".

Contents of the information for participants

1. Front page/heading
2. Introduction
3. Purpose of the trial
4. Benefits of the trial
5. Side effects, stress, risks, complications and inconveniences - preferably listed in a box
6. Other possible treatments
7. Exclusion from and discontinuation of trials
8. Trial plan
9. Contact person
10. Information about financial matters
11. Access to trial results
12. Conclusion that requests the person to decide on participation in the trial.

Appendices:

- "The rights of a trial subject in a biomedical research project"
- The pre-printed consent form issued by the Danish National Committee on Biomedical Research Ethics

Structure and contents

Front Page/Heading

- Title: for instance "Information for participants about participation in a scientific trial involving individuals with dementia". The heading should be as readable and as inviting as possible.
- It must be clearly stated that it is a scientific trial and not a routine examination, a diagnostic examination or a treatment.
- The target group for the trial must be stated on the front page, e.g. healthy people or patients – including which patients.
- The formal name of the protocol. If an abbreviated title is used on the information and not the title stated on the notification form, the original title must be stated as well.
- The name of the relevant department and hospital.
- Footer with issue no., date and protocol number.
- To the extent possible questions should be avoided in headlines as such questions presume views on the part of the reader that may be non-existing. E.g. 'What side-effects occur?' (Presumes that there are always side-effects). Rather use 'Side-effects of the trial' or 'The trial's side-effects'.

Introduction

- Neutral terms such as "request for participation", "ask for" and the like should be used.

- I must be clear who the sender of the text is and who conducts the trial. E.g. 'The trial is collaboration between XX, XX and XX and we request whether you are prepared to participate'. Remember to maintain consistent clarity on these issues throughout the text.
- It is a good idea to explain the significance of research and of trials so that the person understands why his or her participation is requested.
- Explain that a refusal to participate in the trial or any later discontinuation of participation will not influence the person's right to present or future treatment.
- When describing the principle of voluntaries, it may be explained that the researchers benefit from knowing why a participant decides to leave the trial as this may influence results, but that individuals of course are free not to provide this information.

Purpose of the Trial

- The purpose and method must be explained to the trial subject in plain language and without unnecessary medical terms. When medical terms are nevertheless required, these should always be translated into everyday language in a parenthesis and translation should be provided consistently throughout the text. The description must be objective and not create expectations of unrealistic results. It should be pointed out that it is not known whether the trial may benefit the participants – and that this is the reason for conducting the trial.
- Information about the use of and the names of approved and non-approved medicinal products.
- The use of randomisation, blind preparations and treatment-free period must be described. In this connection terms from other semantic fields should be avoided, e.g. 'drawing lots'.
- The general procedure, including the use of invasive examination methods, must be described. Reduce any use of the passive voice, e.g. '10 blood samples are drawn'.
- It must be clear how many trial subjects are involved.

Benefits of the Trial

- The information must include whether the trial subject may or may not expect to benefit directly from the trial. This does not mean the direct benefit that the trial subject may gain through participation in the trial in terms of additional care or remuneration for his or her participation.
- Furthermore, it should be stated whether the trial will be of general benefit for instance to future patients or to science.

Side Effects, Risks, Complications and Inconveniences

- Any known and predictable side effects, risks, complications and inconveniences in connection with the trial must be disclosed. Information about side effects must be provided regardless of whether they are temporary, long-term, frequent or rare.
- In addition, it must be stated that there could be unforeseeable side effects or risks in connection with participation in the trial, including any control treatment. This is often the case when testing of non-approved medicinal products.
- Information must be provided about inconveniences, which are the practical difficulties and discomforts suffered by trial subjects, such as absence from work due to visits for check-ups, blood tests or the like.
- Side effects, risks and complications should preferably be listed in a box so that decoding is easier for the reader.
- Side effects, risks and complications should preferably be listed as 'frequent/not serious' and 'seldom/serious'.

Other Possible Treatments

- The trial subject must be informed of any other possible treatments in cases where the aim of the trial is both scientific and therapeutic.

Exclusion from and discontinuation of trials

- Trial subjects must be informed of any circumstances that may result in their involuntary exclusion from the trial and any circumstances under which the trial as a whole may be discontinued.

Project Plan

- How long will the trial take?
- How many visits?
- How will the treatment be given? And by whom?
- Which examinations will be involved?

It may be useful to tabulate the project plan if it involves many visits. This will provide a quick overview. Avoid using both a table and plain text to explain the same thing.

Reduce any use of the passive voice (is given, is taken) in the text. Use e.g. 'The nurse draws the blood samples' rather than 'blood samples are drawn' so that the reader knows whom he or she is going to meet.

Never use words from other semantic fields in the text. E.g. drawing lots, a cup of blood, and a spoonful of blood. Such words are associated with matters that in the patient's mind are far from the world of health care. Rather use more neutral words such as e.g. 'random distribution', 'decilitre' and 'millilitre'.

When medical terms are used these should always be translated into everyday language in a parenthesis – and translations should be consistently provided throughout the text. E.g. 'electrocardiogram (measuring of the heart's impulses)'

Contact Person

- The information must contain the name, address and telephone number of the chief investigator and at least one contact person associated with the trial. If the contact person can only be contacted at certain times, these should be stated.
- It is recommended that the chief investigator or another professionally competent person is the contact person.
- Introduce the contact person at the beginning of the text and make the identity of this person clear throughout the text in order not to create a distance vis-à-vis the reader.

Information about Financial Matters

- If the researcher receives any funding from private enterprises, foundations etc. in connection with the trial, this should be stated. The names of any sponsors and the amounts from each sponsor must be stated. The application of the financial aid shall be stated, showing which part of the aid goes to the researcher as e.g. a personal fee and which part of the amount is allocated to payment of salary to assisting staff, laboratory tests or other examinations, respectively. The reason for this is that it is up to the committee to assess whether the amount of the fee is reason-able in relation to the researcher's expenses for implementing the trial.
- It must be made clear whether the financial support is given as a fixed amount per trial subject (perhaps within a specified number) or as a lump sum for the entire project, and whether the money is paid to the researcher, to his/her department/institute, to a joint research fund or other recipients. It must also be stated how any excess financial support is to be used.

- Information about whether the chief investigator has any financial connection with the enterprises or foundations interested in the scientific trial in question. (It may also be stated whether other researchers in the group have such affiliations).

Access to Trial Results

- It must be explained where, when and how the trial subject will be able to obtain information about the trial results, negative as well as positive. This could for instance be in the form of a telephone number, a website or the like where the trial subject may obtain the information.
- If a trial subject after completion of the trial is allowed to receive information of which treatment he or she has been given, it would be appropriate to write in the information for participants that "completion of the trial" means that tests of all the trial subjects included should be completed and the data processed. In this way, the misconception that trial subjects can obtain information as soon as they have completed their participation in the trial is avoided. It may be explained that it could take some time before information on results can be provided (preferably further specified if possible).

Conclusion

Always provide a summary by way of conclusion of the text. Request that the person takes a decision and preferably let the person know that any further questions are welcome. E.g.' We hope that this information has given you sufficient understanding of what it means to take part in this trial and that you feel that you have a basis for taking a decision on your possible participation. If you would like to get more information please contact "*name*". Kind regards, *name*

Appendix A2 – The rights of a trial subject in a biomedical research project

As a participant in a biomedical research project you should know that:

- your participation in the research project is completely voluntary and can only take place after you have received both written and oral information about the research project and signed the consent form;
- you may at any time orally, in writing or by any other clear notification withdraw your consent to participation and withdraw from the research project. If you withdraw your consent, this will not affect your right to any current or future treatment or any other right you may have;
- you are entitled to bring a member of your family, a friend or an acquaintance with you to the informative interview;
- you are entitled to time to think it through before you sign the consent form;
- strict confidentiality is observed with regard to information about your health, other purely private matters and other confidential information about you disclosed in connection with the research project;
- information about you, including information about tissue and blood samples from you, will be stored according to the provisions specified in the Danish Act on Processing of Personal Data and the Health Act ;
- you will be able to get access to research protocols according to the provisions of the Danish Open Administration Act. This means that you can gain access to all documents concerning your participation in the project apart from the parts containing business secrets or confidential information about others.
- you have the right to complain and compensation can be paid pursuant to the Act on the Right to Complain and Receive Compensation within the Health Service.

(The above Appendix is published by the Danish National Committee on Biomedical Research Ethics and must be attached to the written information about the biomedical research project)
From: http://www.cvk.sum.dk/English/rightstrialsubject.aspx

Appendix A3 – Information to primary user (example from Belfast site)

Research and Innovation Project

Intelligent System for Independent living and SElfcare of seniors with cognitive problems or Mild Dementia
ISISEMD Project

Participant Information on Participation in a Scientific Trial at Municipality of Belfast

PILOT TRIAL

Audience

Citizens with the diagnosis of mild dementia associated Municipality of Belfast

The research and innovation project was approved on the XX of XXX 2009 by the Science Ethics Committee, and by The Danish Data Protection Agency, 1st of July 2009.

Introduction

We will ask you if you want to participate in the pilot study of a scientific project. The project aims to test a system to support people with dementia in maintaining independent living in their own homes. The system consists of a series of assistive technologies that together will help you to an easier day with more security and less dependencies to health professional. System is tailored to suit your needs, which practically says that you will have installed assistive technologies that fit to you and your home. The pilot project will last for one year.

The target group for this study are people diagnosed with mild dementia, which is connected to: Municipality of Belfast. The [title] Jill Harpur from Belfast Health and Social Care Trust is responsible for the study.

The project is supported by the EU and conducted in 4 countries with collaborative partners from the 5 EU countries: Finland, Denmark, Great Britain, Greece and Italy

What is the purpose of the project?

The project aims at the ideals "healthy aging" and "independent lives at home" for older citizens. This will be achieved by:

1. Supporting people with dementia to perform an independent daily life without the need for health professional, by addressing difficult situations and insecurity
2. Improve citizen's ability to contact relatives and carers
3. etc.

How are people with dementia selected and how many will participate?
Before starting the pilot 20 people with mild dementia linked to Municipality of Belfast are asked, whether they will participate in the pilot study.

In the pilot study, the 20 citizens will be divided into a control group and a test group by drawing lots. The Test Group are the people with dementia, offered to use the assistive technologies at home in addition to the regular home care if such are received. The control group is people with dementia, which follows the usual care by home nursing, Municipality of Belfast. The purpose of having a control group and a test group is to decide whether it makes a difference for people with dementia to use technology to support them in everyday life at home. The study involves a total of 20 people with dementia divided by 10 individuals in each group.

What assistive technology is included in the experiment?
You will have installed one or more assistive technology in your home. It can for example be an electronic calendar, light sensors, alarm monitoring of catering equipment, video telephone, etc. In collaboration with Health personnel we will find, means there may be relevant to you and give you a detailed instruction in how to use them. Health staff will also conduct a continuous follow-up of your use of your tools and help you as needed.

Technical issues about the system configuration and components
This section should say something about which equipment will be installed in the home and how it keeps the user connected to the health professional. There must also describe who will install it and how it would be configured.

The use of the system
How to use the system and by whom?

How is the test carried out?
1. Staff from Municipality of Belfast will carry out a conversation with you in your home to inform you of the tools and adapt the system to your needs

2. A home carer will then contact you and arrange a time for the system to be installed in your home.

3. Your home carer and a technician will deliver the technology and put it your home. The equipment will remain in your home as long as you participate in the study.

4. The home carer will educate you and your relatives in the use of the equipment. You will simultaneously receive a written guide for instructions of how to use the equipment.

5. Nursing home staff will contract with you, about the ongoing contact, and decide whether you need weekly visits by a home carer.

6. When you are finished using the equipment, a home carer will uninstall it.

Who can benefit from the research?
In the project, we will identify to which extent it is advantageous to use assistive technology to support people with dementia and their caregivers. This knowledge will be used for development of new care and treatment and support tomorrow's citizens with dementia and their caregivers.

What side effects, risks and complications may occur?
There are estimated to be no risks associated with your participation in the test, as medically approved equipment are being used. However, when you participate in the pilot study, you must expect that there may be minor technical problems and the agreed workflows must be adjusted. That is why we need your help to focus on how we can improve communication and collaboration between health professionals or guides for the assistive technologies.

If you feel uncomfortable with the system or you need immediate assistance please contact the following:

- Weekdays at. 8AM-4PM:
  - Belfast Health and Social Care Trust tel: xx xx xx xx

- Weekdays after 4PM, evenings and weekends:
  - ISISEMD hotline tel: xx xx xx xx

Setting up the system in your home
The system must be plugged in at all times while it is in your home. In order to cover power and dispatch of your measured values, you will receive a total of DKK xx, which will be transferred to your bank account.

Exclusion and suspension of the trial
You can drag out of the study at any time if you wish if you later on regret your participation. This will be respected and not have any impact on your connection to the health system. You may be excluded from the study if you move from your residence.

How are data collected?
To gather knowledge about the need for and experiences with use of the system for people with dementia and their caregivers, we have scheduled the following data:

	PILOT PHASE 20 citizen with dementia, that uses ISISEMD system
Pilot start	Questionnaires which are about your satisfaction in life and your attitude towards technology.
While the system is in use	Citizens with dementia and their caregivers are asked if they will attend the following: • Visits from researchers in the home • Interview with citizen with dementia • Interview with citizen with dementia and their caregivers Home visits and interviews is expected to last a few hours total
After the finalization of the pilot	Questionnaire, which is about your satisfaction with the system and your life satisfaction in general.

Contact persons

Responsible for the study:
Jill Harpur
Title
Belfast Health and Social Care Trust
Address
Zip code
Tlf: xx xx xx xx
E-mail: jill.harpur@belfasttrust.hscni.net

Home carer Belfast Health and Social Care Trust
Contact person(s): _____
Tlf: xx xx xx xx

Other persons from the project

xxxxxx

When and how research will be available?
Results from the study will be available when the study is completed. In practice this means that once included all subjects have been completed and data is made up. The first results are expected in autumn 2011 and will be published in newspapers, journals and international scientific journals. By contacting Jill Harpur from Belfast Health and Social Care Trust you will be able to obtain copies of the articles.

Facts about the project

FACTS ABOUT THE ISISEMD-PROJECT

The project is running from 1st of March 2009 to 30th of June 2011. The project is funded by the EU of € 2,750,000 (approximately £ XXXXXX) and an equal amount from all partners in the project (project budget totalling approximately £ XXXXXX).

The parties involved in the project:
Denmark: North Denmark EU-Office, University of Aalborg, Frederikshavn Municipality, Eltronic A / S
United Kingdom: Belfast Social and health care
Greece: Trikala Municipality, National Technical University of Athens, converge ICT Solutions & Services SA
Finland: Lappeenranta Municipality
Italy: Alcatel-Lucent Italia SpA, Hewlett Packard Italiana Spa, Socrates Medical Srl
Read more at: www.eu-norddanmark.dk/dk/nyheder/isisemd.htm

Appendix

- **"Your rights as a trial subject"**
- **Consent Statement**

Appendix B1 - ISISEMD Informed Consent Statement – overall for the trial

Informed consent statement for participation in research project

Research project title: ISISEMD

Declaration from the trial participant:

I have read this consent form. I have had the opportunity to discuss this research study with name of Investigator and or his/her study staff. I have received written and oral information and I know enough for the objectives, the methods, the advantages and disadvantages. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate.

I understand that my participation in this Pilot is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of my data by (list of entities with access to data).

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a trial study.

I understand that, ISISEMD consortium intends to offer services to Elderly Persons (EP) and Informal Care Givers (ICG) in such a way that:
EP and ICGs are aware that ISISEMD system intends to offer a set of pilot services, which should not be considered as life critical in any manner. ISISEMD pilot system and pilot services do not substitute the required supervision of the EP and no one should rely on the existence of ISISEMD pilot services for anything that might occur to the EP.
EP and ICGs will hold ISISEMD harmless from and against any claims, costs, damage or injury or to third persons, or property arising directly or indirectly out of, or the use of ISISEMD pilot system and pilot services.

I give my agreement to participate in the research project ISISEMD and have received a copy of the written information for the project for my personal use. I understand that I will be given a copy of this consent statement after signing it.

Participant's name: ……..

Date: …… Signature: ……..

Do you with to be informed about the result of the research project, together with eventual consequences from them?

Yes …….. (set X) No ……. (set X)

Declaration from the responsible person for the trail:

I declare that the trial participant has received written and oral information about the trial and has had possibility to ask questions to me.

I am convinced that it is provided sufficient information in order decision to be taken for participation on the trail and the project.

Name of the responsible person for the trail: …….

Date: …… Signature: ……..

Project Identification:
ISISEMD project is partially funded by the European Commission under the ICT PSP Programme.

Appendix B2 - ISISEMD Informed Consent Statement for the service "Outdoor guard"

Informed consent statement for the service "Outdoor guard" from the project ISISEMD

Research project title: ISISEMD – the service "**Outdoor guard"**

Declaration from the trial participant for using the service "Outdoor guard":

I have read this consent form. I have had the opportunity to discuss this service **"Outdoor guard"** from ISISEMD trial with (name of Investigator) and or his/her study staff. I have received written and oral information and I know enough for the objectives, the methods, the advantages and disadvantages of the project and this specific service. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me.

I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate.

I understand that my participation in the evaluation of **the service "Outdoor guard"** under the framework of ISISEMD trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity and regarding my outdoor location will be kept confidential, but that confidentiality is not guaranteed. I authorise the inspection of my data by (list of entities with access to data).

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a trial study.

I understand that, ISISEMD consortium intends to offer services to Elderly Persons (EP) and Informal Care Givers (ICG) in such a way that:
EP and ICGs are aware that ISISEMD system intends to offer a set of pilot services, which should not be considered as life critical in any manner. ISISEMD pilot system and pilot services do not substitute the required supervision of the EP and no one should rely on the existence of ISISEMD pilot services for anything that might occur to the EP.
EP and ICGs will hold ISISEMD harmless from and against any claims, costs, damage or injury or to third persons, or property arising directly or indirectly out of, or the use of ISISEMD pilot system and pilot services.

I give my agreement to participate in the trial for **the service "Outdoor guard"** under the framework of ISISEMD trial and have received a copy of the written information for the project and this service for my personal use. I understand that I will be given a copy of this consent statement after signing it.

Participant's name: ……..

Date: …… Signature: ……..

Do you wish to be informed about the result of the research project and the service **"Outdoor guard"**, together with eventual consequences from them?

Yes …….. (set X) No ……. (set X)

Declaration from the responsible person for the trail for using the service "Outdoor guard":

I declare that the trial participant has received written and oral information about the trial of the ISISEMD service **"Outdoor guard"** and has had possibility to ask questions to me.

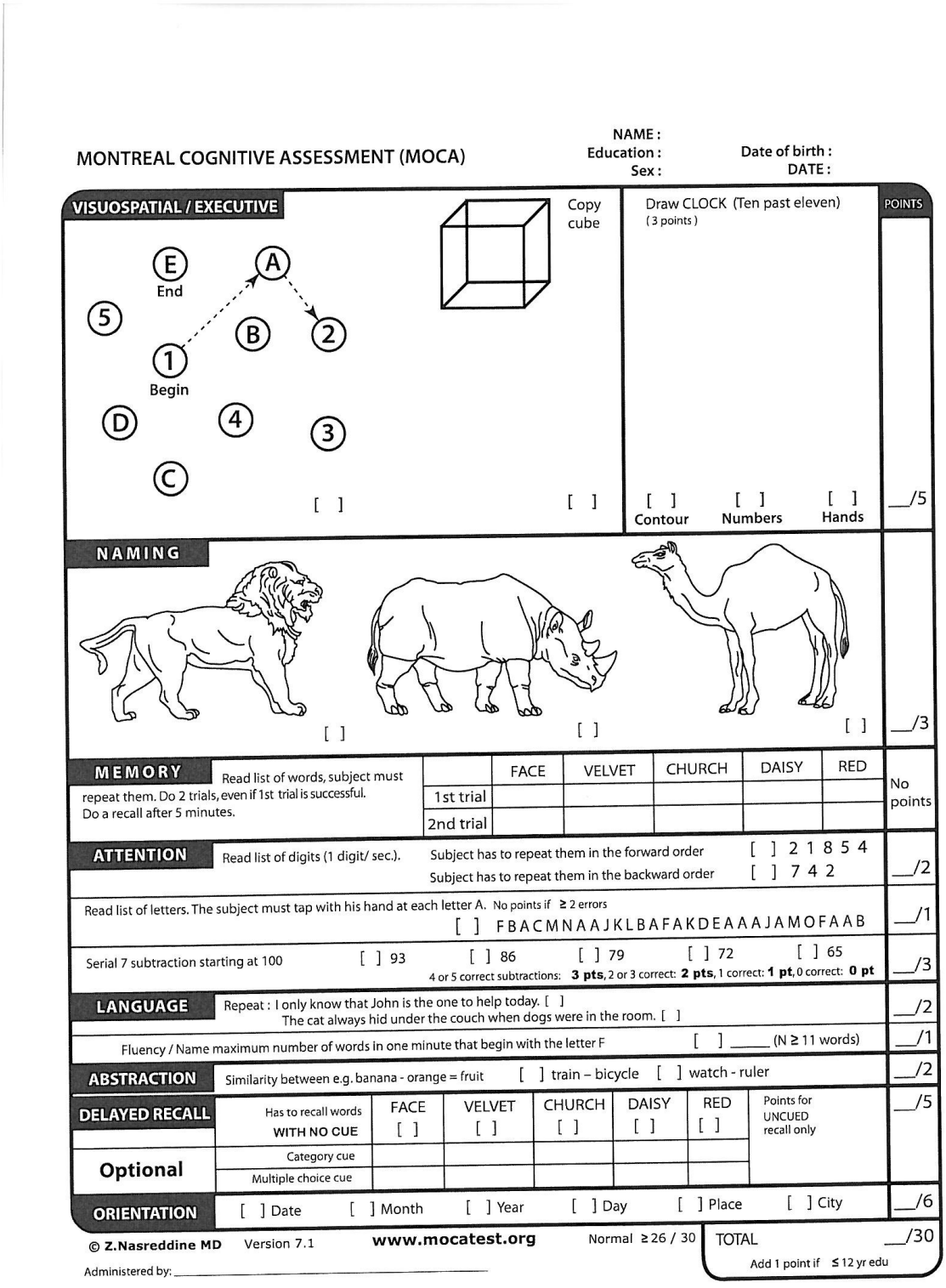
I am convinced that it is provided sufficient information in order decision to be taken for participation on the trail of this specific service and the project.

Name of the responsible person for the trail: …….

Date: …… Signature: ……..

Project Identification:
ISISEMD project is partially funded by the European Commission under the ICT PSP Programme.

Appendix C1 – MoCA test – for primary end-user



MONTREAL COGNITIVE ASSESSMENT (MOCA)

NAME :
Education :
Sex :
Date of birth :
DATE :

VISUOSPATIAL / EXECUTIVE — POINTS

Copy cube

[ ] [ ]

Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

__/5

NAMING

[ ]

[ ]

[ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

__/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

© Z.Nasreddine MD Version 7.1 www.mocatest.org Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr edu

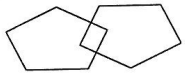
Administered by: _____

Appendix C2 – MMSE test – for primary end-user

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

Instructions: ***Ask the questions in the order listed. Score one point for each correct response within each question or activity.***

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, …) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

1

Source: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf

Provided by NHCQF, 0106-410

Appendix C3 – ADL/IADLs Questionnaire – for primary end-user

This questionnaire is based on the
KATZ BASIC ACTIVITIES OF DAILY LIVING (ADL) SCALE.

Questions	Independent	
	YES	NO
1. Bathing (sponge bath, tub bath, or shower) Receives either no assistance or assistance in bathing only one part of body		
2. Dressing - Gets clothes and dresses without any assistance except for tying shoes.		
3. Toileting - Goes to toilet room, uses toilet, arranges clothes, and returns without any assistance (may use cane or walker for support and may use bedpan/urinal at night).		
4. Transferring - Moves in and out of bed and chair without assistance (may use can or walker).		
5. Continence – Controls bowel and bladder completely by self (without occasional "accidents").		
6. Feeding - Feeds self without assistance (except for help with cutting meat or buttering bread).		

This questionnaire is based on the
LAWTON - BRODY
INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE (I.A.D.L.)

LAWTON - BRODY INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE (I.A.D.L.)			
A. Ability to Use Telephone		**E. Laundry**	
1. Operates telephone on own initiative-looks up and dials numbers, etc.	1	1. Does personal laundry completely	1
2. Dials a few well-known numbers	1	2. Launders small items-rinses stockings, etc.	1
3. Answers telephone but does not dial	1	3. All laundry must be done by others	0
4. Does not use telephone at all	0		
B. Shopping		**F. Mode of Transportation**	
1. Takes care of all shopping needs independently	1	1. Travels independently on public transportation or drives own car	1
2. Shops independently for small purchases	0	2. Arranges own travel via taxi, but does not otherwise use public transportation	1
3. Needs to be accompanied on any shopping trip	0	3. Travels on public transportation when accompanied by another	1
4. Completely unable to shop	0	4. Travel limited to taxi or automobile with assistance of another	0
		5. Does not travel at all	0

C. Food Preparation		**G. Responsibility for Own Medications**	
1. Plans, prepares and serves adequate meals independently	1	1. Is responsible for taking medication in correct dosages at correct time	1
2. Prepares adequate meals if supplied with ingredients	0	2. Takes responsibility if medication is prepared in advance in separate dosage	0
3. Heats, serves and prepares meals, or prepares meals, or prepares meals but does not maintain adequate diet	0	3. Is not capable of dispensing own medication	0
4. Needs to have meals prepared and served	0		
D. Housekeeping		**H. Ability to Handle Finances**	
1. Maintains house alone or with occasional assistance (e.g. "heavy work domestic help")	1	1. Manages financial matters independently (budgets, writes checks, pays rent, bills, goes to bank), collects and keeps track of income	1
2. Performs light daily tasks such as dish washing, bed making	1	2. Manages day-to-day purchases, but needs help with banking, major purchases, etc.	1
3. Performs light daily tasks but cannot maintain acceptable level of cleanliness	1	3. Incapable of handling money	0
4. Needs help with all home maintenance tasks	1		
5. Does not participate in any housekeeping tasks	0		

Appendix C4 – QOL-AD rating scale - for primary end-user

The QOL-AD (Participant Version)

Instructions: Interviewer administers according to standard instructions. Circle participant responses.

1. Physical health	Poor	Fair	Good	Excellent
2. Energy	Poor	Fair	Good	Excellent
3. Mood	Poor	Fair	Good	Excellent
4. Living situation	Poor	Fair	Good	Excellent
5. Memory	Poor	Fair	Good	Excellent
6. Family	Poor	Fair	Good	Excellent
7. Marriage	Poor	Fair	Good	Excellent
8. Friends	Poor	Fair	Good	Excellent
9. Self as a whole	Poor	Fair	Good	Excellent
10. Ability to do chores around the house	Poor	Fair	Good	Excellent
11. Ability to do things for fun	Poor	Fair	Good	Excellent
12. Money	Poor	Fair	Good	Excellent
13. Life as a whole	Poor	Fair	Good	Excellent

Comments:
Permission to use the scale -

Administration instructions available on request.

Appendix C5 – Zarit Burden Interview (ZBI) – for informal caregivers

This questionnaire is based on the **ZARIT BURDEN INTERVIEW**

Form A: to be completed by the caregiver

ZARIT BURDEN INTERVIEW

Indicate how often you experience the feelings listed by circling the number in the box that best corresponds to the frequency of these feelings.

	Never	Rarely	Sometimes	Quite Frequently	Nearly Always
1) Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4
2) Do you feel stressed between caring for your relative and trying to meet other responsibilities (work/family)?	0	1	2	3	4
3) Do you feel angry when you are around the relative?	0	1	2	3	4
4) Do you feel that your relative currently affects your relationship with family member or friends in a negative way?	0	1	2	3	4
5) Do you feel strained when you are around your relative?	0	1	2	3	4
6) Do you feel that your health has suffered because of your involvement with your relative?	0	1	2	3	4
7) Do you feel that you don't have has much privacy as you would like because of your relative?	0	1	2	3	4
8) Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4
9) Do you feel that you have lost control of your life since your relative's illness?	0	1	2	3	4
10) Do you feel uncertain about what to do about your relative?	0	1	2	3	4
11) Do you feel you should be doing more for your relative?	0	1	2	3	4
12) Do you feel you could do a better job in caring for your relative?	0	1	2	3	4

Total for each column _____ _____ _____ _____ _____

Total Score _____

Appendix D - Interview Guidelines for User Satisfaction, Acceptance and QoL

Appendix D1 - Interview Guide for Collection of User Satisfaction and Acceptance for Primary Users

Interview guide for User satisfaction for ISISEMD system for EP

Goals of the interview:

- Measure to what extent the user is satisfied with the service and the importance to have it
- Identify the source of satisfaction or dissatisfaction with the use of the service

Scales: Based on 4-category scale; the higher the score, the more positive the rating of the system

For ease of use:
3 No difficulty
2 Some difficulty
1 Significant difficulty
0 Too much difficulty to use

Importance to have it
3 Most important
2 Quite important
1 Somewhat important
0 Not important for in this situation

Overall satisfaction:
3 – full satisfaction
2- partial satisfaction
1 – no opinion
0 – not satisfied

Services and Devices	Easy / difficult to use	Importance to have in home	Overall Satisfaction
Home safety			
Cooking monitor			
Smoke detector / fire alarm			
water reminder in kitchen			
water reminder in bathroom			
Key reminder when leaving home			
Front door alarm			
Refrigerator door alarm			
Reminders			
Reminder for daily events			
Reminder for date and time, day or night.			
Reminder for the season and type of weather			
Reminder for medicine			

Locating personal belongings			
Can find items when looking for them			
Videophone			
Video call with relatives and/or caregivers			
Memory Lane			
Memory training with family photos			
Brain Games			
Use and strengthen mental ability and performance			
Portable outdoor guard			
Help to find way to home			
Panic button			
Fall alarm			
TOTAL:			

Comments and remarks from EP:

Interview guide for User Acceptance and Independent Use for ISISEMD system for EP

Goals of the interview:

- Measure to what extent the user accepts ISISEMD system and the different technologies
- Identify the source of acceptance or non- acceptance with the use of the system
- Measure how difficult is for the elderly person to use the system independently

Scale for independent use – Based on 4-category scale; the higher the score, the more positive the rating of the system
3 - Use without difficulty;
2- Use independently with difficulty;
1- use with help from someone else;
0 – Do not use

Scale for acceptance - Based on 4-category scale; the higher the score, the more positive the rating of the system
3 – Full acceptance
2- Partial acceptance
1 – without opinion
0 – Do not accept

Services and Devices	Independent use	Acceptance
Home safety		
Sensor for cooking monitor	N/A	
Smoke detector / fire alarm	N/A	
Sensor for water reminder in kitchen	N/A	
Sensor for water reminder in bathroom	N/A	
Key reminder when leaving home	N/A	
Front door alarm	N/A	
Refrigerator door alarm	N/A	
Reminders		
Reminders on the touch screen for daily events		
Locating personal belongings		
Device to find personal items		
Videophone		
Video call on the touch screen		
Memory Lane		
Slide show for family photos on the touch screen		
Brain Games		
Brain games on the touch screen		
Portable outdoor guard		
Lommy device		
TOTAL:		

Comments and remarks from EP:

Appendix D2 – Questionnaires for user acceptance and satisfaction – for caregivers

Informal Caregiver Satisfaction

Based on 4-category scale; the higher the score, the more positive the rating of the system

Activity Area	**Examples of Devices**	**Easy to use**	**Important for care** (fulfils a need, increases quality of care)	**Flexibility** (for making individual settings)	**Automatic functions** (system functions in an intelligent way)	**Easy to integrate into care routine**	**Important for care giving** (fulfils a need, increases quality of care)	**Overall experience with the system** (please share your thoughts)
		3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	3 Very satisfied 2 Somewhat satisfied 1Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	
Reminders	*Reminder for date, time, meals, medication, appointments, etc.*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Medication assistant	*Medicine reminders*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Alert if medicine dose is skipped	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Lifestyle pattern report	*Detect changes in the normal patterns*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Bed detector	*Tells how long they have been in bed*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Tells if they are leaving the bed at night frequently / for long time	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Remote consultation	*Conference with nurses or doctors*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Transfer of information through the Internet	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	

Videophone	*Videophone for communication with family and caregivers*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
PDA/wireless phone	*Phone to receive alerts, reminders, and messages*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Phone to contact loved one	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Multimedia	*Memory stimulation with digital photos*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Training for mental ability and performance	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Positioning	*Using the system to find belongings*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Intelligent front door	*Notification if person is leaving the home*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Alarm if person has left home for long time	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Home safety	*Stove/oven monitor*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Smoke detector / fire alarm in emergency	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Automatic water stop if water is left running (kitchen)	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Automatic water stop if water is left running(bathroom)	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Key reminder when leaving home	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Front door and lock alarm	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Refrigerator door alarm	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Outdoor safety	*Can locate the person outdoors*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	Panic button with tracker if the person becomes lost	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	

	Fall alarm if the person should fall	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
Transfer of tasks	*Tasks are less demanding with support from the system*	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	
	More tasks can be accomplished in the home with less intervention from the professional care team	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	3 2 1 0	

Overall feeling of safety about the home environment
3 I feel significantly safer
2 I feel safer
1 I do not feel safer
0 I feel less safe

Overall feeling of satisfaction about the system
3 I am more satisfied than I thought I would be
2 I am satisfied
1 I am not satisfied
0 I am disappointed

Would you want to use a system like this one after this study?
3 I definitely would use a system like this
2 I would consider using a system like this
1 I would not consider using a system like this
0 I would not use a system like this

Formal Caregiver Satisfaction

Based on 4-category scale; the higher the score, the more positive the rating of the system

Activity Area	**Examples of Service**	**Ease of use**	**Important for care** (fulfils a need, increases quality of care)	**Automatic functions** (system functions in an intelligent way)	**Easy to integrate into care routine**	**Important for care giving** (fulfils a need, increases quality of care)	**Flexibility** (for making individual settings)	**Overall experience with the system** (please share your thoughts)
Videophone	*Communication with family and caregivers*	3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very satisfied 2 Somewhat satisfied 1 Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	
Remote consultation	*Conferences with family, care personnel, or other medical professionals*	3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very satisfied 2 Somewhat satisfied 1 Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	
	Transfer of patient information through Internet	3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very satisfied 2 Somewhat satisfied 1 Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	
Lifestyle pattern report	*Detect changes in the normal patterns for update of patient status*	3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very satisfied 2 Somewhat satisfied 1 Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	

Transfer of tasks	*Tasks are less demanding with support from the system*	3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very satisfied 2 Somewhat satisfied 1 Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	
	More tasks can be accomplished in the home with less intervention from the professional care team	3 No difficulty 2 Some difficulty 1 Significant difficulty 0 Too much difficulty to use	3 Most important 2 Quite important 1 Somewhat important 0 Not important for in this situation	3 Very satisfied 2 Somewhat satisfied 1 Dissatisfied 0 Not satisfied at all	3 Very easy to integrate 2 Easy to integrate 1 Difficult to integrate 0 Did not integrate	3 Makes significant difference 2 Makes positive contribution 1 Not important to regular routine 0 Negatively affects regular routine	3 Very flexible 2 Quite flexible 1 Inflexible 0 Not flexible at all	

Appendix E1 – Scale of Quality of Life of Informal Care-Givers - SQLC

From article - J. M. Glozman, K. G. Bicheva, N. V. Fedorova, Scale of Quality of Life of Care-Givers (SQLC), J Neurol (1998) 245 [Suppl 1] :S39–S41, © Springer-Verlag 1998

I. Professional activity

1. Have you continued at your former place of work after your relative fell ill?	Yes (5)	No (0)
Full-time, for full working day	5	0
Part-time with incomplete working day	3	0
Had to start working (if hadn't worked before)	0	5
Didn't work before either	5	0

2. Do you manage to perform your duties while now being occupied with the patient's care?	Yes (5)	No (0)
As well as previously	5	0
With difficulty	3	0
Partly manage	1	0
Not at all	0	0

3. Did you change your work because of your relative's disease?	Yes (0)	No (4)
If yes, your job is now:		
The same as previously	3	0
Close to previous type	2	0
In another branch	1	0
Changed the job for other reasons not related to the relative's disease	4	0

4. Are you obliged to perform any complementary job for extra money?	Yes (0)	No (5)
As frequently as before	5	
Rarely	4	
Somewhat less	3	
Often	2	
Very frequently	1	
Never	0	
Perform other job for reasons unconnected to the relative's disease	3	

II. Social and leisure activities

5. Do you have time for different kinds of leisure activities in spite of your involvement into the patient's care?	Yes (3)	No (0)
As frequently as before	3	
Somewhat more than before	4	
Somewhat less than before	2	
Rarely	1	
Never	0	
Never did	3	

6. Does care of the patient allow you run the household? Yes (3) No (0)

	Now I have more to d	As much, as previo usly	Somewhat less	Very rarely	Never	Never did
Buying food	2	3	2	1	0	3
Making laundry	2	3	2	1	0	3
Cleaning house	2	3	2	1	0	3
Cooking	2	3	2	1	0	3
Other (indicate)	2	3	2	1	0	3

7. Does care of patient allow you to give a hand to you parents and other relatives? Yes (3) No (0)

More frequently than before as I have now stopped work	4
As frequently than before	3
Somewhat less frequently	2
Very rarely	1
Never	0
Never did	3
More frequently than before as now it is my responsibility	2

8. Do you continue to discuss family plans and problems with your ill relative? Yes (3) No (0)

More often than before	4
As often as before	3
A little less often than before	2
Very rarely	1
Never	0
Never did before	3

9. Does the care of our relative let you to continue to attend to the needs of your children or the grandchildren as well as you did before?

Yes (3) No (0)

	More frequently than before as I have now stopped work	As frequently than before	Somewhat less frequently	Very rarely	Never	Never did	More frequently than before as now it is my responsibility
To control and help children in scholarship	4	3	2	1	0	3	2
To take children to school, to sport activities or for a walk	4	3	2	1	0	3	2
To take children to theatres, museums, etc.	4	3	2	1	0	3	2
Other (indicate)	4	3	2	1	0	3	2

III. Responsibilities of the care-giver to help the patient in his everyday living

10. Does the regular everyday care and attention to the chronically disabled person make you depressed? Yes (0) No (3)

The mood is the same as before	5
Continuous depression (a week or more)	3
Stable depression with weight loss and insomnia	0
Depression for reasons unconnected with relative's disease	5

11. Can the patient stay at home by himself while the family members are out or away? Yes (3) No (0)

Without assistance he is able to:	Always	Sometimes	Never
Dress	2	1	0
Make the bed	2	1	0
Warm up food	2	1	0
Take food left for him (wrapped up or in container)	2	1	0

12. Does your patient need assistance when using public transport or car-driving? Yes (0) No (3)

Never needs assistance	3
Somewhat more often than before	2
Very often	1
Always needs assistance	0
Needed assistance before disease started	3

13. Can your patient regularly take the prescribed medicine by himself? Yes (3) No (2)

Always	2
Sometimes	1
Never	0

14. Can your relative take a bath without assistance? Yes (3) No (0)

Always	2
Sometimes	1
Never	0

15. Can your patient move around without assistance? Yes (3) No (0)

Without assistance he is able to:	Always	Sometimes	Never
Visit his therapist	2	1	0
Go for a walk or shopping	2	1	0
Move around inside the whole house	2	1	0
Go to the lavatory	2	1	0
Get seated on the bed	2	1	0

16. Can your relative call for a physician by himself? Yes (3) No (0)

Always	2
Sometimes	1
Never	0

Appendix E2 – Questionnaire for CAREGIVER ACTIVITY SURVEY (CAS) - for informal caregivers

Source: KENNETH L. DAVIS, DEBORAH B. MARIN, ROBERT KANE, DONALD PATRICK, ELAINE R. PESKIND, MURRAY A. RASKIND AND KATHERINE L. PUDER
THE CAREGIVER ACTIVITY SURVEY (CAS): DEVELOPMENT AND VALIDATION OF A NEW MEASURE FOR CAREGIVERS OF PERSONS WITH ALZHEIMER'S DISEASE, INTERNATIONAL JOURNAL OF GERIATRIC PSYCHIATRY, VOL. 12: 978±988 (1997)

1. Communicating with the person
Please consider the following examples of activities:

- . answering the same question again and again
- . trying to make sense of what the person says
- . leaving reminders for the person

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?
__ hours __ minutes

2. Using transportation
Please consider the following examples of activities:

- . reminding the person about means of transportation
- . taking the person to various places (other than shopping) by car or public transportation or taxi

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?
__ hours __ minutes

3. Dressing
Please consider the following examples of activities:

- . reminding the person to dress
- . choosing what to wear
- . laying out clothes
- . helping the person to dress or undress
- . supervising the person dressing
- . keeping the person from undressing at the wrong time

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?
__ hours __ minutes

4. Eating
Please consider the following examples of activities:

- . reminding the person to eat
- . setting up utensils and food
- . cutting or arranging food on the plate
- . supervising or encouraging the person to eat
- . cleaning the person after eating

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?
__ hours __ minutes

5. Looking after one's appearance
Please consider the following examples of activities:

- . reminding the person to brush their teeth, brush their hair, apply cosmetics, shave or care for nails
- . helping the person to groom
- . setting out items for grooming activities
- . supervising grooming activities
- . maintaining the person's appearance over the course of the day

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?
__ hours __ minutes

6. Supervising the person
Please consider the following examples of activities:

- . keeping an eye on the person to be sure that they do not wander or get into some kind of difficulty
- . looking out for the person
- . preventing the person from getting lost
- . finding the person if they get lost

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?
__ hours __ minutes

About you
Please answer the following questions about yourself and your situation if you are filling out these forms for the first time.
1. What is your relationship to the person you provided care for?
(Please circle one number)

1 Spouse
2 Daughter, son, or other relative
3 Friend or neighbour
4 Other (please specify)

2. Do you live in the same household as the person you provided care for?
(Please circle one number)
1 Yes
2 No

3. In what year were you born?

4. What is your sex?
(Please circle one number)
1 Male
2 Female

Permission to use the test and correspondence to:
Dr. K. L. Davis, Department of Psychiatry, Mount Sinai School of Medicine, New York, One Gustave Levy Place, New York, NY 100978.
Email: kenneth.davis@mssm.edu

Appendix F– Examples for test tasks and test scenarios

Below some step by step examples of tests tasks are shown.

It is assumed that each region has created a new CG1 and EP1 and assigned client EP1 to CG1.

Task A: (from the portal) - login as region, find EP1 and assign the service for daily reminders, brain games, memory lane for EP1;

Nb.	Test description	Expected test result	Observation	Tester dd-mm-yyyy/ Init
1.	Log-in as region	See list with patients assigned to FCG1		
2.	Find <id>_EP1	Information for EP1 is found		
3.	Assign <id>_EP1 to service for daily reminders, brain games, memory lane	EP1 is successfully assigned to the A2 services, brain games, memory lane		
4.	Logout region user from portal	The user is successful logged out		

Task B: (As a care-giver) - login as CG1 and create different reminders for EP1 with the necessary settings
Note – please allow around 30 min interval among different reminders to avoid overlapping.

Nb.	Test description	Expected test result	Observation	Tester dd-mm-yyyy/ Init
1.	Log-in to the portal as <id>_CG 1	The user is logged in with the right attributes		
2.	Find reminder services for <id>_EP1	The reminder services for EP1 is successfully found There is no active reminders for EP1		
3.	Create reminders for every day - breakfast, lunch, dinner, afternoon breakfast to <id>_EP1 as events for every day, with sounds and audio messages and with dismiss time 3 min, interval of repetitions of 5min and two times to repeat. The speaker must be on. Pls select the time to be in the period of the following 2-3 hours so you can see the reminders.	Three reminders are successfully created – you can see them in the list of active reminders		
4.	Create reminders for one time - for guest at home and dress to go out as reminders for today (pls note you should mark for one day duration). Assign sound and audio, with dismiss time 3 min, interval of repetitions of 5min and two times to repeat. The speaker must be on. Pls select the time to be in the period of the following 2-3 hours so you can see the reminders.			
5.	Create reminders for one time with free text “Call friend”. Assign sound and audio, with dismiss time 3 min, interval of repetitions of 5min and two times to repeat. The speaker must be on. Pls select the time to be in the period of the following 2-3 hours so you can see the reminders.			
6.	Press the link on the portal for returning from the selected service.	The portal is directed to the expected url. Verify that it works as expected and looks like expected.		
7.	Logout the <id>_CG1 User from the portal:	The user is successful logged out		

Task C: (as a patient EP1 – from CareBox)

Log-in as EP1 and see the information shown on the GUI and hear the upcoming reminders

Nb.	Test description	Expected test result	Observation
1.	On GUI EP – log-in as EP1	You can see the reminders list with the next two reminders on the left and the picture slide show on the right.	
2.	Observe and hear how the reminders appear on GUI EP		
3.	Close CareBox		

Task D: (As a care-giver from the portal) - Log-in as CG1 and update/remove reminders for EP1

Nb.	Test description	Expected test result	Observation	**Tester** dd-mm-yyyy/ Init
1.	Find <id>_EP1 and the reminders services for EP1	Information for EP1 and active reminders are found		
2.	Update the reminder “guest at home” to be in the evening hours and save the changes			
3.	Find reminder for afternoon breakfast and delete it	The reminder afternoon breakfast should not appear on the list of active reminders		
4.	Logout the <id>_CG1 User from the portal:	The user is successful logged out		

Repeat Task C: (as a patient EP1 – from GUI EP) – to see the changes of the settings in the reminders on the CareBox screen

Task E: (As a care-giver from the portal) Log-in as CG1 and add/remove two more pictures for EP1 in the service "Memory Lane"

Nb.	Test description	Expected test result	Observation	Tester dd-mm-yyyy/ Init
5.	Find <id>_EP1	Information for EP1 is found		
6.	Find the service for "Memory lane" and add two new pictures	Two new pictures are added		
7.	Find and delete one old picture from the list	One picture is deleted from the folder with pictures		
8.	Logout the <id>_CG1 User from the portal:	The user is successful logged out		

Task F: (As a patient EP1) from CareBox – see the changes in the CareBox in the list of the pictures for "Memory Lane"

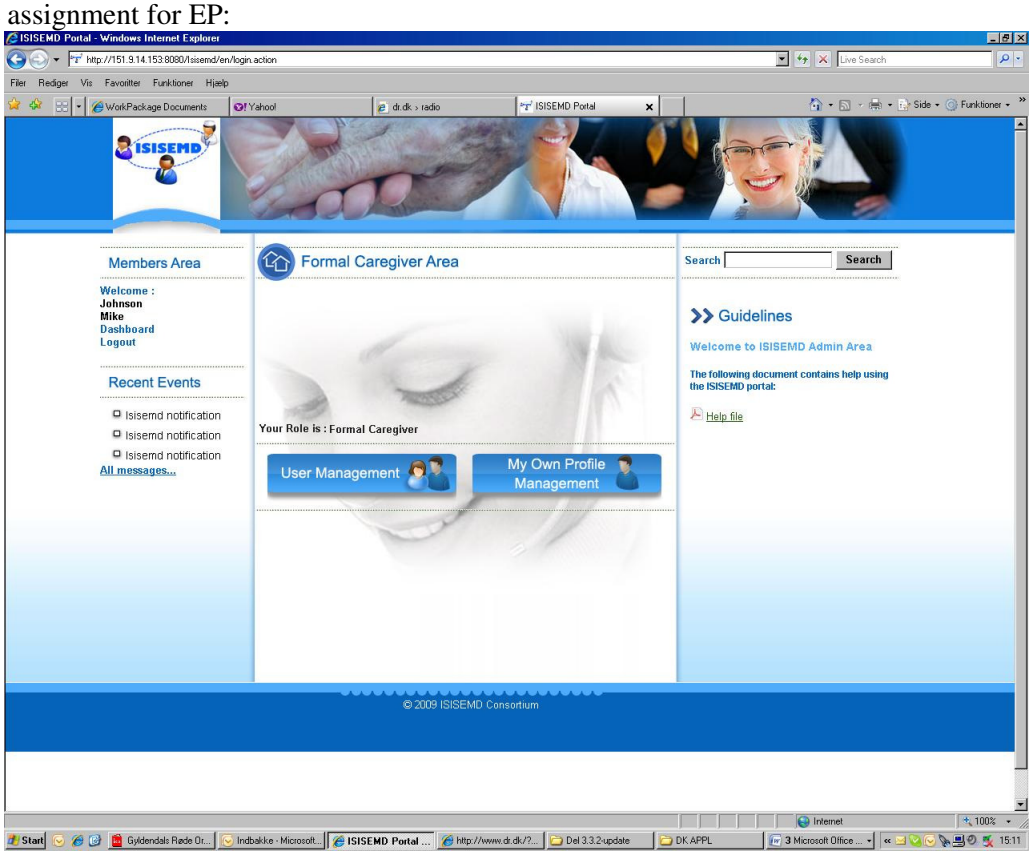
Nb.	Test description	Expected test result	Observation	Tester dd-mm-yyyy/ Init
4.	On GUI EP – log-in as EP1	You can see the reminders list on the left and the picture slide show on the right		
5.		See changes in the pictures from task E		

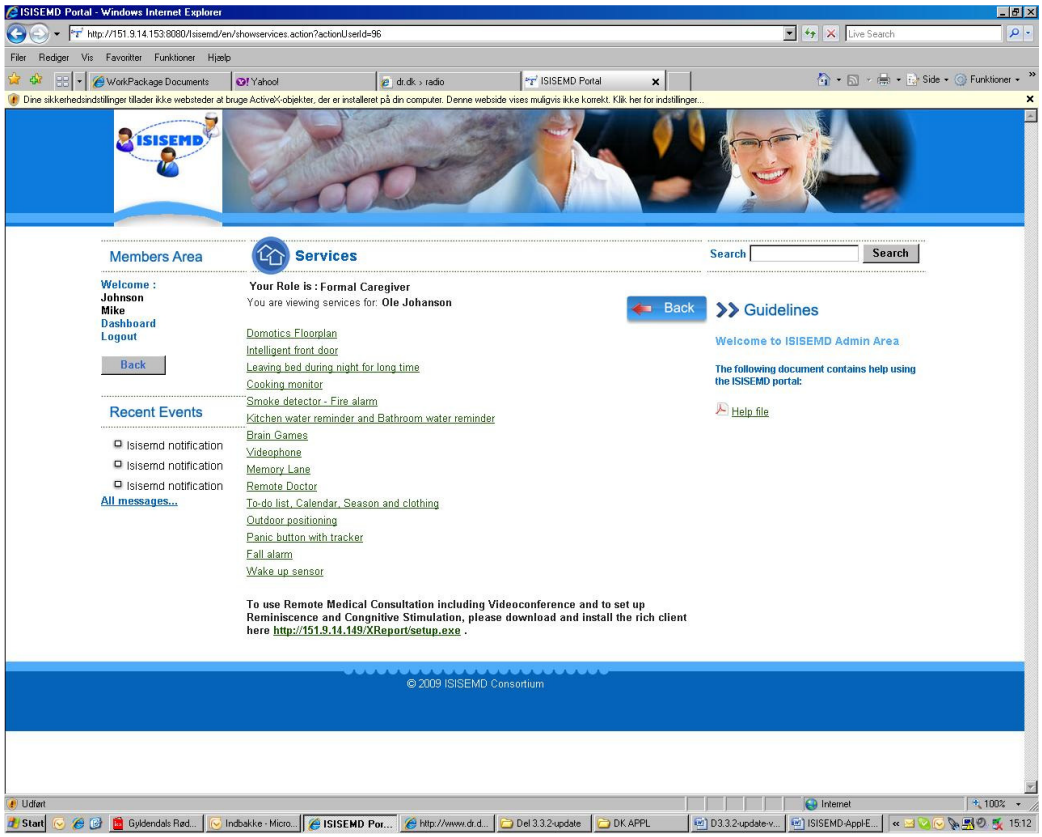
Task G: (As a patient EP1) from CareBox – play Brain Game

Nb.	Test description	Expected test result	Observation	Tester dd-mm-yyyy/ Init
1.	On GUI EP – log-in as EP1	You can see the reminders list on the left and the picture slide show on the right		
2.	Find button Brain Game on the right side of GUI EP and start the game	Game starts in the down right corner of GUI EP		
3.	Play the brain game by clicking	You can see a penguin		
4.	Close/Finish the brain game	The brain game is no longer shown on GUI EP		

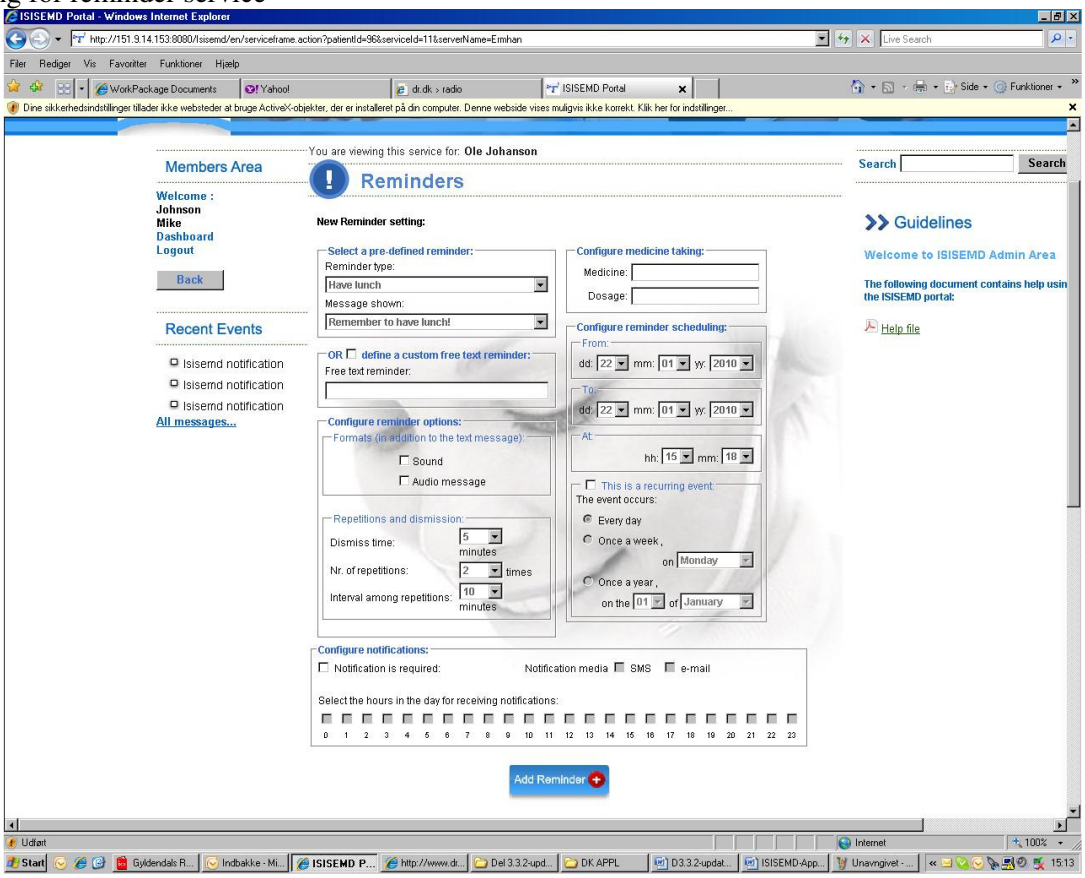
Appendix G– Screen shots from User Guides

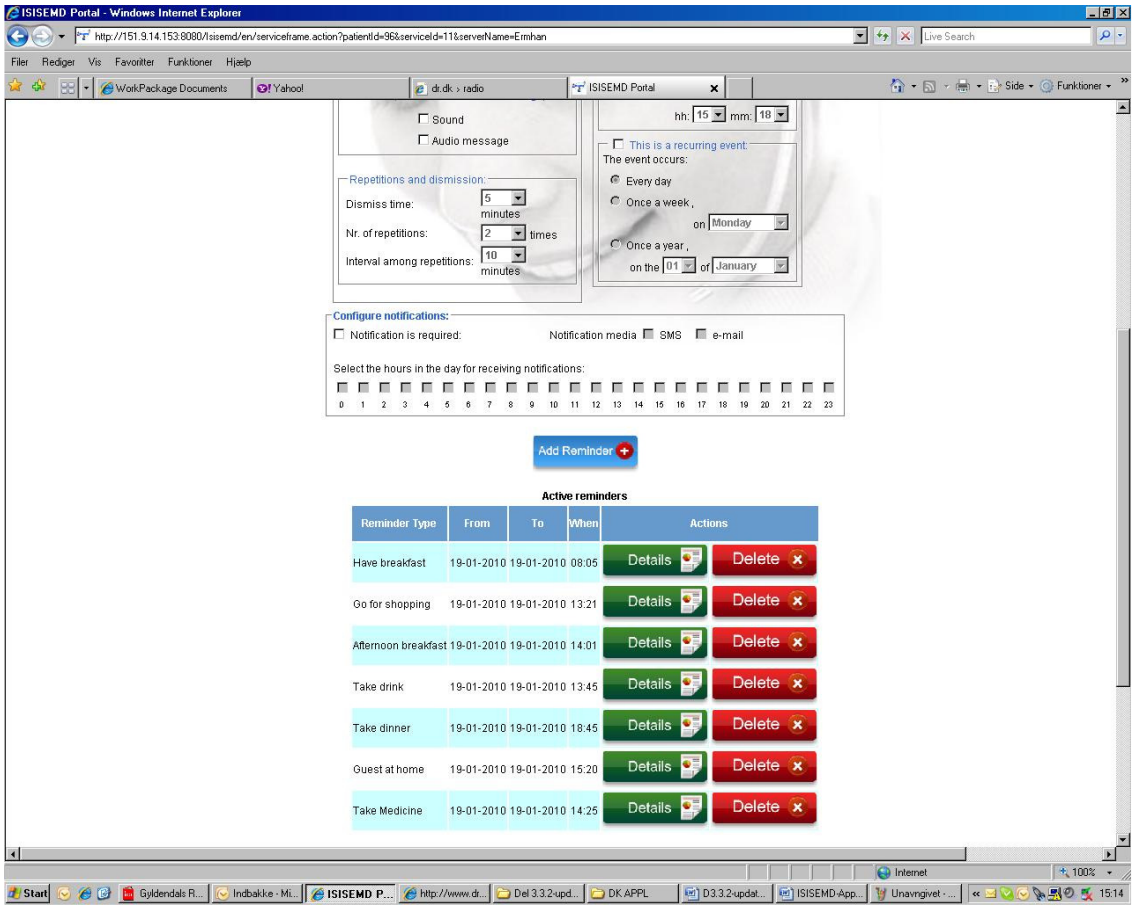
Service assignment for EP:



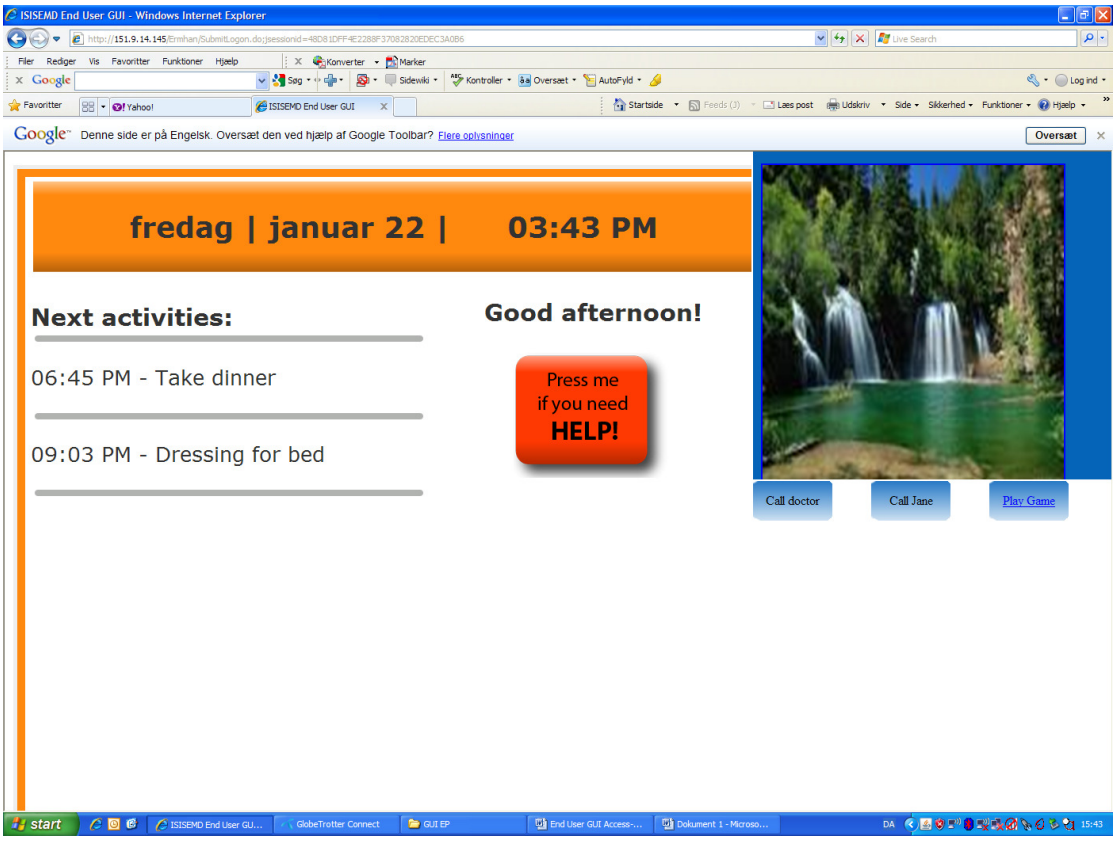


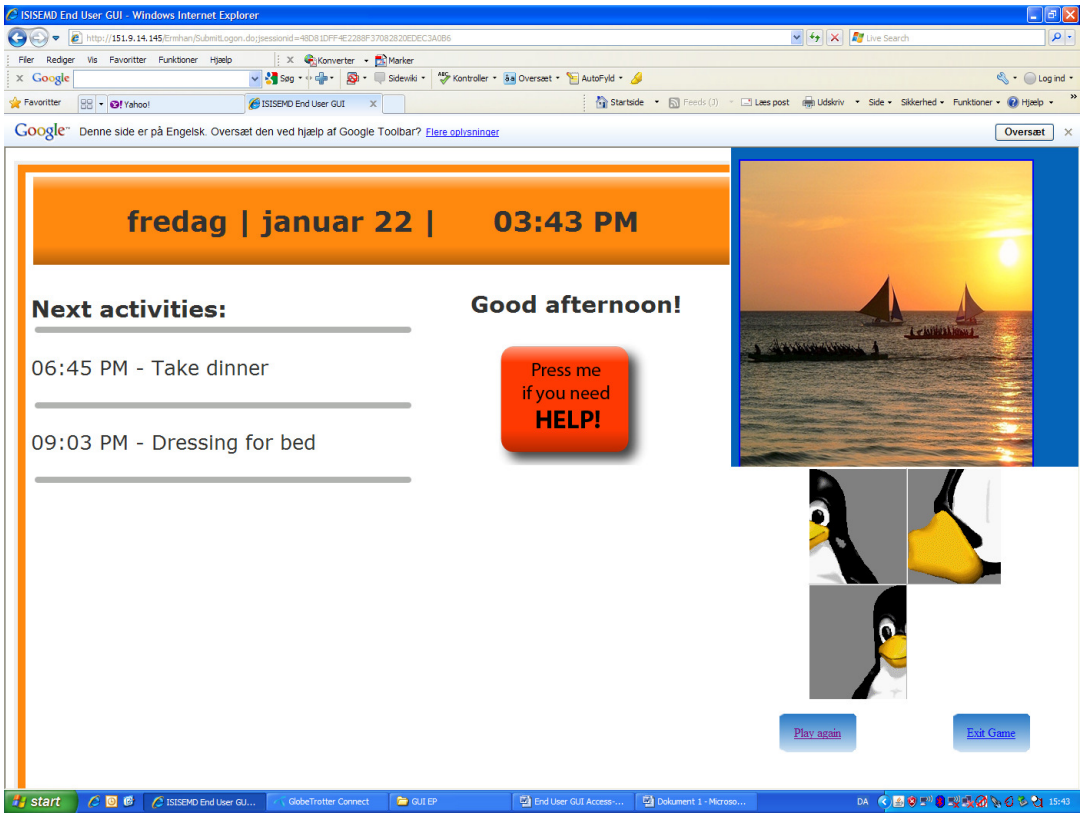
Setting for reminder service

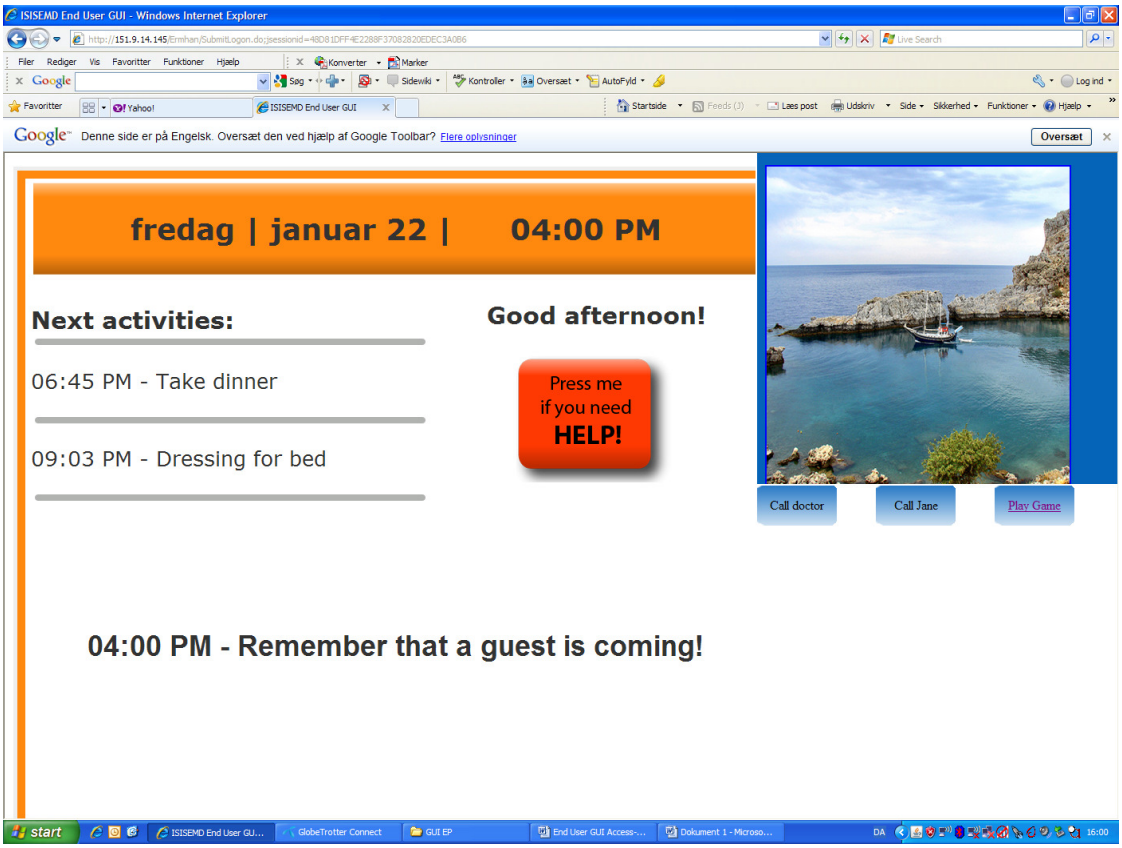




CareBox GUI


ISISEMD End User GUI - Windows Internet Explorer
Google Denne side er på Engelsk. Oversæt den ved hjælp af Google Toolbar? Flere oplysninger
Oversæt
fredag | januar 22 | 03:43 PM
Next activities:
06:45 PM - Take dinner
09:03 PM - Dressing for bed
Good afternoon!
Press me if you need HELP!
Call doctor
Call Jane
Play Game


ISISEMD End User GUI - Windows Internet Explorer
Google Denne side er på Engelsk. Oversæt den ved hjælp af Google Toolbar? Flere oplysninger
Oversæt
fredag | januar 22 | 03:43 PM
Next activities:
06:45 PM - Take dinner
09:03 PM - Dressing for bed
Good afternoon!
Press me if you need HELP!
Play again
Exit Game


ISISEMD End User GUI - Windows Internet Explorer
Google Denne side er på Engelsk. Oversæt den ved hjælp af Google Toolbar? Flere oplysninger
Oversæt
fredag | januar 22 | 04:00 PM
Next activities:
06:45 PM - Take dinner
09:03 PM - Dressing for bed
Good afternoon!
Press me if you need HELP!
Call doctor
Call Jane
Play Game
04:00 PM - Remember that a guest is coming!

List Figures

List Tables

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Abbreviations

GDS	Global Deterioration Scale
FAST	Functional Assessment Staging Test
MMSE	Mini Mental State Exam
EP	Primary end-user group
ICG	Informal care giver
FCG	Formal care giver
CG	Care givers
MoCA	The Montreal Cognitive Assessment
ADL	Activities of Daily living
IADL	Instrumental Activities of Daily living
QOL	Quality of Life
QOL-AD	Quality of Life - Alzheimer Disease
ZBI	Zerit burden interview
CAS	Caregiver activity survey
SQLC	Scale of Quality of Life of Care-Givers
ITIL	IT Infrastructure Library paradigm
SLA	Service Level Agreement
ATD	Assistive Technological Device
AD	Alzheimer Disease
AA	Alzheimer Association
MCI	Mild Cognitive impairment
OT	Occupational Therapist
DoW	Description of work
HTA	Health Technology Assessment
CUA	Cost-utility analysis
QALYs	Quality-adjusted life years
HCI	Human-computer interaction
MMI	Man-Machine-Interaction