



PETAL
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Deliverable 4.1a

Demonstrator Prototype and Field Trial Preparation

Responsible Unit: ANA

Contributors: All Partners

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1 INTRODUCTION

In this Work Package, the platform developed in WP3 will be tested by validating its use in real contexts. We plan to carry out trials in the home of 16 people (distributed in four different areas) suffering from dementia. We plan two cycles of trials: this will allow to assess the added value of the proposed solution with respect to the state of technique, and to quantify its benefits from the economic point of view.

T4.1 Demonstrator Development

The activities of this task are aimed to package the technology developed during the project into a solution easily deployable within a real house. This will be done by selecting appropriate hardware components that minimize the installation effort and intrusiveness, and by tuning the software in order to make the configuration phase quick and possibly suitable for DIY.

There will be developed two versions of the demonstrator prototype, at months 12 and 24. In addition, the objectives to be achieved within this deliverable will provide to technical partners a set of user requirements guidelines that will serve as the foundations of the solution. It will use a guideline of end-user's recruitment and enrolment, the methodologies to enable the collection of data from user focus groups, expert groups, and advisory groups.

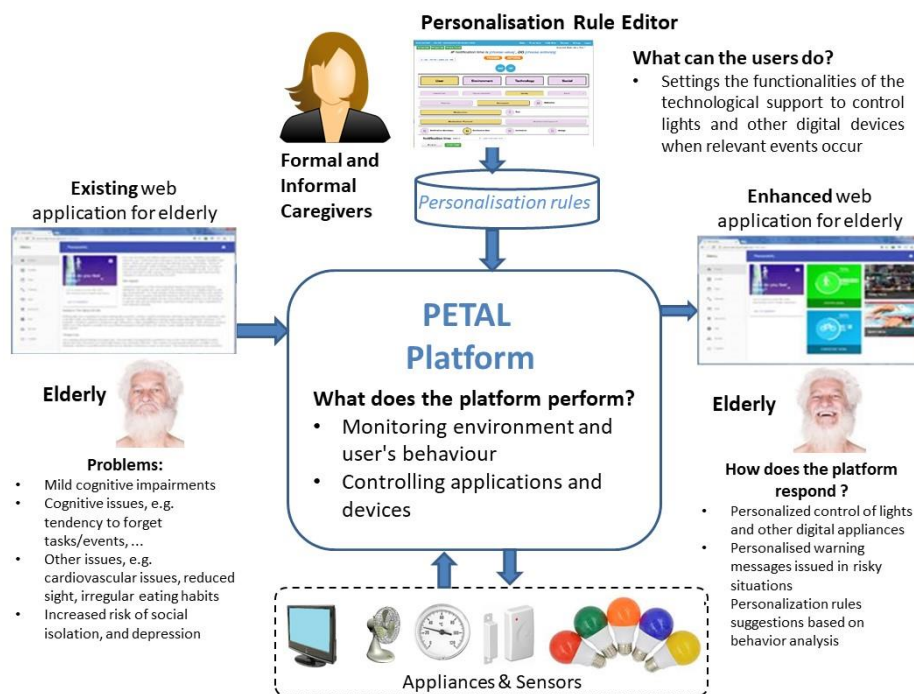


Figure 1: Personalization Rule Editor

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2 FIRST PROTOTYPE COMPONENTS

2.1 Lighting system

The PETAL Lighting System was developed to support elderly with MCI and their formal or informal caregivers in their activities of daily live in their homes as well as to provoke positive effects on the patients' health and the caregivers' burden.

Lighting that addresses positive health effects in human beings is usually described by Human Centric Lighting (HCL). This term was implemented in 2013 into the lighting industry and describes all kinds of lighting that positively affect human beings' mood, alertness, performance, health and wellbeing. Usually there are following components considered: 1) use of daylight, 2) high-quality artificial light supplementing daylight whenever it is missing, 3) use of sensors to optimize light usage and 4) easy-in-use light control schemes.

With the new LED-technology luminaires that fulfil the HCL-approach can be developed and penetrate the lighting market. But there are still gaps for new luminaires with special features and functions for specific user groups e.g. patients with cognitive declines. PETAL addresses patients with Mild Cognitive Impairment (MCI), an early stage of dementia that also comes along with impairments in memory functions, spatio-temporal orientation, alertness, planning and problem solving. A market analysis conducted by Bartenbach in 2018 showed that there is no mobile light solution that fits these goals and can be used easily by this target group in their home settings. Therefore, Bartenbach developed a new standing-luminaire for another AAL-project (GREAT – Get Ready for Activity – Ambient day scheduling with dementia) in cooperation with *emt*, a swiss partner and expert in electronics. This luminaire fulfils all requirements that are addressed in the PETAL-project as well. But, because one luminaire is not enough to equip a whole flat with about 4 rooms as is aimed in PETAL, a product analysis was performed to find out which products can be added to fit the PETAL-project goals. The PETAL-lighting system should be very flexible and adaptable in modularity and scalability to fulfil the needs of a customer.

We defined the following requirements as crucial for the lighting system:

- 1) All components must be available on the market
- 2) All components must be easily installable
- 3) All components must have an internet connection to connect it with the PETAL-Rule Editor
- 4) The whole PETAL system must cost below 4,000 EUR.

The product analysis resulted in a lighting system consisting of different Philips lighting components and a standing-luminaire from Bartenbach & emt (see Figure 2 and Figure 3). In addition, daylight sensors will be used to gather information about the current light levels at important locations.

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Figure 2: GREAT-luminaire



Figure 3: Philips Hue White ambiance and Philips Hue light stripe white and colour ambience

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The advantages of this lighting concept are, that no electric knowledge is necessary to install the components as well as that the system is easily to dimension to fit different flat architectures with different sizes of rooms.

The PETAL Lighting System components were chosen to reach specific light effects (see

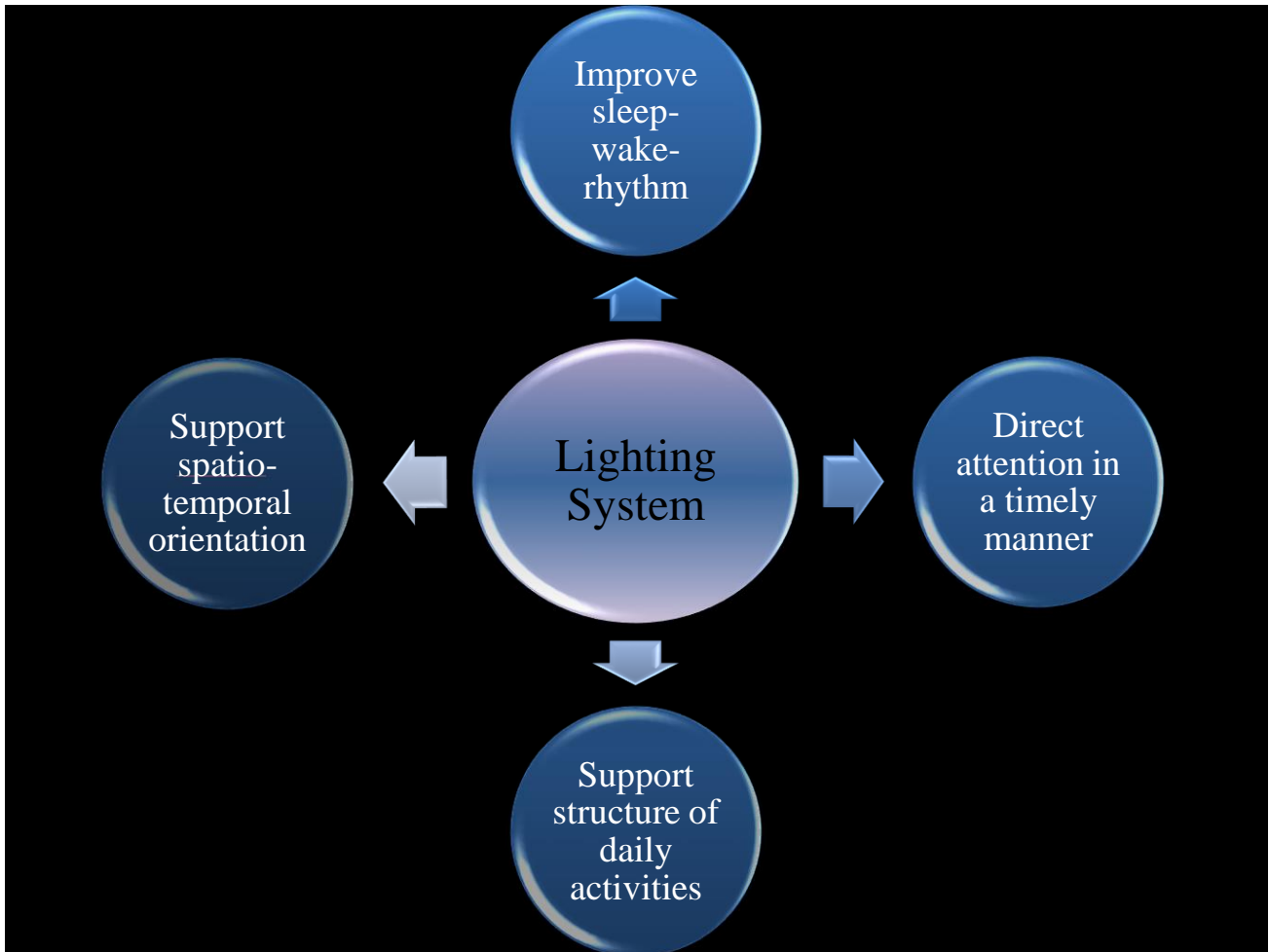


Figure), namely to improve the sleep-wake-rhythm, to direct attention in a timely manner, to support the structure of daily activities and to support spatio-temporal orientation.

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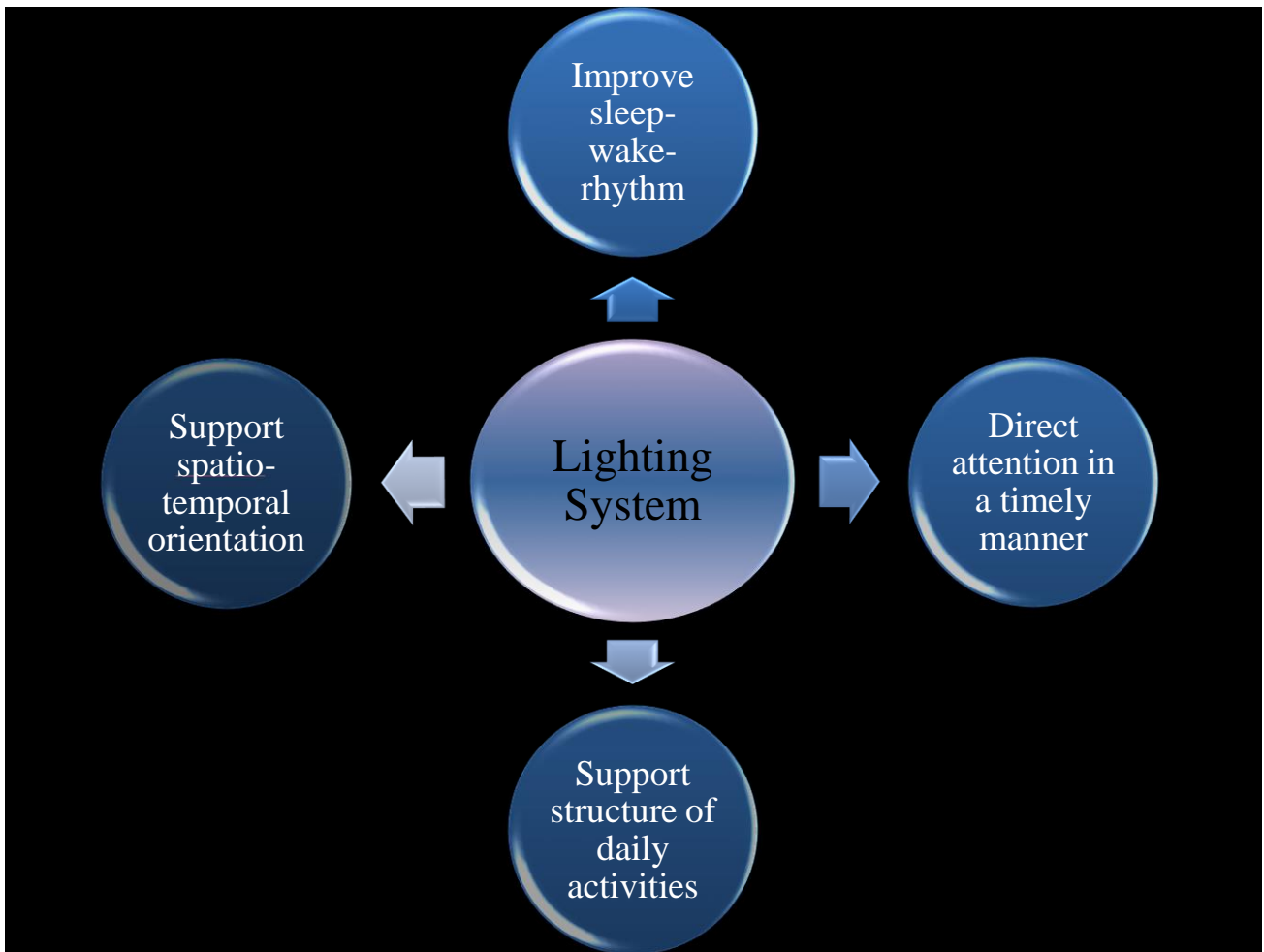


Figure 4: Expected light effects

Improve sleep-wake-rhythm:

To improve the sleep-wake-rhythm we use different colour temperatures and illuminance levels at different times of the day. In detail, this means that the whole flat will provide a colour temperature of 4000 K during the daytime and 2700 K during the night time. Different scientific papers showed that high colour temperatures during the night cause melatonin suppression [e.g. Higuchi et al. 2016]. Therefore, lower colour temperatures should be used during the night. Melatonin is a hormone, that plays an important role in moderating sleep-wake-states and it supports the transition from being awake to sleep. Sleep problems like frequent interruptions of sleep as well as problems falling asleep are quite common in the elderly population which is a result of Zeitgeber-weakness (light is the strongest Zeitgeber on human being's sleep-wake-rhythm) and biological degradation of the human being's eye with increased age. In order to improve Zeitgeber-strength, bright light with a high colour temperature (e.g. 4000 K) will be provided during the day and reduced light levels with lower colour temperature will be provided during the late evening and night. If the mobility of a person makes it possible, daylight will also be used to improve the sleep-wake-rhythm. Daylight is the brightest light

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source that is available and therefore is the most efficient Zeitgeber. But if a person's mobility is reduced, missing daylight can be supplemented by artificial bright light inside a flat.

Direct attention in a timely manner:

It is proven that light attracts attention and that light has an influence on the acute alertness level of human beings. We can use this knowledge to guide the attention of an observer by using daylight or artificial light signals. For artificial light white or coloured light can be used.

Support structure of daily activities:

Usually our daily activities follow a more or less stable time schedule. We wake up, wash ourselves, eat breakfast, do some activities (do household, work, do some hobbies, etc.), eat lunch, do some more activities, eat dinner, relax, go to bed, sleep. When people stop working because of retirement or because they suffer from diverse diseases, this rhythm starts to decompose. This frequently leads to sleep problems, energy loss during the day and, mood disturbances like depression. Beside using daylight, artificial light can be used to support and maintain a regular day schedule by providing different light settings for different times of the day and specific activities. Basically, a biodynamic light curve will be used, that varies in colour temperature and light intensity in a 24 hours rhythm. In the morning people will wake up with slowly increasing light levels that starts with low relaxing colour temperature (warm white, "orange" light) and ends with high activating colour temperatures (cold white, "bluish" light). During the day activating light with high colour temperature will be provided to support daily activities and, in the evening a slow reduction in light levels and colour temperature prepare observers for going to sleep. Beside biodynamic lighting, ambient light scenes and light cues can be used to support specific activities e.g. bright, high quality light improves visual comfort and therefore eases visual tasks or moving around safely. Light cues can also be used to make a person aware of important activities e.g. turning on the light in the kitchen at lunch time remembers a person about preparing a meal and eat at the right time.

Support spatio-temporal orientation:

People with MCI often have problems with spatial and/or temporal orientation. Light can be used to help patients finding the right place easier and at the right time. e.g. finding the bathroom during the night faster. Biodynamic light gives a person a natural information of the time of day, when temporal orientation is impaired e.g. bright light means that it is during the day, low intensity melatonin light means that it is during the night.

In the project PETAL we will use different kinds of lighting to reach the above described effects: daylight; artificial light with melatonin light, orientation light, wake up light and signal light. Figure summarizes the different used kinds of lighting and the expected effects. In sum they are creating the PETAL lighting concept.

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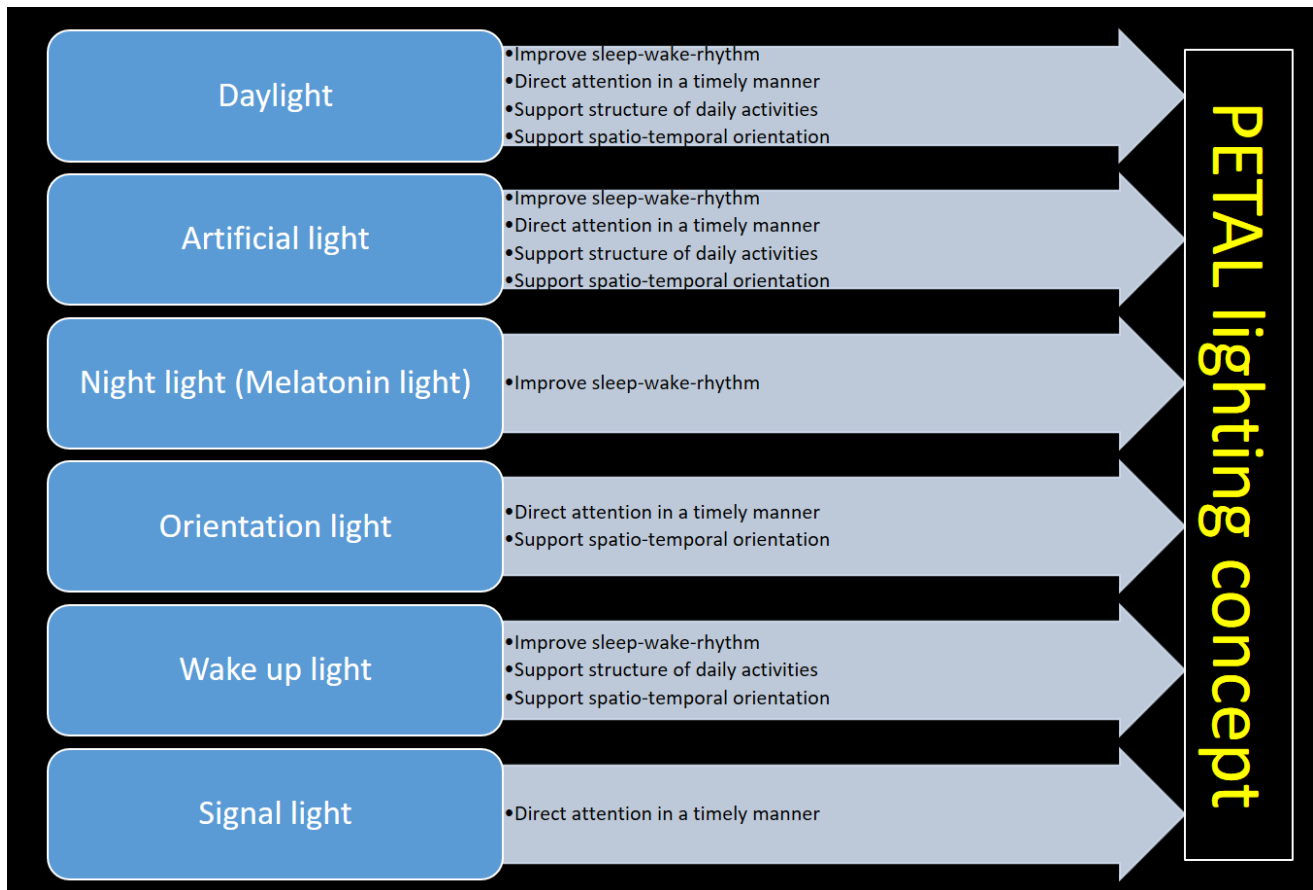


Figure 5: PETAL lighting concept - used lights to reach specific effects

In order to fulfil the expected visual and non-visual effects products had to be found that fits to our project goals. In a first step, photometrical requirements for the products were defined (see

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Table 1 Technical specifications for the PETAL Lighting System). A market analysis on lighting products and their availability was carried out as basic for the correct product choice. The inclusion criteria for the products are described above.

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Table 1 Technical specifications for the PETAL Lighting System. CCT...Correlated Colour Temperature in Kelvin, Eh...horizontal illuminance in lux, Ev...vertical illuminance in lux

Requirements	Technical specifications	Location (room)	Sensors
Use of daylight to stabilize activity-rest-patterns	Daily light dosage of 5000lxh should be reached	Indoor and outdoor	Daylight sensors
Good artificial light for higher visual requirements	$E_{table} = 1000lx$, glarefree	Living room (most common place)	-
Activating ("light shower") and relaxing light cues to guide behaviour	see GREAT cues: activation $E_v=600lx$ CCT = 4000 K, relaxation $E_v=120lx$, CCT = 2700 K	Living room (most common place)	Daylight sensor
Wake up light for stabilization of sleep-wake-cycle	$E_{max} =$ increasing to approx. 200lx CCT = increasing from 2200 to 4000 K	Bed room	-
Changes in CCT to provide stabilization of sleep-wake-cycle	$CCT_{Day} = 4000 K$, $CCT_{Night} = 2200 K$	Whole flat; exception kitchen: $CCT_{Night}=2700 K$	-
Orientation light to guide person safely during the night	$E_{floor} = 25 lx$ dimnable	Bed room	Movement sensor (presence/absence)
Signal lighting to guide attention	Approx. 300lx White and coloured light (RGB...red green blue)	Living room (most common place)	-
Light detection to prevent unwanted events	-	Bath room	Light sensor, movement sensor

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2.2 Network of sensors

A network of sensors and actuators will be installed to collect contextual information about the home environment and the users. Changes in sensors state may trigger personalization rules related to their value. The inclusion criteria for the selection of the sensors are: all sensors must be commercial, all sensors must be easily installable, all sensors must have a communication channel to connect them with the PETAL platform.

Due to this we consider if the sensors are standalone or wireless and the measurements taken into account are:

Environmental measures:

- Motion (true/false)
- Light detection (lux)
- Temperature (C°)
- Humidity (%)
- Gas (true/false)
- Windows/Doors state (Open/Close)

Obviously, all these metrics will be related to the different environments which compose the actual context of use, i.e. during the trials it will be possible to define rules referring the motion or the temperature of a specific room

The following are environment measures which are not related to a specific environment/room, instead they are more general:

- Weather forecast (external humidity, temperature real and feels like, pressure, chance of precipitation, wind speed)
- Date and time

User measures:

- Position/Room (in which room the user is)
- Position/Time (how long a user stays in a room)
- Heart Rate (bpm)
- Sleep (how long did the user sleep tonight? How long did the user spend in light, deep or REM sleep?)
- Physical Activity (steps, distance, calories)
- Going out/in from/to home

Technology measures:

- State of appliances/devices
- Battery level of appliances/devices

The platform architecture is described in detail in Deliverable D3.1.

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Sensors KIT	Price	Portability	Standalone	Wireless Connectivity	Motion	Temperature	Light level (lux)	RGB Light Sensor	Humidity	Sleep Tracking and Stages	Heart Rate	Steps, Calories, Distance	Floors Climbed	Gas	Body Temperature	Body Position	Proximity
Fitbit Charge 2	€99,99	wearable	yes	yes	yes	no	no	no	no	yes	yes	yes	yes	no	yes	yes	no
Xiaomi Mi Band 3	€22,41	wearable	yes	yes	yes	no	no	no	no	yes	yes	yes	yes	no	yes	yes	no
Hue Motion Sensor	€34,99	portable and fixed	yes	yes	yes	yes	yes	no	no	no	no	no	no	no	no	no	yes
Hue Bridge	€53,52	portable and fixed	yes	yes	no	no	no	no	no	no	no	no	no	no	no	no	no
Estimote Proximity Beacons	€99,00	portable and fixed	yes	yes	yes	yes	yes	no	no	no	no	no	no	no	no	no	yes
Estimote Location Beacons		portable and fixed	yes	yes	yes	yes	yes	yes	no	no	no	no	no	no	no	no	yes
Grove Gas Sensor (MQ5)	€6,90	fixed	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no
Arduino UNO R3	€26,39	fixed	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no
DFRduino Wireless Ethernet Shield	€5,14	fixed	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no
DH11 Temperature & Relative Humidity	€3,54	fixed	no	no	no	yes	no	no	yes	no	no	no	no	no	no	no	no

Figure 6: Sensors considered in PETAL

Motion, light level and temperature can be measured by HUE Motion Sensors¹. The HUE Motion Sensor have a range of 5 meters and a detection angle of 100 degrees in both horizontal and vertical direction. IHue motion sensors are connected to the Hue Bridge through ZigBee communication protocol, then the Hue Bridge exposes some REST services, which can be called

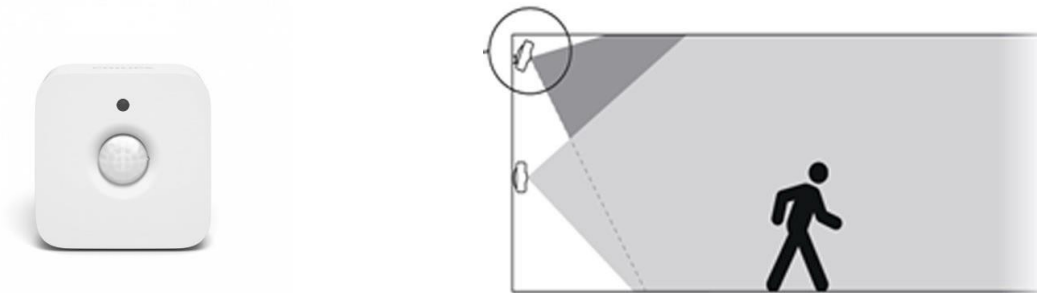


Figure 7: Hue Motion Sensor and Best Angle to Detect Movements

¹ www2.meethue.com

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by the Context Delegate running on the OpenHab gateway. For instance, if there is a Hue Motion sensor and a Hue light registered to the openHAB, in the HUE Bridge there will be rest services used to get the current state of lights/motion/temperature, and a Rest service used to update the status of registered lights.

We considered to use Estimote Beacons² for taking data about the location and proximity. Estimote Proximity Beacons have a range of 70 meters instead Estimote Location Beacons can detect the presence in a range of 200 meters.

The beacons send via Bluetooth a signal with an ID which identify them. When a smartphone running the Proximity Context Delegate is nearby, it detects the signal and, since a beacon is associated to a room, it communicates the user position to the context server (it needs wireless connection for this). The Proximity Context Delegate we developed exploits the Estimote SDK which inform it when the smartphone enters (or exits) to (from) a region identified by the beacon; when a user enters in a region we can start a timer and stop it when the user exits from the region; in this way, we can update the context manager sending the amount of time the user spent in a specific room.

During the Field Trials carried out for another AAL project we tested this solution which pointed out an issue: to identify the user position it needs that users have always with them a device and this situation, especially at home, is not always realistic. A possible solution may consider a wearable device that can be reasonable worn most time and is able to support both Bluetooth and Wi-Fi connection at the same time. We looked at smartwatches and most of them are not able to do this, some have Bluetooth and Wi-Fi but do not support open communication with both at the same time. There are two smartwatches that seem able to do this: 1-LEMFO LEM7 Android 7 Smart Watch 2- Zeblaze Thor 4 Smartwatch Android 7



Figure 8: Estimote Proximity Beacons

² <https://estimote.com/>

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2.3 Integration of the Cognitive Stimulation Application

The Cognitive Stimulation Application is integrated with the Platform via endpoints published in Context Manager rest service.

Every 2 hours (configurable), Kwido Mementia gathers the situation of the people using the tool and send it to the Context Manager via REST endpoints. Context Manager analyses data and generate events to respond according the rules defined for each user.

The data sent from Kwido Mementia to Context Manager contains this information:

- Emotional State rank
 - Sad, 0 to 1
 - Discouraged, 1 to 2
 - Satisfied, 2 to 3
 - Pleased, 3 to 4
 - Happy, 4 to 5
- Training result rank
 - Stupendously 80.00 to 100.00
 - Nimble 60.00 to 79.99
 - Well-Maintained 40 to 59.99
 - Not progressing well 0 to 39.99
- Cognitive State rank
 - Expert, 4
 - AAML, memory losses associated with age, 3
 - MCI, mild cognitive impairment, 2
 - MoCI, moderate cognitive impairment, 1
 - Automatic, 0
- Self-Assessment Value rank
 - Is a numeric value, representing a typical exam scale value from 0 to 10
- Training Time rank
 - Numeric value
- Time since last connection
 - Numeric value

There is an AWS Lambda recurrent service that acts as a bridge between Mementia and Context Manager. To do so, the information from Kwido Mementia is fetched recurrently by a REST API and sent to the platform by the REST API exposed.

In Kwido Mementia, besides exposing the required REST API endpoints for the synchronization, an extra field has been added to the users, containing in this Context Manager integration case, the user identifier from the security system in place, Auth0.

This way, every time a new user is provisioned in the platform via Auth0, that field will be added to the Mementia user.

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3 FIELD TRIALS PREPARATION

3.1 Ethical and data protection considerations

3.1.1 GENERAL CONSIDERATIONS

The ethical and legal issues related to working with human voluntary end users within the PETAL project are significant. They address two distinct categories: issues related to the implementation of the project and issues related to the solutions adopted in the project. Both must apply the national and international ethical rules specific for end-users and to society in general, from the concept phase to test installations and eventually launching in the market. AAL projects, by their nature, raise a broad range of ethical concerns, most of them related to the technology involved that is often unfamiliar to the end-users and being sufficiently complex to not allow a full transparency for end-users and other stakeholders (privacy, control of personal data, confidentiality, autonomy and dignity).

In generally the ethical rules in AAL concerns refers to:

- end-user's recruitment,
- end-user's participation to project development,
- the informed consent as a standard procedure,
- the protocol of participation in prototypes testing and validation,
- information on how the end users can withdraw from the project at any time,
- the possible compensations provided for participating (expenses or fees paid, etc.),
- the possibility to contact a person in their own country for ethical issues and related questions.

The exit rights for individual end-users (withdrawal from the project at any time, without giving a reason and without incurring costs or penalties) must be clearly specified and also the finalization of the project must be carefully managed because it may create problems in the terms of losing a help the end-users got accustomed with. Other important issues that require ethical awareness are information and data management, the storage and transmission of personally identifiable information, the application of the national rules of the involved partners, the statement or permission by national and/or partner's institution ethical committees (whenever required), and the macro level distributive ethics (justice, equality of access, choice etc.).

Of great importance and help in the ethical management is the permanent communication with the National Contact Point.

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3.1.1.1 Data Protection aspects

3.1.1.1.1 Regulations on protection of individuals and handling personal data

a. At European level

The new Directive of the European Parliament and of the Council from 27 April 2016 (Regulation 2016/679 and Directive 2016/680), which sets up the new General Data Protection Regulation that became effective since 25th of May 2018, when the previous directive (Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) was repealed.

Key differences between Directive 95/46/EC and the new GDPR

- Geographic reach and scope: The previous European Data Protection Directive utilized much more of a light-touch approach than GDPR, setting out aims and requirements for data protection standards that were then implemented through national legislation. By contrast, GDPR is a binding piece of regulation, which has become legally enforceable from May 25th 2018, and it applies to all EU nations and every company holding data on EU citizens.
- Definition of personal data: GDPR expands the definition of "personal data" to include a much wider range of consumer information. Whereas the Data Protection Act only pertained to information used to identify an individual or their personal details, GDPR broadens that scope to include online identification markers, location data, genetic information and more.
- Consent policies: This is one of the defining differences between GDPR and the Data Protection Act. Under the old rules, data collection did not necessarily require an opt-in, but under GDPR clear privacy notices must be provided to consumers, allowing them to make an informed decision on whether they consent to allow their data to be stored and used. This consent can then be withdrawn at any time.
- Data breach policies: With the previous rules in place, businesses were under no obligation to report when data breaches occur, although they were encouraged to do so. This has changed with the advent of GDPR, with any future breaches having to be reported to the relevant authorities within 72 hours of the incident.
- Accountability: GDPR places a much greater focus on explicit accountability for data protection, placing a direct responsibility on companies to prove they comply with the principles of the regulation, rather than the hands-off approach of the Data Protection Act. This means firms need to commit to mandatory activities such as staff training, internal data audits and keeping detailed documentation if they wish to avoid falling foul of the GDPR rules.
- Data protection governance: The Data Protection Act did not stipulate how the governance of data security functions should have been allocated, requiring only a basic commitment to the concept from management. GDPR changes this, as any company employing more than 250 people is mandated to appoint a dedicated data protection officer, as does any firm processing more than 5,000 subject profiles annually.
- Penalties and compensation: Formerly, non-compliance with the Data Protection Act could see companies fined up to £500,000, or one per cent of annual turnover. Under

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GDPR, these limits have risen significantly to €20 million, or four per cent of annual turnover, whichever is higher. It's also worth remembering that GDPR allows individuals to claim compensation for material and non-material damage resulting from data security lapses, whereas the former rules only covered material damage.

b. At National level in piloting countries

✚ In Romania:

All the organizations involved in research are under the jurisdiction of National Authority for the Supervision of Personal Data Processing and the legal framework is represented by:

- Law no. 226/2009 on the organization and functioning of the official statistics in Romania
- Law no. 677/2001 on the protection of persons regarding the processing of personal data and on the free movement of such data
- Law no. 682/2001 on the ratification of the Convention for the Protection Individuals related to Automatic Processing of personal data, adopted in Strasbourg on 28.01.1981, as amended subsequent
- Confidentiality rules of statistical data - National Statistics Institute

However, all the national rules and regulations in Romania regarding data protection will have to be harmonized and comply with the requirements of the new GDPR, as per 25th of May 2018

✚ In Italy:

The Italian Data Protection Authority (Garante per la protezione dei dati personali) is an independent administrative authority set up by the so-called Privacy Law (Law No. 675 of 31 December 1996) and regulated subsequently by the Personal Data Protection Code (Legislative decree No. 196 of 30 June 2003), as amended by Legislative Decree No. 101 of 10 August 2018.

Accordingly, several of its provisions were amended or repealed and sections were added. The decree has made use of the margin of manoeuvre afforded by the GDPR to Member States as regards, in particular, processing activities based on legal obligations or for purposes in the public interest (Article 6(1), letters c) and e)); processing of biometric, genetic and health-related data (Article 9(4) and Article 36(5)); processing activities covered by Chapter IX of the GDPR (journalism, labour, research, archiving, etc.). As a result, several provisions of the 2003 Code were left in place as they were found not to be in conflict or overlap with the GDPR and to provide added value for the relevant stakeholders based on the implementing experience of the past 15 years.

✚ In Austria:

All the organizations are under the jurisdiction of National Authority for the Supervision of Personal Data Processing and the legal framework is represented by:

- Datenschutz-Grundverordnung (EU) 2016/679: Verordnung (EU) 2016/679 des Europäischen Parlaments und des Rates vom 27. April 2016 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten, zum freien Datenverkehr und zur Aufhebung der Richtlinie 95/46/EG
- Datenschutzgesetz (DSG): BGBl. I Nr. 165/1999 idgF.

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All the national rules and regulations in Austria regarding data protection are harmonized and comply with the requirements of the new GDPR.

3.1.1.1.2 General Rules regarding data protection

- Transparency - the right of the person to be informed: that a category of its personal data is under processing, also the purpose of processing and the recipients of the data.
- Person's right to access all his data under processing.
- The right to demand rectification, blocking or deletion of incomplete, inaccurate data
- Person's consent about his/her data processing.
- Data have to be processed in the interest of their owner, for accomplishing a task of public interest or for the fulfilment of a contract. Also, data have to be processed in an adequate and not extensive way, and will not be further processed beyond the initially specified, explicit and legitimate purposes.
- Data keeping must permit identification of their owner only on the period necessary to accomplish the purpose for which they are collected.
- Special attention regarding sensitive personal data of racial, political, philosophical religious

3.1.1.2 Ethical aspects in the PETAL Project

This section describes the ethical aspects required by PETAL Project implementation, established in accordance with the specific national and international rules, recommendations and procedures.

a. Short description of the activities involving voluntary subjects (end users) conducted in the PETAL project and their Ethical implications

The specific objectives of the project are:

1. To use Light and Cognitive Stimulation Tools in combination with Smartphones and tablets, as main interfaces; and to use other secondary peripherals (beacons, light bulbs, sensors, accelerometers, smartwatches) for certain actions and interventions.
2. To identify the best technological opportunity for offering a caregiving system targeted at older adults during the period of both field trials of the project. We will conduct research on the systems that were previously analyzed and detailed.
3. To design formal and informal caregiving services targeted at older adults that live at their own home. From the very beginning, end-user organizations that are part of the consortium will be involved in the identification of needs, establishing priorities for an iterative development. Secondary and tertiary end users that have demonstrated their commitment to the proposal will form an integral part of the design process, facilitating their participation online in all cases where it is not possible to participate in person – the presence of partners from the same country tends to promote their involvement.

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4. To maintain and improve, as much as possible, both cognitive function and quality of life among patients with MCI by using light and Cognitive Stimulation Tools.
5. To consider the cultural and administrative diversity within Europe, in terms of systems of care for the elderly. The participation of end-user associations from countries like Romania, Italy and Austria with the involvement of research institutions and companies with experience in this sector guarantees this fact.

According to the described project objectives, PETAL will target elderly people with MCI, a segment of the population that is not very familiar with new technologies and their fundamental rights could become unprotected. For this reason, PETAL will carefully consider the ethical aspects of the project with the aim to ensure the adequate protection of the privacy and the personal rights of the users at every moment and in every situation. This aim will not only affect the end-users participating in the project, but will also consider the ethical aspects relevant for the persons and organizations participating in the project and in general the limitations and regulations that must be applied to every project activity: research, development, testing, evaluation and dissemination.

Research and development in the PETAL project will be conducted in Romania, Spain, Italy and Austria. In addition, field testing and evaluation will be performed in Romania as well as in Italy.

A summary of the plans and actions foreseen to handle the ethical aspects of the project will be presented in the following lines. By the term ethical we mean all the issues that concern questions about life and death, about revealing personal data, revealing diagnosis, about daily life activities, care and guidance.

The ethical aspects that do affect the project are:

- Personal contact details: such as photographs, name, address, phone number, email, etc., video and audio information, will also be a subject of protection.
- Personal information on marital, living status, level of independence
- Personal preferences: with regards to media usage, entertainment, information, cultural events
- User location information: when relevant, it could also be the subject of ethical concerns.

Over the course of the project, when the system will be more developed and we can observe more specifically the possible ethical problems, the consortium will specify the necessary technological measures to protect the privacy of people interacting with the system in the formal and informal care scenarios.

b. Ethical issues and Personal Data collected during the focus groups and questionnaire-based surveys

WP1 - End User Participation

This Work Package is aimed to gather end user requirements from both the users with mild cognitive impairment and caregiver's perspective. It will also address the first prototype evaluations in terms of usability and accessibility.

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The input of the end-users (voluntary subjects) was crucial in this work package in order to identify their preferences for the existing formal and informal care services, to profile the typical MCI end users' profile and to determine end-users need with regard to formal and informal care services.

This objective was achieved during two phases of consultations with end-user representatives:

1. Phase one: focus groups with the end users held by the end-user organization in Romania (ANA), Italy (SLF & APOL) and Austria (BART)
2. Phase two – In-Lab testing concerning the Rule Editor held as well by ANA (Romania), SLF & APOL (Italy) and BART (Austria).

All researchers are responsible for ensuring that participants:

- are well-informed about the purpose of the research they are being asked to participate in
- understand the risks they may face as a result of being part of the research
- understand the benefits that might accrue to them as a result of participating
- feel free to make an independent decision without fear of negative consequences
- may drop out at any time during the research

1. Information for participants

Informing participants about the project and procedure will form part of the recruitment process. All prospective participants contacted will be provided with one- or half-page flyer describing the research as well as some background information about the project, explaining how the data will be used and whether the information will be kept confidential. The information sheet should be given to participants prior to the focus group and should also be given in hard copy on the day of the focus group.

2. Participant consent - All participants should sign an informed consent form.

Participants should have the opportunity to provide informed consent prior to participating in the focus group or survey.

3. Management of possible user's complaints and withdrawal request

User complaints and withdrawal requests are managed by the end user partners. Each user has the right to quit the trial at any time without stating reasons. In the informed consent, it was clarified that the rejection of participation or early withdrawal has no adverse consequences for participant.

4. Recruitment

Potential participants are contacted by phone or (preferably) in writing by post/email. At this point, the research and rationale for selecting them to participate should be properly explained. If the individual agrees to participate, this is known as 'first consent'.

5. During the focus groups

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The interviewer should remind the participant(s) of the purpose of the research and why they have been selected. They should confirm the participant's(s') agreement to participate. Confidentiality should also be covered: how will the data be used and stored, and will they be named or identified in the report? Finally, the researcher must make it clear that the participant can stop the interview/leave the focus group at any time and withdraw from the research, even after they have given their consent to participate.

6. Safeguarding and disclosure issues

At the start of each focus group (even if it is a second session with a participant) the researcher/interviewer/facilitator as well as in the opening letter for the survey will explain that the data collected will remain confidential.

7. Locations

For focus groups, ideally the location would be somewhere quiet and comfortable where conversations cannot be overheard to protect the confidentiality of the participant.

8. Vulnerable people

The focus groups should respect the principles that apply when conducting qualitative research with vulnerable adults:

- written materials should be printed in large letters and the design of materials should be appropriate for the audience.
- use images or visual aids and simplified language.
- accommodate to the needs of the participant for example, participants who would prefer to write or type their answers instead of talking should be provided with a template with the questions and space for answers - so a printed version of the focus group questions, in form of a questionnaire, should always be available for all participants involved in the focus group.
- in the case of mentally ill or cognitively impaired patients, it is important to measure comprehension and develop valid tools for it, before obtaining informed consent to participate in the research study.

9. Data protection & confidentiality

- All information provided will be securely kept on a password protected computer. No names or organizations will be identified within the research process.
- Data from any focus group and quantitative survey will be kept securely and fully anonymized.
- Names and other identifying features will not be used in any reports.
- Any demographic information we collect and use will be used purely for statistical data analysis and profiling.

-

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- Any personal and sensitive data (names, ethnicity, age, gender, marital and living status, level of independence) will not be kept with the data collected from the focus groups/surveys
- In case of video recording of the focus group, all participants consent for this specific purpose (video-recording and distribution) will be obtained before the focus group.
- Questionnaires will be anonymous and encrypted for data centralization and statistical data analysis purposes.
- PC's used for data storage and analysis will be password protected.
- In case of data sharing among project partners: only anonymous data will be shared and only via secure connections.
- Participants ID data will always be stored separately from other personal data collected for statistical purposes related to monitoring and/or evaluating the field trials as a whole or single elements like the Rule Editor.

c. Ethical issues within Pilot Testing

WP4 – Demonstrator Development and Field Trials

In this Work Package, the platform developed in WP3 will be tested by validating its use in real contexts. We plan to carry out trials in the home of 16 people (distributed in four different areas) suffering from dementia. We plan two cycles of trials: this will allow to assess the added value of the proposed solution with respect to the state of technique, and to quantify its benefits from the economic point of view.

Through the tasks of this WP the consortium will evaluate with end users the PETAL system. This evaluation will be carried out at the older adults' homes or in elderly care facilities, in a real environment. Results from the first two cycles will be used for further refinement and development of the system, both from a functional and technical point of view. The output from the last cycle will be crucial for the final Business Plan delivery.

This work package will carry out testing pilots of the PETAL system and services in a real-world environment: the homes of older adults or care facilities. The objective is to involve 4 end-users per country, which amounts to a total number of 16 end-users throughout Europe, testing PETAL at their homes.

At the beginning of each activity the end-users will be thoroughly informed about the project, the application to be developed within the project, the purpose, objectives and methodology of current research to be conducted, what is expected from them and the possibility to drop out at any moment. All volunteer end users participating in research activities have to sign an informed Consent form.

The field trials with voluntary end-users will consider the aforementioned national legislation and local regulations. In every project that supposes the involvement of human subjects, the recruitment of old voluntary end-users will be made based on previously established inclusion-exclusion criteria. Within the Pilot the end users will remain as much as possible the same along the entire duration of the project. If a new end-user recruiting becomes necessary for replacing someone who withdrew his/her participation, then the entire procedure of end-user's recruitment, including Consent Form and the other ethical matters is performed. The contact details of the local contact responsible for the ethical aspects in each of the pilot testing sites

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are provided to each voluntary end-user. Each investigator is trained about the legal and ethical rules to be pursued during the work sessions with the end-users.

All different pilot partners will make sure they comply with local requirements in terms of approval from their ethics committee (or relevant equivalent bodies) when enrolling in the research process.

Information procedure

Before participants give their consent, they should be properly informed about the project, and the pilot study. They will be informed about:

1. What they will be asked to do
2. The expected duration of their participation
3. Who will be conducting the study, whether anyone else will be present
4. Whether they will be audio- or video- recorded and what exactly will be recorded
5. A reasonable estimation of whether it will be boring, difficult, stressful etc.
6. What they should do if they wish to withdraw, with information that this is their right and won't have negative consequences, particularly on their reimbursement (if reimbursed)
7. Who will have access to their data, where and how long it will be stored, with appropriate information about anonymity and confidentiality
8. For what purposes and in which ways the results of the study will be used

To facilitate understanding of the research methodology and concept, several actions will be undertaken. All information about the study (not only during the recruitment process, but at all stages of the study) will be provided in formats suitable for the particular participants.

It is compulsory that all the researchers working on the pilots have previous relevant experience in working with elderly and in implementing and developing tailored conduct and strategies.

Data protection

1. Treatment of data is governed not only by professional ethics, but by the data protection legal requirements. Data protection refers to all stages of data management: collection (design of data collection methodological instruments), processing, storage, transfer.
2. Over all stages of the pilot testing and beyond, confidentiality and anonymity of participants' data must be strictly preserved. In all computer files, participants will be referred to by a code that cannot identify them.
3. All computer files should be stored only on secure equipment.
4. Particular care should be taken on security issues if files are transferred between partners for analysis. This should be undertaken using secure means and the transferred data should not include any ID.
5. Audio and video files should not be shown beyond the immediate research team unless a written agreement from the participants has been obtained prior to the registration.
6. Only anonymous data can be reported in project deliverables or in public documents. Reports should mainly include aggregate data. Should individual information be necessary (like comments from individual participants) it must be reported such as to not embarrass the individual and preserve his/her anonymity.

d. Management of possible user's complaints and withdrawal requests

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As specified including in the Informed Consent procedure, the end-user volunteer is entirely free to withdraw the study at any time, at its convenience and with no penalty. However, he is informed that the explanation of withdraw is important for the investigators and the study, so it is up to the end-user volunteer to provide it at his/her convenience.

Any complaints made by the end-users will be addressed to the local responsible contact person, whose task is to properly address them and specify them in the study report.

The researchers involved in the preparation of evaluation trials and end-user feedback collection and analysis within each pilot site have the obligation to comply with the ethical and legal framework detailed in this document, even after the cessation of the activity in the respective organization.

e. The Exit Strategy

A special attention will be paid to the exit strategy.

The participating professional care organizations will offer PETAL as an operational service beyond the life time of the project.

However, when they cease to provide the services, end-user have the possibility to purchase it for a small price. Yet, we need to keep in mind that PETAL is a research project, which means that there is always a certain risk involved, that the idea fails (due to various reasons). Therefore, at the beginning of the project we informed the participants who volunteer to test and validate the service that, after the project ends, it may be possible that they face some discomfort because of service discontinuation.

A special set of measures will be applied in order to manage the possible discomfort experienced by the end-user when s/he must give up the devices s/he already learned to use and the useful services provided by the Rule Editor app. This set of measures will include:

- Clear information about the role, of the end-users, i.e. the expectations as voluntary contributors to the accomplishment of PETAL project goals, phases and activities. During the project running, this task was accomplished in the introductory presentation of each field trial with the end-users.
- During initial training session after the installation of the system at the person's home s/he will be informed about the measures that project's team adopted for minimizing the possible discomfort experienced by him when giving up the equipment and stopping to receive the smart services:
 - The possibility to keep running the system by buying the equipment and the services at a good price
 - The possibility to withdraw their participation at any time during the trial phase without any repercussion,
 - The possibility to solve any unwanted situation or complaint by calling or e-mailing the principal investigator of the pilot site, whose contact details will be entrusted to him/her during the initial training session after the installation of the system.

The last two items will be specified in the Informed Consent form.

- A closing seminar will be arranged at the end of the project at each piloting site, with the end-users and their caregivers being invited to attend.

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3.1.1.3 Data Protection Plan for PETAL Project

a. General aspects regarding personal data

Methods of personal data collection:

Within PETAL activities, volunteer end-user's data will be collected during focus groups, quantitative surveys and pilot testing.

Personal data to be collected:

- Socio-demographical data: age, gender, marital status, living status
- Preferences for: information means, entertainment means
- Skills: computer and programming literacy
- Sensitive data: Self evaluated physical health and level of dependency

Within the PETAL project multiple aspects of the data collection processes and methods have been examined. After studying the legislation in Europe and of each implicated country, the data protection plan presented below has been developed, covering all of the aspects cited above.

b. General issues concerning Data Protection Plan

Purpose of the data protection plan: The data protection plan becomes part of the signed agreement between PETAL consortium and the investigator(s) participants in the project. All members of the research team with access to the data are bound by the contract to follow all aspects of the data protection plan.

The main aim of this plan is to prevent persons who are not signatories to the restricted data use agreement or the supplemental agreement with research staff from gaining access to the data.

The plan will cover:

- Management of both the raw data file received from the PETAL consortium as well as any copies made by the research teams, and any new data derived solely or in part from the raw data file.
- Security of computer output derived from the data.

c. Data Storage and Handling Processes

The protection of participants' privacy is a responsibility of all individuals involved in research with human participants. Privacy means that the participant can control the access to personal information; he/she decides who has access to the collected data in the future. Due to the principle of autonomy the participants have to be asked for their agreement (informed consent) before private information can be collected. It should be also ensured that all of the individuals involved in research work, understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in the research.

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Privacy plays a role at different levels:

- Hints to or specific personal information of any participant in publications.
- It should be prevented to reveal the identity of participants in research deliberately or inadvertently, without the expressed permission of the participants.
- Dissemination of data among partners.
- Access to data method of access, data formats, method of archiving (electronic and paper), including data handling, data analyses, and research communications. Offer restricted access to privacy sensitive information within the organization of the partner.
- Protection of the privacy within the organization of volunteers (employers, etc.) throughout the whole process like, communications, data exchange, presentation of findings, etc.
- Destruction of data once the purposes for which the data were obtained (and for which the consent form was signed) is over.

Workstations will be configured and used in a manner that is consistent with the security practices that will protect data against exposure, but also against tampering and loss of study data sets.

All of the computers used for data storage will be password protected. No removable storage media such as CDs or flash memory drives will be used for data storage or transfer.

Participants have to be able to control the dissemination of the collected data. The investigator is not allowed to circulate information without anonymization. This means that only relevant attributes, i.e. gender, age, etc. are retained. Another possibility is to keep the identity of the participants, but only with prior consent of those.

As already mentioned, protection of confidentiality implies informing the participants about how their data may be used (i.e. data sharing).

As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the participants' name and its replacement with a code is no guarantee of complete confidentiality. Therefore, no personal ID data should be collected during any kind of quantitative and qualitative research excluding participants' Informed Consent form.

d. Encoding and anonymization

Information should be anonymized for protecting participant's identity.

Anonymization provides a safeguard against accidental or mischievous release of confidential information.

There are different ways in which personal data can be modified to conceal identities:

- Coded information contains information, which could readily identify people, but their identity is concealed by coding, the key to which is held by members of the research team using the information.
- Anonymized data with links to personal information is anonymized to the research team that holds it, but contains coded information, which could be used to identify people. The key to the code might be held by the custodians of a larger research database.

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Unlinked anonymized data cannot be used in any way by anyone to identify individuals. As a minimum, anonymized data must not contain any of the following, or codes for the following:

- Name, address, phone/fax. numbers, e-mail address, full postcode.
- Any identifying reference numbers.
- Photograph, video or audio files of participants
- Names of relatives/carers

Researcher and database developers should always consider – when designing studies, before passing information to others, and before publishing information – whether data contain combinations of such information that might lead to identification of individuals or very small groups. We will follow the unlinked anonymized data policy, after considering that PETAL Project may include users with identifiers like age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way, with any analysis of the data being based on group analysis.

Data will be encoded, and anonymized using numerical codes. During trials and the development stages, the correspondence with the users list will be saved into an encrypted local database.

To avoid accidentally compromising the data, information about the data's sensitivity and any available information on participants' consent will not be stored alongside the data.

e. Data destruction

Any personal data gathered from participation in the project will be kept to a minimum. In cases that collection of sensitive information is required i.e. when it comes to train or improve a technological device relevant for the project the following measures will be followed:

- Dissociation of personal identifiable data as it was specified above.
- Destruction of paper/documents by the time the project ends.
- Erasing of electronic documents containing sensitive information by the time the project ends.

f. Evaluation Criteria of this Data Protection Plan

These data protection plan evaluation criteria will be followed as guidelines throughout the project and its fulfilment will be supervised, deviations from it will be minimized and appropriately justified.

The proposed criteria that will be observed to measure the fulfilment of this evaluation plan will be the following:

- The users have been informed about the objectives of the project
- The users have given their consent to participate
- What procedures have been in place to preserve the dignity, autonomy and values (human and professional) of the end-users?
- All the data collected in the user requirements questionnaire are necessary (but also are the minimum, in order to avoid asking for non-relevant, but sensitive, information)

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- For any data not initially expected or specified in the consent form, a justification for its needs has been reported to the respective ethical committees (if required). This may include:
 - Video information about the users.
 - Audio information about the users.
- For any data not initially expected or specified in the consent form, additional consent forms have been provided to the users.
- Sociodemographic identification data have been dissociated from the rest of information about the users (except for when it is absolutely necessary for data analysis)
- Sociodemographic identification data have been encrypted on a separate database
- Risk of identifying users in profiles or scenarios have been minimized
- Any file exchanging personal information from the users have been encrypted.
- Scenarios show conflict with legislations about privacy and security
- For those scenarios showing conflict with legislations about privacy and security, necessary adaptations to fulfil these legislations have been carried out.
- Special procedures are planned for safeguarding the right to privacy, self-determination and other ethical issues in of end users related to technology-enabled concepts for confidential communication between the older person and informal and formal carers, service providers
- Dissemination activities performed do not allow identification of the users.

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3.2 Participation of Primary and Secondary End Users

3.2.1 Recruiting Criteria

3.2.1.1 Recruiting Criteria for MCI patients

MCI is a quite frequent condition in the elderly population. It is generally characterized by an initial deterioration in a single or multiple cognitive domains, such as memory, executive functioning, attention, or visuospatial abilities while generally global cognition and basic activities of daily living are mostly fine. However, many studies have suggested that persons with mild cognitive impairment are at increased risk of progressing to dementia. Preventive interventions and appropriate treatments should be able to improve cognitive performance and retard or prevent progressive deficits, thus it is crucial to intervene as soon as possible with those persons. In older adults with MCI, even subtle declines in cognitive abilities or everyday functioning are associated with e.g. decreased independence and safety, additional burden for caregivers, reduced chance of reverting to normal cognitive status, and, as said before, increased likelihood of developing dementia. The PETAL project takes on with these challenges and developments: based on an innovative technological solution, it aims to assist elderly people with MCI in order to satisfy their unique requirements for managing an active and independent life at home, while increasing awareness and control of their current lifestyle. This will be achieved through an intelligent platform able to monitor users' behavior (movements, interactions) and support personalized control of lights and appliances in their environment, as well as providing them with relevant and tailored information in an intuitive and natural manner.

Thus, the reasons why the PETAL consortium decided addressing people with MCI instead of those affected by mild dementia (as originally planned) are rooted in a more in-depth consideration of the type of solution that PETAL aims to provide to its target users. Indeed, giving the technological connotation of the proposed solution and the intended active involvement of end users (caregivers and even elderly having some familiarity with technology) in using the developed platform for personalization purposes, we preferred considering a class of elderly with reduced impairments in judgments/reasoning, less difficulties with everyday activities, with a more autonomous lifestyle, and with less needs in terms of care management, also considering that patients in greatest need of chronic care management are those least likely to engage with technology. Indeed, elderly with MCI have a stronger potential to learn to use new technologies than those with dementia, and introducing systems for people with MCI when they are more able to adapt and interact with the technology may have more potential.

As such, in order to ensure that the PETAL platform will properly support the needs of MCI older adults, the specific lifestyles, capabilities, living environments and ambitions of MCI elderly people must be considered in order to find adequate concepts and solutions for the purpose of promoting their independence.

In this respect, we are following a set of criteria in order to recruit as well as monitor the MCI patients that will take part in this project:

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- Diagnoses – MCI; the diagnose is based on multiple cognitive tests (MMSE, Rey’s Figure, Verbal Fluency Test, QoL, etc); all of these tests are more thoroughly detailed in D4.2a.
- Dependency – As the definition of MCI patient states, they have to be active and independent persons, although they often have more difficulty or may take longer than their normal counterparts in performing more cognitively demanding instrumental activities of daily living (IADLs) such as driving, telephone use, finding belongings, grocery shopping, medication management, food preparation, traveling alone, and handling finances.
- Studies – MCI as well as dementia is highly associated with active and higher educated patients. This is why, the level of studies plays a significant role in the recruitment process.
- Technological Literacy – PETAL system may be used by the patient himself if he/she is accustomed to technology use;
- Living – Taking into consideration the system that PETAL Project offers, patients who live alone are more prone to benefit from this light and cognitive stimulation system than those living accompanied by a spouse or a family member. Thus, we can facilitate monitoring and analysis of their behaviour.
- Professional Activity – While some may consider this aspect not so relevant, the field of professional activity may have forced the patients to submit to a habitual thinking pattern that required stereotypes, repetitive actions and small or even no creativity tasks. Hence, if the above mentioned are proved, professional activity should be considered a risk factor from the point of view of reducing neuroplasticity and thus increasing the chance of faster cognitive deterioration.
- Residence – The residence might be a flat or even a house, with only a single floor and with an area of no more than 75 sm.

3.2.1.2 Recruiting Criteria for caregivers

Our consortium recognizes the importance and the valuable role of caregivers in the elderly. The target group of our project is characterized by two main categories: formal and informal caregivers.

Formal caregivers are providers associated with a formal service system, who may work independently or be employed by various specialized institutions like nursing homes, institutions specialized in providing medico-social home care, non-profit organizations, charity service groups, seniors’ centers and hospices. Although formal carers may have different professional backgrounds, knowledge and education levels they are all united by professional ethics in line with a person-centered care model (Broker et al., 2004), which represents a holistic alternative to conventional care practices.

Informal caregivers are any relative, partner or friend who has a significant relationship with, and provides a regular and ongoing assistance to another person without payment for the care given. Informal care far exceeds formal care in the number of hours of care provided, as well as in terms of monetary value (OECD, 2005). In fact, even in countries with a well-developed

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supply of formal long-term care, the number of informal carers is estimated to be at least twice as large as the formal care workforce (Ferrer, 2015).

The caregivers, both formal and informal, were selected based on a set of criteria:

- Experience – previous experience on dealing with MCI or other neurological patients.
- Technological literacy – although the Rule Editor does provide an intuitive and easy to use platform, a minimum level of technological literacy is required in order to properly manage and use the Editor.
- Willingness and desire to involve in PETAL Project development.

3.2.2 Recruiting process

Both caregivers – formal and informal and MCI patients were recruited during the initial phases of PETAL Project implementation – specifically during requirements gathering through focus groups and questionnaire administration. Both of these actions were carried out in the end-user organizations' countries – Romania, Italy and Austria.

3.2.2.1 Recruiting process for MCI patients

ANA

The recruiting process took place in two medical centers, namely:

- 1) The Memory Center of ANA - the outpatient center which is diagnosing and treating patients with neurodegenerative diseases (from MCI to mild and moderate stages of AD and other dementias) and where most of the patients come accompanied by their informal carers (usually life partners or children) and
- 2) The Clinic of Geriatrics-Gerontology and Old Age Psychiatry from the Elias University Hospital, where the head of clinic is Prof. Dr. Luiza Spiru (also the President of ANA) - where patients with neurodegenerative diseases in all stages (from MCI to severe cases of AD and other dementias) are hospitalized for short- and long-term care; here they are being taken care mainly by professional carers, trained in dealing with these categories of patients.

PETAL Project was initially presented to MCI patients gathered from the above-mentioned centers in the early developmental stages of the project – they contributed through questionnaires and focus groups to the overall requirements and needs the platform had to cover. Further, we selected the ones that met the criteria previously detailed and asked for their consent to participate in the field trials.

APOL

In South Tyrol (Bolzano), the recruitment phase of the elderly for field tests will take place in collaboration between Apollis and the Griesfeld Foundation. The Griesfeld Foundation operates two retirement homes and 14 mini-apartments for the elderly belonging to the Municipality of

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Egna-Neumarkt (BZ). It is planned to conduct the field work in two of these apartments. Of course, the inhabitants taking part in the field tests have to fulfil the general selection criteria of the project.

One characteristic of the mini-apartments is that they are barrier-free – and therefore meet the needs of older people with mild physical disabilities. In order to have access to these apartments, people must be over 65 years of age, they must want to live in an environment designed according to a concept of housing "fit for the elderly", where they have ample opportunities for self-determination and independence. Most of the inhabitants live alone, they get only very basic assistance from the Foundation.

FSL

All subjects were enrolled in the Memory Clinic through a specific selection process applying the above inclusion criteria. The Memory Clinic (CDCD) of Santa Lucia Foundation is focused on the prevention, diagnosis and treatment of various forms of dementia. CDCD patients follow a multidimensional diagnostic process, exploring the medical history as well as cognitive and behavioral function. Patients are closely followed over time with scheduled visits involving also their caregivers. So, all MCIs selected to participate in Petal have had an evaluation in the last 6 months attesting their cognitive status. Starting from the participants recruited during the requirements survey, we proposed the possibility to test our solution to those who showed a particular interest in Petal.

BART

Bartenbach will use its already existing network in the healthcare sector for recruiting patients with MCI or their caregiver for the field trials. In the past, Bartenbach has cooperated many times and in diverse projects with the Tirol Kliniken with its' sites in Innsbruck and Hall (Austria). In the last years, especially the wards for geriatric patients were involved in the projects. Bartenbach has already informed Dr. Josef Marksteiner, the head of the department for geriatric psychiatry and psychotherapy, Tirol Kliniken Hall, about PETAL at the beginning of the project. The clinic in Hall consists of an outpatient clinic with memory consultancy hour and an inpatient ward for geriatric patients. We have already used this contact for reaching the patients and caregivers for completing the requirement-questionnaires in work package one. Dr. Josef Marksteiner has already confirmed his commitment in the recruitment process. For the recruitment we will mainly look for diagnosed patients visiting the outpatients' memory hour. They will be informed directly while their visit, if selection criteria are fulfilled. After that a Bartenbach employee will contact the possible participant for further and more detailed information and as future contact point for the field trials during the project.

If necessary, further contacts e.g. to VAGET, an association for homecare of elderly with cognitive decline in Tirol, will be used to find participants for the field trials. In addition, AAL Austria, which already carries out field trials in different regions in Austria, can be contacted, if we could not find enough households through our common channels.

3.2.2.2 Recruiting process for caregivers

The project PETAL is cofunded by the Active and Assisted Living Programme (AAL-2016) and the following National Authorities and R&D programs in Italy, Spain, Austria and Romania.



ANA

As part of the developmental process of the project, we also involved caregivers from the same both centers. PETAL project was firstly introduced through a presentation at The Clinic of Geriatrics-Gerontology and Old Age Psychiatry from the Elias University Hospital where the concept and the operating principles of this system were explained. Furthermore, they were asked as well for a general opinion of it. The invitation to attend the focus group was addressed by the head of the clinic, Prof Dr. Luiza Spiru and all the caregivers able to attend did participate. Also, the young residents expressed their desire to participate in order to better understand the proposed solution and also to contribute with practical suggestions from the perspective of younger persons, more accustomed with new technologies and thus more creative in indicating innovative outcomes. Due to the positive feedback, the caregivers expressed their willingness and desire to further participate and be actively involved in both the development and system testing. In addition, even more caregivers expressed their will to participate in the project when the focus group for in-lab testing was held. Being part of the Clinic of Geriatrics-Gerontology and Old Age Psychiatry from the Elias University Hospital medical personnel, they matched the requiring criteria for enrolling in the project as well.

APOL

The recruitment of test persons for the in-lab test in Bolzano-Bozen (BZ) and Bressanone-Brixen (BZ) took place through different channels: in particular personal contacts of the facilitator or of colleagues with informal caregivers and persons working in hospitals or in facilities for the elderly, but also family caregivers who were presented to us by contact persons (for other informations see deliverable D1.3a, paragraph 4.1.4).

N.B. "Participant consent": Considering the recruiting procedures and the extensive information phase at the beginning of the in-lab tests Apollis did not ask the test persons to sign a informed consent form for the in lab tests. This will of course be the case for the field trials.

FSL

In Rome, the recruitment process took place within the Memory Clinic of FSL. A specific selection of possible participants was made contacting the relatives of patients with a diagnosis of MCI, previously selected by the internal database. To all the caregivers that manifested an interest in Petal, were asked to participate in the requirements survey through self-administered questionnaire prepared by the partners for this purpose. Then, a small group of informal caregivers participated also during the usability test, together with some formal caregivers.

Finally, for the Field trial test, FSL focused mainly on the recruitment of the caregivers of the MCIs patients interested to participate in our project. Hence, informal caregivers were contacted by the researcher team to explain the project and its purposes. Once both, MCIs and their caregivers, express the motivation to test Petal system, an appointment at the FSL were scheduled, in order to provide all the necessary information and allow a better understanding of the timelines and their role in the Field Trial Test.

BART

Please visit section 3.2.2.1 – Recruiting process for MCI patients - BART

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4 CONCLUSIONS

This document describes the results of the activities that have been done in the PETAL Project to package the technology developed during the project into a solution easily deployable on a real house. This activity has been carried out by involving all the PETAL partners, and it has exploited several techniques ranging from questionnaires, to focus groups, to interviews.

The findings so far have identified a series of aspects that need to be supported by the project to ensure its later adoption. First, a number of situations have been identified by caregivers when the seniors with MCI need specific aid (e.g. getting up from bed at night especially for going to restroom). Impressions, comments and suggestions regarding the aspect as well as functionality of the Rule Editor were also established. The planned PETAL platform, thanks to its monitoring features and its capability of generating proper and personalized reminders, alarms and warnings considering the specific needs of the elderly, is expected to be very helpful in this respect, not only for elderly but also for caregivers.

Second of all, ethical and field trial preparation guidelines were established in order to ensure a proper course of action. In addition, recruiting process and criteria has also been described.

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