Deliverable 5.1

Trial Concept

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Abstract

D5.1 "Trial Concept" describes the evaluation framework that partners involved in WP 5 "Field trials and Evaluation" will use in order to validate the feasibility, functionality, acceptability and usability of the Living Well system.

What is new in this Version

Since the last release of this deliverable the lay out of the deliverable has been changed in line with the other deliverables.

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Version	*Date*	*Changes*	*Name Organisation*
1.0	01-08-2017	First version	INRCA
2.0	21-08-2017	Comments and integrations	DPL and SHD
3.0	11-09-2017	2th phase of comments and integrations	INRCA, DPL and SHD
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Content:

Executive summary 4

1. Introduction 4

1.1 Scope of this document 5

2. Living Well evaluations objectives and methods (1st iteration) 7

2.1 Technical evaluation 9

2.1.1 Equipment requirement 9

2.1.2 Equipment availability 9

2.2 Trial evaluation 10

2.2.1 Inclusion Criteria 10

2.2.2 Recruitment procedure 11

2.2.3 Study Design and Methods 11

2.3 Evaluations Outcomes 15

2.3.1 Failure/success criteria for the evaluations results 15

3. Ethical Issues 16

3.1 Ethical Approval 17

3.1.1 Informed consent 18

3.1.2 Privacy and Data Protection 18

4. Site Profiles Description 19

4.1 INRCA, Italy 19

4.2 The Parabool, The Netherlands 20

4.3 Stëftung Hëllef Doheem, Luxembourg 21

5. Risks Management 22

6. Safety 23

Annexes 27

Annex 1 Computer/Tablet requirements 27

Annex 2 Informed Consent 31
Annex 3 Protocol for older adults 33
Annex 3 Protocol for caregivers 34

Acronyms

User-Centered Design (UCD)
Human-Centered Design (HCD)

Executive summary

D5.1 "Trial Concept" describes the evaluation framework that partners involved in WP 5 "Field trials and Evaluation" will use in order to validate the feasibility, functionality, acceptability and usability of the Living Well system.

The document describes in detail the methodology and expected outcomes of these field trials. The main results of these studies are the feedback provided by end users. This document also describes potential risks that may arise during these studies and the plans set to overcome them.

1. Introduction

In 2015, almost 47 million people worldwide were estimated to be affected by dementia, and the numbers are expected to reach 75 million by 2030, and 131 million by 2050, with the greatest increase expected in low-income and middle-income countries[1]. These numbers clearly show that *dementia* has become a *major problem* for the *health* with a relevant economic impact on our society: the estimation of the overall societal costs amount is about €14 500 per year in patients at home, but rises up to €72.500 per year in patients who need residential care[2]. Enabling patients with dementia and their carers to improve their **quality of life** and **dignity** is a great challenge. From the perspective of the subject affected by this disease, the impact is highly significant. Day–to–day routines are quite difficult and even simple tasks can become complex due to the progressive decline in recognition and memory. Moreover, subjects may develop various restless behaviours such as fidgeting and agitation. As the disease progresses from early to severe stages, the person affected needs more care and support to carry out everyday tasks. As a result, caring for a person with dementia can be a significant personal and emotional challenge. Caregivers frequently report experiencing high levels of stress, mental and physical fatigue, social withdrawal and sleeplessness.

In the light of this background, the Living Well project aims to develop a computerised system to help and support older adults and their caregivers who are living independently in their own home and are dealing with memory and other cognitive issues. Of particular interest are people with signs and symptoms of dementia, whether a particular disease has been diagnosed or not. The system will consist of a virtual personal assistant designed to help independent older adults to manage their daily activities and overcome potential problems of forgetfulness.

Figure 1. The Virtual Personal Assistant

[1] Winblad, Bengt, et al. "Defeating Alzheimer's disease and other dementias: a priority for European science and society." The Lancet Neurology 15.5 (2016): 455-532.

[2] Gustavsson A, Brinck P, Bergvall N, et al. Predictors of costs of care in Alzheimer's disease: a multinational sample of 1222 patients. Alzheimers Dement 2011; 7:318–27.

1.1 Scope of this document

The purpose of this document is to delineate the plan for the trials execution. It is located in Task 5.1 "User's recruitment and mobilisation" within the WP 5 "Field trials and Evaluations". The deliverable is divided into five main sections:

1) the first section presents the validation approach in terms of objectives, outcomes and methods.
2) The section about ethical issues discusses all ethical responsibilities that the consortium will deal to during the project.
3) The "Site profiles description" introduces the three pilot sites.
4) The "Risks management" section discusses the potential risks that may affect project goals and pilot goals.
5) The section about safety issues is aimed at demonstrating that the Living Well system do not expose users to potential harms.

2. Living Well evaluations objectives and methods (1st iteration)

A great challenge of the Living Well project is to provide a human-centred perspective that can be integrated in the main development cycles of the system. The active involvement of users and a clear understanding of context of use are the key strengths to overcome the main barriers in applying technology for seniors. This strategy represents the core of the User-Centered Design (UCD), a design philosophy which encompasses various methodologies and techniques which seek to involve the end-user in the design process with the end-user being defined as the 'person who will ultimately be using the product'. The goal of UCD is to optimise the usability, human factors and hence the user experience (UX) of a product. The International Standards Organisation standard ISO 9241-210, extended the definition of UCD to "address impacts on a number of stakeholders, not just those typically considered as users", referring to the design approach as Human Centred Design (HCD). The terms HCD and UCD are used synonymously and as such the term UCD will continue to be used throughout this document.

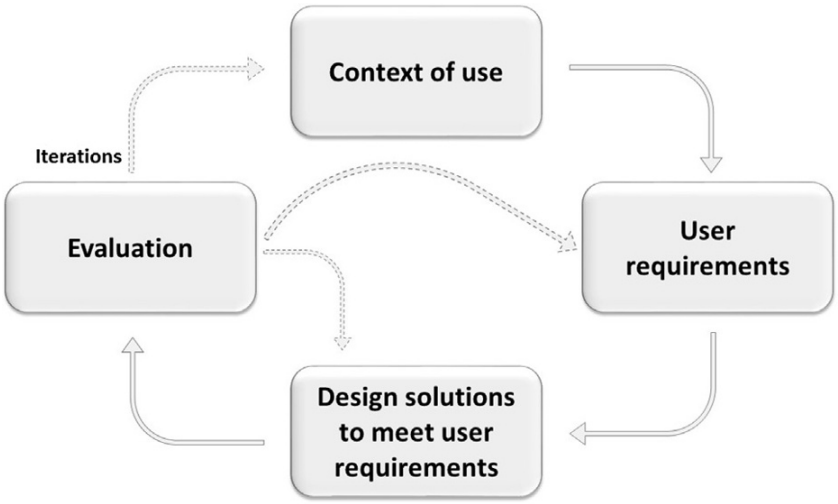


Figure 2 The UCD approach

The UCD approach is a process consisting of four fundamental activities related to user involvement (Figure 2). The Living Well project implemented this approach as described in the following bullet points:

a) user groups are specified and the context of use is described (Activity 1: understand and specify the context of use). This activity is covered in WP 2 "User requirements";

b) a set of specific requirements are defined in order to create a degree of fit between device and user (Activity 2: specify the user requirements). This step is performed within the WP3 "System Design and Specifications";

c) the design prototype is produced on the basis of these specifications and it is presented to the user in the form of user testing (Activity 3: Produce design solutions to meet requirement). It is the core of WP4 "Development";

d) once feedbacks from the user have been received, the process begins again until all user requirements have been met (Activity 4: evaluation). The evaluation phase is the objective of WP5 "Field Trials and Evaluations".

As for its iterative nature, the process requires that information are gathered from the user at each step and actions are taken based on that, in order to interpret the information correctly.

During the project lifetime, 3 different Iteration will be performed.

Based on the UCD approach, this document is related only to the evaluation phase and it is aimed to discuss activities that will be covered within the WP 5 "Field Trials and Evaluations".

The objectives of the pilot evaluations are mainly to assess the feasibility, usability, acceptance and functionality of the system and the ability of the potential target user to use the system and receive valuable information from it to help them address the complex needs of people with mild cognitive impairments.
More specifically the validation studies will address the following aims:

1-To assess the **acceptance and usability** of the system and its usage over long term use by end users.
2-To evaluate **functionality** of the system in collecting data
3-To assess the **feasibility** of the users to operate the system including independent use at home, charging the tablet,
4-To evaluate changes in the **quality of life** experienced by the end-users and their informal caregivers.

The pilot evaluations will be setting up in three different sites: Italy, The Netherland and Luxembourg (a complete description of each site is giving into Section 4).
This multi-site design will allow evaluating the Living Well system in different social and cultural contexts. Overall, the multinational approach proposed will ensure wide acceptability of the developed technology and prepare the possibility of Europe-wide deployment after project life. Moreover, these three sites are representatives of the burden of this disease: the total estimated worldwide cost of dementia has reached $818 billion (£521 billion) and will become a trillion dollar disease by 2018, finds the World Alzheimer Report 2015[1]. In Europe there has been a significant increase in the costs expected for 2015, up from $240 billion in 2010 to $300 billion today (£191 billion). In respect to the figures for

[1] https://www.alz.co.uk/research/WorldAlzheimerReport2015.pdf

the Living Well participating countries there are about 260.000 people affected with dementia in Netherlands (2015), more than 1 million people in Italy, and around 3.500 in Luxembourg.

2.1 Technical evaluation

2.1.1 Equipment requirement

Anne works on a computer that runs the operating system Microsoft Windows 10.

Computers (tablets) with operating systems of Apple (iOS) or Google (Android) are not supported.

Virtask advises the use of a tablet computer.

The advantages of these systems are:

- All necessary base functions like camera, microphone, speakers, and touch screen are present;
- The size of the screen is ideal for the application;
- The compact systems minimize the amount of wiring;
- The system works well without the use of mouse and keyboard; this means that the tablet does not look like a computer;
- Tablets are more mobile than most other devices.

Annex for Computer/tablet requirements

2.1.2 Equipment availability

The use of new hardware in the project

The entire project has a duration of three years (2017 – 2020). The user test period will also take three years divided into multiple phases. In the budget of the project, the purchase of new hardware is taken into account.

Even though users might already have computers, we will assume Anne will run on new computers for the sake of functionality.

Hardware budget is part of the end user organizations budget.

Equipment will be purchased by the end-user organisations.

- In October, INR have ordered 20 Microsoft Surface systems for this project;
- In October, SHD have ordered 10 Microsoft Surface systems for this project;
- DPL will also order new tablets.

2.2 Trial evaluation

In this section a detailed description of the first field trial is presented.

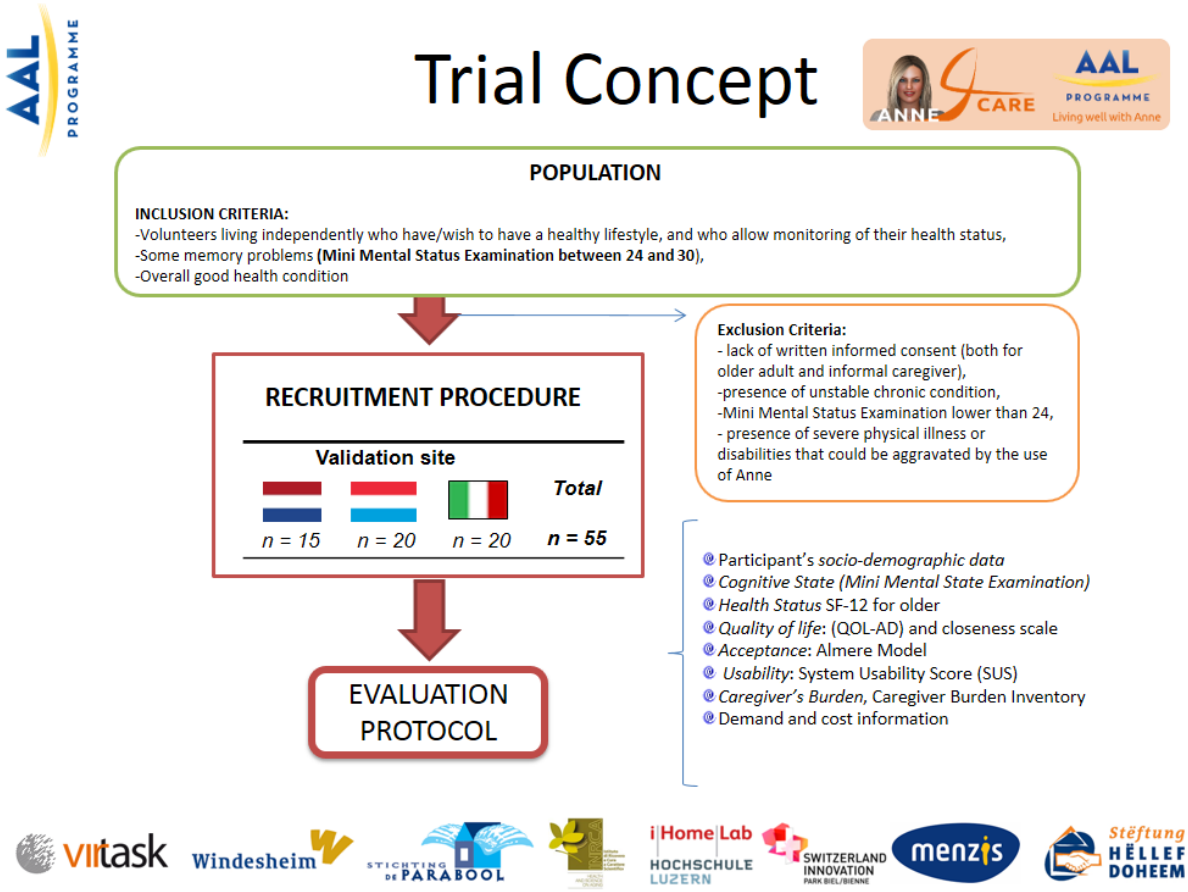


Figure 3 The Trial Framework

2.2.1 Inclusion Criteria

A sample of 55 end-users will be enrolled (20 in Italy, 15 in the Netherland and 20 in Luxembourg). A reserve list of potential participants will be constructed in each site as a back-up reserve to be used in the event of drop-outs or failure to attend the study.

Inclusion criteria for the enrolment are described in the table below.

Target	Characteristics	Measure

Older Adult (60+)	• Volunteers living independently who have/wish to have a healthy lifestyle, and who allow monitoring of their health status. • Presence of some memory problems • Overall good health condition	• Mini Mental Status Examination between 24 and 30 and Cognitive Assessment Kit if needed • Trained support staff (e.g. nurses, educators, psychologists, etc) will collect information about health status using close-ended questions.
Informal Caregivers	• informal caregiver of a person with memory problems	• Caregiver Burden Inventory

Table 1 Inclusion Criteria

The presence of at least one of the following criteria will exclude the user from the enrolment:

- lack of written informed consent (both for older adult and informal caregiver),
- presence of unstable chronic condition, a Mini Mental Status Examination lower than 24,
- presence of severe physical illness or disabilities that could be aggravated by the use of Anne

2.2.2 Recruitment procedure

The recruitment plan will be similar for all 3 pilot sites. Twenty subjects will be recruited in each site through clinical centres, municipality recreational centres, and voluntary organizations, presentations during meetings and by personal contacts. Initial screening will include a short phone interview, intended to exclude participants that do not fit the criteria for participation (i.e., age, independent living, cognitive status). Eligible participants will then be invited to come to the pilot sites for further discussion. When participants first arrive to the centre, study personnel will explain the study to them including all assessment, procedure, risks and benefits. The participant will be asked to sign an informed consent prior to any testing done.

2.2.3 Study Design and Methods

The first field trial will run for 8 weeks in each site.

The field test will be managed by skilled personnel and researchers that will guarantee both the supervision of the tests by specialized staff and the detailed measurement of the first interaction between users and the first system prototype. Data coming from this stage

will be used to assess and/or refine achieved S/T requirements and come to the second prototype for the second round of field trial.

The first field trial procedure consists of the following phases:

- Recruitment and Baseline phase based on specific inclusion and exclusion criteria.
- Instruction Phase. In this phase both older adults and caregivers will be instructed to use the system's functionalities.
- Evaluation of the interaction.

Quantitative and qualitative methods will be used in this first iteration.

The quantitative and standardized instruments to use are:

1. The Mini Mental State Examination (MMSE)- The MMSE is a screening tool that provides a brief yet objective measure of cognitive function. MMSE scores are useful in quantitatively estimating the severity of cognitive impairment. The MMSE consists of a variety of questions, has a maximum score of 30 points, and ordinarily can be administered in 5-10 minutes. A score below 15 represents cognitive impairment and in the Living Well studies is considered an exclusion criterion.
2. The SF-12v2™ Health Survey, a widely used instrument, is a 12-item subset of the SF-36v2™. It is a brief, reliable measure of overall health status. It is useful in large population health surveys and has been used extensively as a screening tool. It takes just 2 or 3 minutes and contains about 8 health physical functioning: Role-physical, Bodily pain, General health, Vitality, Social functioning, Role-emotional, Mental health.
3. The Quality of Life in Older Adults with Cognitive Impairment (QOL-AD) questionnaire is based on literature reviews of quality of life in older people. The questionnaire has 13-items covering physical health, energy, mood, living situations, memory, family, marriage, friends, chores, fun, money, self and life as a whole. The QOL-AD uses straightforward language for simplicity. The assessment is scored on a 4-point Likert score ranging from 1 (poor) to 4 (excellent) with total scores ranging from 13 to 52. The higher the score, the better quality of life the participant has. For patients with advanced cognitive impairments, a caregiver will also take the assessment.
4. The Almere model (Heerink et al. 2010) is a Likert scale-based questionnaire designed primarily to measure older adults' acceptance toward socially assistive robots. The questionnaire focuses on the following 12 construct: (1) anxiety, (2) attitude toward technology, (3) facilitating conditions, (4) intention to use, (5) perceived adaptiveness, (6) perceived enjoyment, (7) perceived ease of use, (8) perceived sociability, (9) perceived usefulness, (10) social influence, (11) social presence and (12) trust.
5. The closeness scale is a measure of self-other inclusion and relationship closeness. It is used to evaluate the closeness with the avatar at the end of the usage period.
6. The System Usability Score is a questionnaire which provides a quantitative measure of how usable a system is based on a ten statement Likert Scale, scored from

0-100 with 100 indicating perfect usability. Sauro et al carried out a study of 500 interactive products and found an average score of 68. The scale can also be split into individual scale of usability and learnability (i.e. the ease with which an application or product can be picked up and understood by users: a higher learnability level determines a less effort in training and time for a person to use the system) (each scored from 0-100).

7. Caregiver Burden Inventory. It is a 24-item multi-dimensional questionnaire measuring caregiver burden with 5 subscales: (a) Time Dependence; (b) Developmental; (c) Behaviour; (d) Physical Burden; (e) Social Burden; (f) Emotional Burden. Scores for each item are evaluated using a 5-point Likert scale ranging from 0 (not at all disruptive) to 4 (very disruptive). All of the scores on the 24-item scale are summed and a total score >36 indicates a risk of "burning out" whereas scores near or slightly above 24 indicate a need to seek some form of respite care.

Each instrument will be verbally administered in a face-to-face session by a trained interviewer who filled the response on a paper version of the questionnaire.

The table below summarizes the different methods that will be used to assess the interaction between the older user and the system:

Dimension	Method	Baseline	Evaluation
Cognitive State	Mini Mental State Examination	X	
Health Status	SF-12v2	X	
Socio-Demographics Data	ad hoc items	X	
Quality of Life	QOL-AD	X	X
Relation to the avatar	Closeness Scale		x
Usability and Learnability	Standardized test (SUS or similar) and		X
Acceptance	The Almere model	X	X

Table 2 Methods to gather data from older adults

The table below summarizes the different methods that will be used to assess the interaction between the informal caregiver and the system:

Dimension	Method	Baseline	Evaluation
Burden	Caregiver Burden Inventory	X	X
Socio-Demographics Data	ad hoc items	X	
Quality of Life	QOL-AD	X	X
Usability and Learnability	Standardized test (SUS or similar) and Cognitive Walkthrough		X
Acceptance	The Almere model	x	X
Demand and Cost Information	ad hoc items A/B Testing ranking of features		X

Table 3 Methods to gather data from caregivers

2.3 Evaluations Outcomes

2.3.1 Failure/success criteria for the evaluations results

The table below shows the failure/success criteria for the evaluations results:

Usability	- Perceived usefulness - Perceived easiness of use - Satisfaction with the use	- Ad-hoc questions following ISO standard + observation in use	- High degree of system usability
Acceptability	- Attitude and predisposition towards the system - Adaptability to the changing needs	- MPT Assistive Technology Device Predisposition Assessment - The Almere model	- High degree of attitude towards the system - High degree of acceptability
Promoting self-management and enhancing autonomy	- Number of needs satisfied by the platform - Improving the QoL of the PwD	- Ad-hoc checklist on needs pre and post the technological intervention - QOL-AD[2] instrument or similar	- Needs are satisfied - Improvement or stability
Lifestyle management	- Appropriateness of the training on healthy nutritional habit, physical activity - Maintenance of cognitive ability	- Interviews - Clinical evaluation	- Improvement of stability after the technological intervention
Impact on informal caregiver	- Psychological well-being and quality of life improvement - Social well-being	- Ryff's Psychological well-being scales[3]	- Improvement

[2]Logsdon, Gibbons, McCurry & Terry. (1999). Quality of life in Alzheimer's Disease: patient and caregiver reports. *Journal of Mental Health and Aging, 5*(1), 21– 32.

[3]Ryff's Psychological Well-Being Scales (PWB), 42 Item version

https://www.karger.com/ProdukteDB/katalogteile/isbn3_8055/_98/_53/suppmat/p192-PWB.pdf

End user involvement in UCD	-High degree of end users involved in the proposal	- Number of involved users - Number of dropouts	- 20 users a site - Less than 20%
Tablet hardware	- the tablet hardware is stable and work the whole test period	- datalog of the telemetry data give information about the use of hardware	- less than 10% hardware issues
Technical function of Anne	- sound and screen are clear - Anne works as it is meant to be - commands Speech recognition is a succesfactor.	- datalog of the telemetry data give information about the use of Anne.	- Anne is 99% of the time active on the screen. -
Speech recognition *function*	- commands Speech recognition can be a problem. This is not only related to Anne. All Speech recognition systems have the same limitations.	- training the user and give enough local support is very important	- Less than 25% of the users fall off.

Table 4 Evaluation outcomes

1
3.Ethical Issues

All ethical issues that this project may be exposed to, will be handled by the partners in their home countries with the local ethical committees. In particular, the work will be subject to the following ethical-related directives regulations and international conventions and declarations:

- The Charter of Fundamental Rights of the EU (2000/c 364/01),
- REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)[4],

[4] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016, source: http://ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf

- The reform of the data protection rules that was launched on January 2012 is not in force yet, but we will consider it and apply once it will be in force,
- Directive 2001/20/EC of 4 April 2001 on clinical good practice,
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions,
- Opinions of the European Group on Ethics in Science and New technologies including in particular:
    - Opinion of the European group on ethics in science and new technologies to the European commission, number 7, 21st of May, 1996
    - Opinions of the European Group on Ethics in Science and New technologies (as from 1998)
- Helsinki Declaration in its latest version.

Ethics approval has been submitted and approved by the IRB (Institutional review board) for technical approval and to the Ethical Committee according to the European Community act 2001/20/CE subsequently implemented and integrated by the ethical committees and regulatory organizations in the three sites during the life of the project.

National specific differences on this topic determined slight shifts of time but all the sites obtained the formal approval.

Pilot Site	**Time needed to get ethical approval**	**Status of the Ethical Approval**
Italy	3 months	Achieved
The Netherlands	2 months	Achieved
Luxembourg	3 months	Achieved

Table 5 The process of ethical approval in the three sites

3.1 Ethical Approval

Research ethics requires that all research involving human participants, personal data, or human tissue should be reviewed, and research ethics approval obtained, before data gathering commences. Each partner involved in the trial evaluations will apply for ethical approval from Local Ethical Committees completing the appropriate application form and submits it to their Ethics Administrator.

3.1.1 Informed consent

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

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

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

Clear explanations were given to the participants about the contents of the document:

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

In Annex1, a sample of the informed consent form (in English) can be seen.

3.1.2 Privacy and Data Protection

The collected data related to end users will be treated in accordance with the data protection standards. During the whole process of data collecting and information analysis, end users will be aware of the information needed from them. Data will be de-identified and a

study number will be always be used to identify them without revealing their real names or any other personal information, both within the partnership and in dissemination activities. Pictures will be taken only with the subject's consent and subjects will be asked for their written consent for those pictures to be shown in any publicity material.

A common database will be created to collect all the data in a comparable way.

All data concerning participants' performance will be recorded and stored in the remote database hosted by INRCA. INRCA will respect the legal and ethical European (Under Directive 95/46/EC of the European Parliament) and national requirements.

4. Site Profiles Description

4.1 INRCA, Italy

INRCA is the leading Italian public Institute in gerontology and geriatrics, devoted to improve quality of life of older persons. It consists of five centres in Italy, comprising four geriatric hospitals, an Alzheimer day care centre, a nursing home and scientific and technology research units.

The objectives of the Institute are focused on successful ageing and the promotion of health of the older person and prevention. Social gerontology is one of the most important research fields, developed in both national and international sphere, cooperating with universities and other research institutes. Currently, there are four lines of research: (1) Biogerontology: cellular determinants, molecular and genetic aging, longevity and age-associated diseases; (2) Prevention and treatment of frailty: management of geriatric diseases and syndromes; (3) Aging and Medicines and (4) Multidimensional assessment and continuity of care. INRCA pursues its goal mainly in an interdisciplinary way, through clinical and translational research, training in the biomedical field as well as in the organization and management of health care services, in particular by means of highly specialized hospitalization and health care.

For the Living Well project, the *Geriatrics Operative Unit* of INRCA will be involved. It aims at studying, screening, diagnosing and treating dementia and other age-related diseases. In particular, this OU has a long-standing experience in the diagnosis and care of neurologically-based problems in adults and geriatric individuals (including MCI, mood disorders, etc). The research activity is mainly focused on multidimensional aspects of aging, in particular by means of the use of Comprehensive Geriatric Assessment, including cognitive decline, quality of life, life-style, psychosocial and nutritional aspects in aging. It has a know-how on studying the multidisciplinary approach in aging. Moreover, for what concerns the research on the technology acceptance, the Centre of Innovative Models for Ageing Care and Technology aims at studying the needs of the elderly in the User Centred Design process, as well as the impact and acceptance of the technology to support everyday life, great emphasis is given to technological innovation, promotion and acceptance of

technology for the elderly. The lab is indeed involved in various activities aimed at the study of usability and acceptance of smart environments to support the independence and autonomy of the elderly. This commitment is supported through regional, national and international collaborations with universities, research institutes and companies specializing in technology, home automation and artifacts from the house computer, without architectural barriers, with sensors that detect possible hazards, smart appliances and tools with communication interfaces easy for their remote control. For the analysis of Human-Machine and Human-Computer Interactions, and of the acceptability and usability of technology, the Centre benefits from the presence of the **Casamica Lab,** a smart home of about 60 square feet, located close to the Rehabilitation Unit of the INRCA hospital in Ancona. The intelligent environment consists of a kitchen, a bedroom and a bathroom, equipped with assistive devices and home automation technology. The Casamica lab was designed to enable greater independence of older people and to avoid their admission to care facilities. It represents a unique opportunity to directly test technology with the people in real life, thanks its strategic location.

4.2 The Parabool, The Netherlands

The Parabool (DPL) provides support for children, (young) adults and elderly with an intellectual disability. Support is offered through multiple facilities for children, living, working and ambulatory care. At the Parabool the life and way of living of clients is central. In which possibilities and talents are found together, even as creating the best environment for living, working, care and leisure. The Parabool wants to give people the care and support they deserve, with the perspective on self-management in daily life of the client. Everyone's individuality is cherished to get most out of everyone. Clients develop themselves to reach their place at their level in society.

In total 600 clients are cared for by 300 employees at 28 different locations. The locations are spread in the Salland area in the province Overijssel. The locations have various purposes, for example an orthopedagogical day centre for children and young adults who suffer from a delay in cognitive development, intellectual or physical disability. Every child or young adult is stimulated through specialistic and individual care by professionals. Such as physiotherapy, ergotherapy and music therapy. There are also clients who live at locations of the Parabool, mostly small-scaled to ensure the feeling of safety and adjusted to the special needs of the client. Besides living, multiple work and daycare facilities can offer daily structure and a place in society. Clients can work for example at the bakery, the laundry facility or the textile atelier. Another possibility is ambulatory care at home for family -or parenting difficulties, financial problems, emotional problems or all other daily life cases.

In the few past years the Parabool has runned a small pilot with virtual assistant Anne. The Parabool believes that technology can improve quality of life and support the independence and autonomy of people with an intellectual disability and reach for a fully place in society. Most important is that technology is safe, supports current care and is easy to use. During the project multiple clients will join the project to investigate if and how Anne fits best to the client.

4.3 Stëftung Hëllef Doheem, Luxembourg

Stëftung Hëllef Doheem (SHD) is the largest not for profit community nursing, health and social care Provider in the Grand Duchy of Luxembourg. Besides general nursing activities, support in acts of daily living (ADL) and domestic support task, SHD also provides specialised nursing care as well as palliative / end of life care. Although SHD caters for all age groups it specialises in the care of elderly people. The care provided is 360° around the needs of each individual client through the support of a range of health professionals such as physiotherapists, occupational therapists, psychologists and dieticians. It also manages a number of Day Care centres which are caring for people with severe disabilities as well people suffering from mild to severe forms of dementia.

Around 5.000 clients per year are cared for by SHD staff care for on a long term basis. About 1% of them are aged under 20 and 12% are over 90 years old. Almost 70% of SHD's long term care customers are in the 70 to 90 age bracket. In addition, SHD's nurses and treat around 13.000 short term patients (i.e. injections, bandages, drips, blood tests….).

SHD is also the national Telecare Provider called Sécher Doheem (SD meaning safe at home). The multidisciplinary team of SD (ICT technicians, specialised nurses and call centre operators) have been introducing Telecare technologies such as fall detectors and epilepsy detection technologies since 2003. Around 5.000 Telecare customers generate around 55.000 alarms per year of which around 6.500 require some form of active help interventions.

For clinical research on human subjects, research protocols need to be submitted for approval to the ethical committee of the Research Institution and to the National Research Ethics Committee (CNER) prior to the start of a project (http://www.cner.lu/en-gb/procedures/submissionofanewstudy.aspx). The law dated 28 August 1998 on hospital institutions mentions that no trial, study or experiment can be performed on humans for the development of biological or medical knowledge unless the project has been previously subjected to the opinion of a research ethics committee. As the LIVING WELL project includes some level of study and experiments on humans through the prototype and field tests, SHD will submit the research protocols to the CNER.

5. Risk Management

Pilot project risks have the potential to affect project goals and pilot goals.

The project partners have defined risk as any event which is likely to adversely affect the ability of the project to achieve the defined objectives. Pre-defined procedures will be taken into account in order to minimise the possible occurrence of adverse events in the construction and deployment of the project.

	Risk	**Level**	**Impact**	**Contingency Plan**
End-users enrolment	Drop-outs and the failure to attend the study.	Medium	Medium	A reserve list of potential users that meet the inclusion criteria will be constructed in each site.
Acceptance	The new technological solution does not match to the user's expectations in terms of comfort.	Low	Medium	The previous knowledge and experience of the partners will be used during the pilot evaluations to avoid any problem in respect to the end users. Moreover, during the pilot the participant will be specifically asked about the systems and any feedback provided will be delivered to the technical team for implementation.
Functionality	The system is unable to collect data.	Low	High	During the functional trials, the functionality of the system will be validated long before the system is used with potential users, this to ensure that the system is stable in terms of data collection, data processing and data analysis and presentation.
Feasibility	The participants are unable to use the system alone and unable to operate the system.	Medium	Medium	The participants will require assistance in the beginning and detailed explanation to be able to operate the system alone. Study personnel will explain the operation to the subjects; Participants will also receive a written manual and a video of how to use the system. This video will be

				placed on their smartphone so that they can view it any time. In addition, during the pilot trials, a researcher will contact the participants by phone or visit them at home once a week to see if they are using the system and if there are no problems.
Usability	The participation of the users is low as participants do not regard the system to be useful for them.	Low	Medium	The validation sites have experience in conducting this kind of activities and they have direct links with end-users and stakeholders. Devoted dissemination campaigns and publicity will be carried out before the start of the validation phase, to ensure a wide participation. Moreover, experts in gerontology, psychology and geriatrics will be involved to motivate the participants and avoid drop-outs.
	The participants do not think they will require such a system and therefore do not intend to use it.	low	medium	The system was designed based on user needs as are expressed in the literature and based on WP2 "User requirements". Therefore we do not expect such a scenario. In the case it will occur, the teams will explain the usefulness of the system to the participants and show the many ways it can help in improving daily life.

Table 6 Risk Management

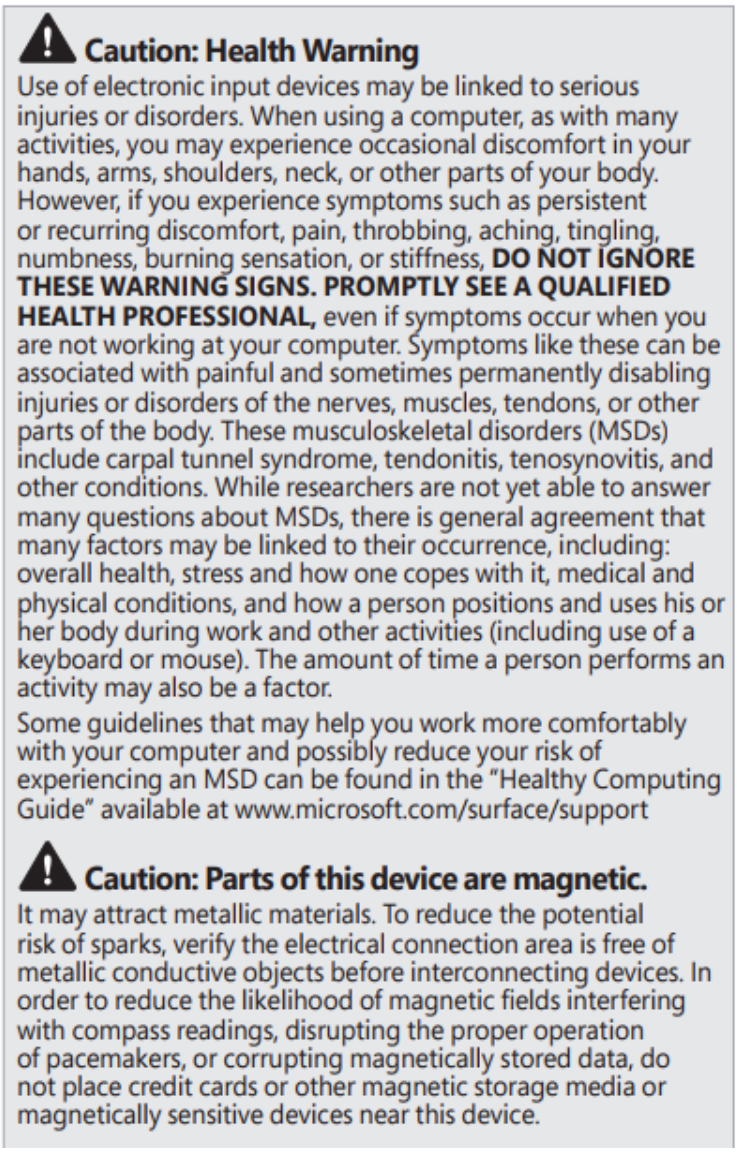
6.Safety

The safety issue of Anne can be explained twofold: the application in itself or the Microsoft Surface hardware to use.

For what concerns the application installed in the Microsoft hardware, any specific safety precautions are required during its usage and the users of Anne will not be exposed to potential harms.

At the construction of Anne, technical partners have taken into account the following security aspects:
-Secure communication between all systems (SSL),
-Specially protected database for medical diary,
-Information on the use of Anne is stored as Anonymized data,
-There is a difference between user and a user administrator and manager of the system. Separate account and authorizations are also used.

At the contrary, the use of Microsoft Surface is related to the following product safety issues reported by Microsoft in the "product safety guide" and already contained in the product package:



Caution: Health Warning

Use of electronic input devices may be linked to serious injuries or disorders. When using a computer, as with many activities, you may experience occasional discomfort in your hands, arms, shoulders, neck, or other parts of your body. However, if you experience symptoms such as persistent or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, **DO NOT IGNORE THESE WARNING SIGNS. PROMPTLY SEE A QUALIFIED HEALTH PROFESSIONAL,** even if symptoms occur when you are not working at your computer. Symptoms like these can be associated with painful and sometimes permanently disabling injuries or disorders of the nerves, muscles, tendons, or other parts of the body. These musculoskeletal disorders (MSDs) include carpal tunnel syndrome, tendonitis, tenosynovitis, and other conditions. While researchers are not yet able to answer many questions about MSDs, there is general agreement that many factors may be linked to their occurrence, including: overall health, stress and how one copes with it, medical and physical conditions, and how a person positions and uses his or her body during work and other activities (including use of a keyboard or mouse). The amount of time a person performs an activity may also be a factor.

Some guidelines that may help you work more comfortably with your computer and possibly reduce your risk of experiencing an MSD can be found in the "Healthy Computing Guide" available at www.microsoft.com/surface/support

Caution: Parts of this device are magnetic.

It may attract metallic materials. To reduce the potential risk of sparks, verify the electrical connection area is free of metallic conductive objects before interconnecting devices. In order to reduce the likelihood of magnetic fields interfering with compass readings, disrupting the proper operation of pacemakers, or corrupting magnetically stored data, do not place credit cards or other magnetic storage media or magnetically sensitive devices near this device.

Figure 4: Safety cautions during the use of Microsoft Surface

These safety cautions will be explained to users during the instructional phase planned in the study design.

Moreover, during the implementation of the project, the law and regulations will be continuously examined and applied in case of important changes. Furthermore, participants will be closely followed by research study personnel to maintain the highest safety and limit the risk of danger.

References

Brooke J. (1996) SUS: a "quick and dirty" usability scale. In P. W. Jordan, B. Thomas, B. A. Weerdmeester, & A. L. McClelland. Usability Evaluation in Industry. London: Taylor and Francis.

European Union (EU). (2015). Which priorities for a European policy on multimorbidity?

http://ec.europa.eu/health/ageing/docs/ev_20151027_ccl_en.pdf

European Union (EC). (2016). Dementia.
http://ec.europa.eu/health/major_chronic_diseases/diseases/dementia/index_en.htm

Eurostat. (2017). Database. http://ec.europa.eu/eurostat/data/database

Geo Demo. (2017). Demography in figures. www.demo.istat.it

Heerink, M., Kröse, B., Evers, V., & Wielinga, B. (2010). Assessing acceptance of assistive social agent technology by older adults: the almere model. *International journal of social robotics*, *2*(4), 361-375.

Logsdon, R.G., Gibbons, L.E., McCurry, S.M., & Teri, L. (1999). Quality of life in Alzheimer's disease: Patient and caregiver reports. *Journal of Mental Health Aging 5*, 21–32.

Logsdon, R.G., Gibbons, L.E., McCurry, S.M., & Teri, L. (2002). Assessing quality of life in older adults with cognitive impairment. *Psychomatic Medicine, 64*, 510-519.

M.F. Folstein, S.E. Folstein, P.R. McHugh, Mini-Mental State. A practical method for grading the cognitive state of patients for the clinician, J. Psychiatr. Res. 12 (3) (1975) 189–198.

Novak, M., & Guest, C. (1989). Application of a multidimensional caregiver burden inventory. *The gerontologist*, *29*(6), 798-803.

Ryff CD: Psychological well-being in adult life. Psychological Science,1995,4, 99-104.

Scherer, Marcia J., and Gerald Craddock. "Matching person & technology (MPT) assessment process." *Technology and Disability* 14.3 (2002): 125-131.
Ware JE, Jr, Kosinski M, Keller SD. "A 12-Item Short-Form Health Survey: Construction of Scales and Preliminary Tests of Reliability and Validity." Medical Care. 1996;34(3):220–33.

Ware JE, Jr, Kosinski M, Keller SD. How to Score the SF-12 Physical and Mental Health Summary Scales. 3d. Boston: The Health Institute, New England Medical Center; 1998.

2 Annexes

2.1 Annex 1 Computer/Tablet requirements

Function	Requirement	Comment
Main functions		
Screen diameter	10 - 13 inch	
Operating System	Windows Version 10 (Pro)	

Computer type	Tablet / laptop	laptop is not the preferable choice because keyboard is not necessary.
Operating System		
Operating System	Windows 10 (pro)	Pro version if present
Processor		
Processor type	Intel Atom of Celeron or bigger	
Processor cores	Quad core	
clocking	Minimal 1300 MHz	
Memory		
Memory (RAM)	Minimum 4 GB	
Store type	SDD/HDD minimal 64 GB	
Store capacity expansion	not necessary	
Screen		
Screen quality	Full HD (1080p)	
Screen resolution	1280 x 800 pixels 1920 x 1080 pixels	
Screen technology	Touchscreen	

Screen type	IPS panel	
Light sensor	not necessary	Will be turned off
Video		
Video processor	No specific requirements	
Connectivity		
Wireless connection	Bluetooth & WIFI	
USB connection	USB, USB-A, USB-B	
HDMI	Not necessary	
Sound		
Loudspeaker(s)	Integrated	Perfect quality
Headphone connection	Yes	3,5 inch jack (Bluetooth)
Microphone intern	Yes, preference: screen integrated	Perfect quality
Microphone connection point	Yes	3,5 inch jack
Camera		
Camera	Yes, screen integrated	
Camera quality	Minimal 2 megapixels	

Camera second (rear)	Not necessary	
Keyboard		
Keyboard	Virtual - QERTY	AZERTY (Belgian)
Keyboard (external)	Optional	More expensive types standard
Power (Battery)		
battery capacity	Minimal 6000 mAh	
Battery life	4 hours use	
Power adaptor	Minimal 4 Amp	
Wireless charging	Strong preference	If present
Others		
GPS	Not necessary	
Weight of the tablet	Not more than 1,2 kg	
Color of the tablet case	No preference	No bright colors

2.2

2.4 Annex 2 Informed Consent

Project title: Living well with Anne		
Principal Investigators:		
Background: the Living Well project aims to develop a computerised system to help and support older adults and their caregivers who are living independently in their own home and are dealing with memory and other cognitive issues. The system is composed by a virtual personal assistant designed to help independent older adults to manage their daily activities and overcome potential problems of forgetfulness. The Living Well project requires a pilot study phase. During this phase, 60 voluntary participants will be recruited in three different European States (Italy, The Netherland and Luxembourg). Participants will be introduced to the correct use of Anne and then they will be invited to use the system for an agreed period of time. During this period the volunteers will be interviewed by researchers. The interview will last approximately 30 minutes and researchers may take note or tape/videotape the interaction between the system and the users. Privacy and confidentiality will be always guarantee during the pilot study.		
Participant Declaration:		
I have read or have had the information about the project and I understand the contents.	Yes	No
I have been given an opportunity to ask questions and am satisfied with answers.	Yes	No
I consent to take part in the study.	Yes	No
I understand that participation is voluntary and that I can withdraw at any time.	Yes	No
I understand that withdrawal will not affect my access to services or legal rights.	Yes	No

I consent to possible publication of results.	Yes	No
I consent to the use of images, video and sound recordings containing personal data.	Yes	No
I give my permission to: Use the data obtained from you in other future studies without the need for additional consent.	Yes	No
Researcher Declaration:		
I have explained the study to the participant	Yes	No
I have answered questions put to me by the participant about the research	Yes	No
I believe that the participant understands and is freely giving consent	Yes	No
I guarantee the protection of natural persons with regard to the processing of personal data and on the free movement of such data according to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.	Yes	No

Participant's Statement:

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand I may withdraw from the study at any time. I have received a copy of this consent form.

Participant's Name:

Contact Details:

Participant Signature:

Date:

The form needs to be signed by the consenter and dated.

Researcher's Statement: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Signature:

Date:

2.5

2.6

2.7

2.8

2.9

2.10 Annex 3 Protocol for older adults

RECRUITMENT PROTOCOL (Older Adults)

Participant Identification

Code_____

Country:

1 Italy

2 The Netherland

3 Luxembourg

Date of Interview:_____/_____/_____ (Day/ Month/Year)

Name of Interviewer:_____

2.11 Annex 3 Protocol for caregivers

RECRUITMENT PROTOCOL (informal / professional Caregivers)

Participant Identification

Code_____

Country:

1 Italy

2 The Netherland

3 Luxembourg

Date of Interview:_____/_____/_____ (Day, Month, Year)

Name of Interviewer:_____