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Field Trial Plan

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ABBREVIATIONS

Abbreviation	Description
PETAL	PErsonalizable assisTive Ambient monitoring and Lighting
MCI	Mild Cognitive Impairment
PRE	Behavioral assessment before Petal use
POST	Behavioral assessment after the Petal use
QoL	Quality of life

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1. INTRODUCTION AND PURPOSES

The PETAL project aims to provide an intelligent platform able to support older adults affected by Mild Cognitive Impairment (MCI) in the daily living in order to improve their autonomy and ameliorate the quality life. This platform will be able to gather relevant information monitoring users' behaviour and remotely control their lighting system through intuitive Web & tablet applications. The intelligent platform will enable caregivers to remotely personalize, in a context-dependent way, assistance of the MCI directly in their homes. Moreover, the elderly will also have the opportunity to train different cognitive functions through a cognitive stimulation tool that will be exploited with frequent sessions.

The possible effect of the whole Petal-system on the elderly affected by MCI and their caregivers will be also explored by applying an evidence-based approach. For each field trial, two multidimensional assessments will be handled before (PRE) and after (POST) the Petal-system use. In order to assess the added value of the proposed, we plan two cycles of field trials: the first, shorter, at M16 (for four months) and the second, longer, at M26 (for six months). In this document, our aim is to describe in more detail the principal stages of the field trials plan. In particular, the deliverable is structured into the following main paragraphs: after the presentation of Petal- field trial design with a short description of each step, we delineate the multidimensional assessment for the Petal users and the training modules that will help them to familiarize with the intelligent platform and the cognitive tool. Next, we describe some crucial steps from the practical point of view and the possible analyses necessary to explore the effect of the whole Petal-system. Some concluding remarks trace the end of the present report.

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2. FIELD TRIAL PLAN

2.1. Study design

During the field trials, all MCI subjects will perform a multidimensional assessment before (T^0) and after (T^1) the use of the Petal-system. To permit a certain familiarization with the intelligent platform, we plan to organize two types of training: one for the Cognitive tool that the elderly will use during the field trial test and one for the Rule Editor addressed to the caregivers who will be able to create their own custom rules for a smart home. Within this part of the field trial test, the house of MCI older adults will be equipped with an intelligent system consisting of sensors, light bulbs, gateways and a lighting solution in order to permit the use of PETAL-system as soon as possible. Finally, a post assessment of the clinical variables will be performed to permit a comparison with the base-line assessment. Figure 1 shows a possible diagram of the crucial steps to perform during the field trials test.

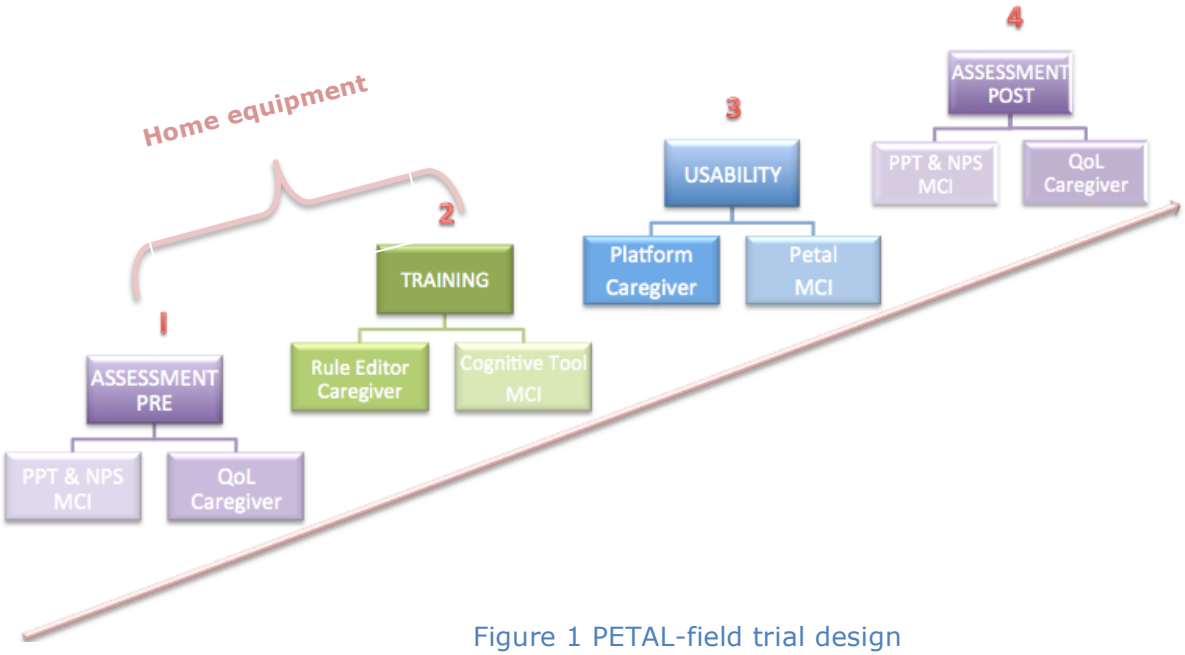

Figure 1 PETAL-field trial design

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3. DEFINITION OF EVALUATION TOOLS

Light therapy has shown great promise as a non-pharmacological treatment to help regulate sleep and improve cognition in individuals with cognitive impairment. Studies (Yamadera et al. 2000; Riemersma-van der Lek et al 2008) have demonstrated that daytime light exposure can consolidate sleep at night and increase night-time sleep efficiency, while increasing daytime wakefulness and reducing evening agitation. One landmark study (Riemersma-van der Lek et al 2008) showed that light can improve sleep as well as cognition. Longer and better sleep during the night can reduce disruptive behaviours associated with dementia and, by extension, have a positive impact on caregivers, both in institutions and at home. Hence, the expected PETAL system effects for end-users are an improvement of well-being (for example in mood and apathy symptoms), of the sleep-wake-rhythm, to direct attention in a timely manner, to support the structure of daily activities and to support spatial-temporal orientation.

However, these positive effects can only be expected if they are not masked by other developments. MCI patients – probably more than elderly people in general - are quite likely experience an abrupt deterioration in their state of health due to internal or external causes. In addition, emotionally stressful events - such as serious illness or death of a loved one - could occur that have a negative impact on well-being and performance. As far as possible, these disruptive factors must be identified and recorded as such, either ex post by interviews or through a kind of diary (see below), and taken into account when interpreting the test results.

In order to register possible effects of PETAL-system in specific functional areas more sensitive to ageing and correlated to dementia risk, the MCI participant will perform a multidimensional assessment before (PRE) and after (POST) its use. In particular, they will perform a neuropsychological evaluation investigating the cognitive functioning, especially fluid cognition, including processing speed, attention, memory and executive functions. Moreover, we will investigate functional and psychopathological symptoms (for example depression, apathy, sleep disturbance) as well as subjective wellbeing, such as life quality and satisfaction.

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In Petal project a special consideration is directed to secondary end-users such as formal (i.e. professional workers in healthcare system) and informal caregivers (i.e. family members etc.) that are likely to be overwhelmed with responsibilities and duties in maintaining the elderly with a proper lifestyle. Thus, a short clinical assessment will be performed PRE and POST in order to register a possible knock-on effect on their well-being and burden traits. Finally, to record end-users' feedbacks and impressions about the Petal-system use, a short self-administered questionnaire will be setup and then will be performed at the end of each field trial test.

3.1 MCI assessment

3.1.1 Neuropsychological battery

The global cognitive level of patients is evaluated through the Mini Mental State Examination (MMSE; Folstein et al., 1975). The 22 items that make up the scale roughly evaluate the spatial and temporal orientation, the short- and long-term verbal memory, the language and the constructional apraxia (inability or difficulty to build, assemble, or draw objects). A score below 23 is generally indicative of a cognitive decline compatible with the diagnosis of dementia.

For a more detailed assessment of the individual cognitive domains we will use a battery of tests specifically designed for the diagnosis of subjects with a dementia syndrome, the Mental Deterioration Battery (MDB; Carlesimo et al., 1996). The MDB is composed of eight tests: four expressions of the processing of verbal material and four of the elaboration of visuo-perceptive material. The cognitive areas investigated by the battery tests are short- and long-term memory, language, logical-deductive reasoning, constructional apraxia

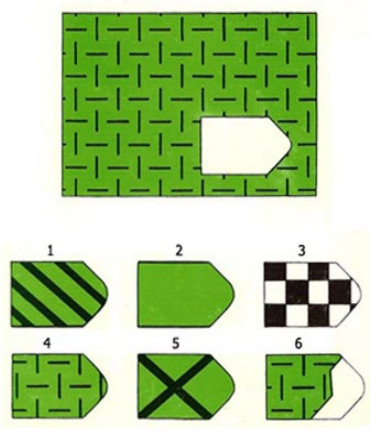

Figure 2 Raven's Progressive Colored Matrices

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and executive functions (a set of cognitive processes that are necessary for the cognitive control of behaviour).

In particular the following tests will be administered to MCIs:

- Rey Auditory Verbal Learning Test with immediate and delayed recall (Rey, 1958; Carlesimo et Al., 1996): for the evaluation of the short and long term episodic anterograde memory;
- Copy of freehand drawings and Copy with programming elements (Hécaen, H & Assal, G., 1970): to evaluate the simple constructional praxis and executive functions;
- Raven's Progressive Coloured Matrices 47 (PM 47; Raven, J.C., 1938): for logical-deductive reasoning abilities;
- Phonological Verbal Fluence and Semantic Verbal Fluency (Benton, 1967): for language and executive functions.

In addition, the following test will be administered to all subjects:

- Wisconsin Card Sorting Test (WCST, Heaton et al, 1981): for the evaluation of the ability to elaborate abstract categories and the ability to change the category according to a modification of the contingent situation.
- Colour-word test or Stroop test (Stroop, 1935): used to evaluate the difficulty in suppressing an automatic response;

Two examples of the neuropsychological test within the complex battery are shown in Figure 2 and Figure 3.

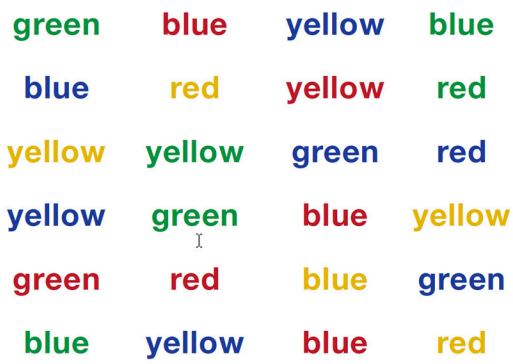

Figure 3 STROOP Test

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3.1.2 Quality of Life and Psychopathological assessment for MCI

The quality of life (QoL) in older adults includes four domains of importance: behavioural competence, the objective environment, psychological well-being, and perceived QoL. Each of these domains is highly relevant to the assessment of QoL in older adults with cognitive impairment. For this reason, for the assessment of quality of life in older adults with Mild Cognitive Impairment we will use the Quality of Life–Alzheimer's Disease (QoL-AD) Scale (Logdson R. et al.; 2002). QoL-AD is a 13-item questionnaire designed to provide both a patient report and a caregiver report of the patient's QOL. To facilitate its use with cognitively impaired individuals, the QoL-AD uses simple and straightforward language, responses are structured in a four-choice format that is consistent across all questions, and all items are rated according to the patient's current QoL.

Psychopathological symptoms will be investigated through the interview with the patient, the caregiver and through clinical observation with the Neuropsychiatric Inventory (NPI; Cummings, 1994). This will permit us to evaluate the frequency and severity of impairment of different behavioural domains of the MCI such as: delusions, hallucinations, aggressiveness, anxiety, aberrant motor behaviour, sleep and feeding disorders, depression, apathy, irritability, euphoria and disinhibition and assess the degree of psychological discomfort of the caregiver in relation to each area. Finally, for the assessment of functional autonomy we'll use the Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (iADL), which respectively evaluate the integrity of the basic and instrumental functions of daily life.

3.2 Caregivers assessment

The assessment of formal and informal caregivers aims to evaluate possible changes in their quality of life and well-being after the PETAL-system use.

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As a matter of fact, caregivers may present a psychological burden due to the responsibility and the effort by assisting the elderly in their daily activities. The measurement of the degree of burden will be made with the Zarit burden Interview – revised version (ZBI) (Hérbert, Bravo, and Préville; 2000) a 22-item self-report inventory, which was administered to the primary caregiver during the assessment interview. ZBI has been translated and validated in 18 languages all over the world. The questions covered the areas most frequently mentioned by caregivers as problems, including caregiver's health, psychological well-being, finances, social life and the relationship between the caregiver and the impaired person. Examples of statements used are "Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?" or "Do you feel that your social life has suffered because you are caring for your relative?" etc. The caregiver indicated how much discomfort this concern caused by choosing the most appropriate phrase from "not at all" to "extremely." It's assumed that discomfort caused by these situations places burden upon the caregiver.

Figure 4 Example of Self-administered Caregivers assessment

3.3. **Personal interviews with caregivers and elderly persons, diary**

The results of the various tests and standardized questionnaires will also be integrated with a personal interview with the caregivers and elderly people who participate in the field tests to get a more complete picture of the life situation of the people involved. The questions that will be asked will focus on the "typical days" of the elderly, on the activities they prefer to carry out and on those they least love, on expectations for the project and on the greatest needs. In addition to this, important information on the biography of older people (most important steps: health state, family situation, ...) and any information on events that have affected people's lives will be collected. The caregivers - supported by the reference person of the research team - are encouraged to keep a kind of diary in which all important events that could have negative effects on the well-being, performance or health of the elderly person are reported.

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At the end of the test, any important events that have occurred during the test will be gathered. The objective of collecting this information is to have support in interpreting the final results, which may also vary depending on events that occurred during the course of the tests.

4. Training modules and content

4.1 Rule Editor Training for MCI and Caregivers

On the one hand, our platform will allow MCI to create their personal rules according to their habits and their needs in the daily living activities. On the other hand, it will consent to formal and informal caregivers to personalize specific rules in order to best fit their preferences and the needs of the elderly who they care for. As described in the project, the intelligent platform provides personalized control of lights and digital appliances, personalized warning messages issued in risky situations, persuasive messages to stimulate the elderly in healthier habits (e.g., do more physical activity). To permit a better comprehension of the platform and vast possibility that our project offers to caregivers monitoring and helping the elderly also remotely, we plan to organize a specific training before Petal-system use. Hence, MCI patients and their caregivers will be asked to participate in a training session for at least one-hour organized by each of the four partners that will handle the field trial test (FSL, ANA, Apollis, Bartenbach). The training session will be structured as above:

As previously said, the technological platform will be based on Trigger-Action rules-editor, where *Trigger* are situations that occurs in elderly context and *Action* are the specific action the platform has to do (for more detail on the Rule Editor platform, please consult D1.3a). Thus, a particular focus will be given to trigger-action language and its use in the rule editor. Each training session will start with PowerPoint presentation about the rule editor platform and successively a video tutorial will show examples of specifying rules through the Rule Editor.

Then, the MCI patients and their caregivers will write some rules in natural language, where at least one consists of two triggers and one action. After this, they will try to specify them under the

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supervision of the psychologist who will help him only for building the first rule and afterwards the caregiver will proceed alone. This is the time when we plan that users will consolidate the knowledge about the Rule Editor.

After this training, they start to use the rule editor autonomously in their everyday life and will have constantly technical support for any inconvenience.

At the end, each subject will receive a user manual for the Rule Editor in order to improve their autonomy during the field trial test.

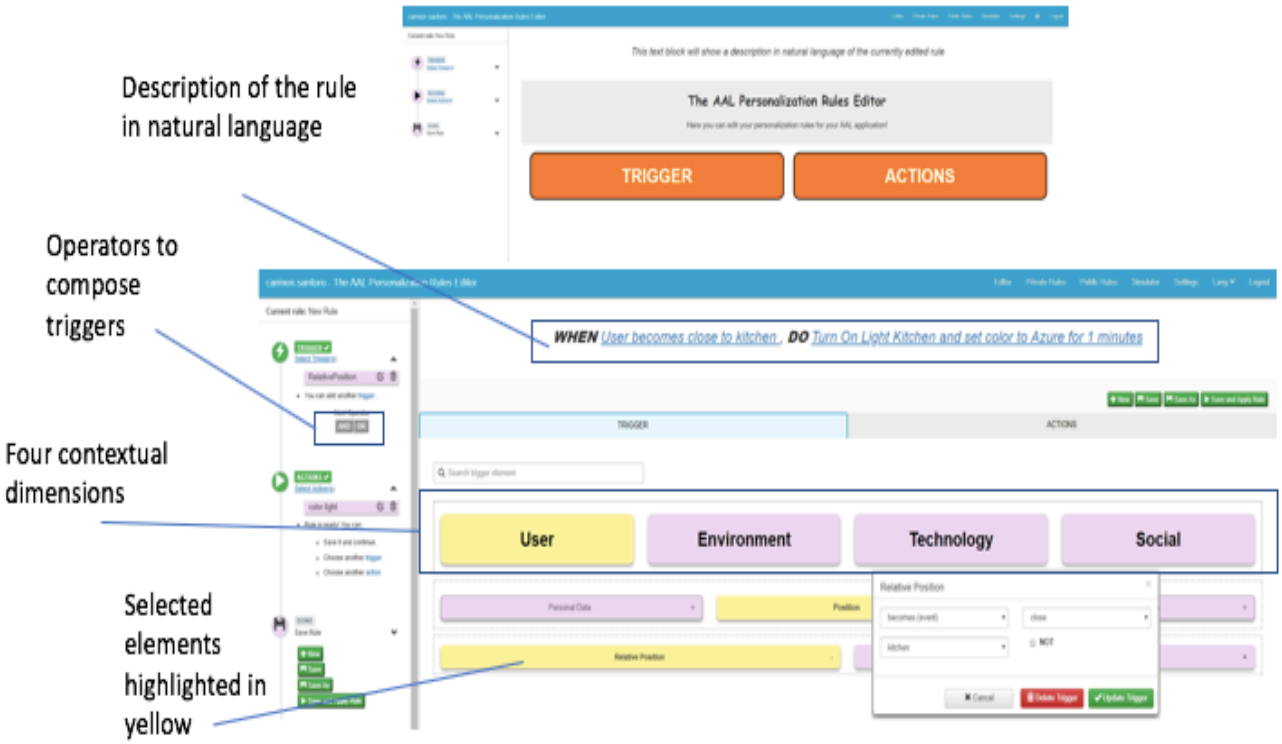

Figure 5 Trigger-Action Rule Editor

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4.2 Cognitive Stimulation tool training for MCI

While training caregivers implies the use of rule editor platform, cognitive stimulation tool for MCI consists of a multi-device cognitive stimulation platform. Thus, for the elderly we plan to organize a training session where they could not only familiarize with the platform but also with the

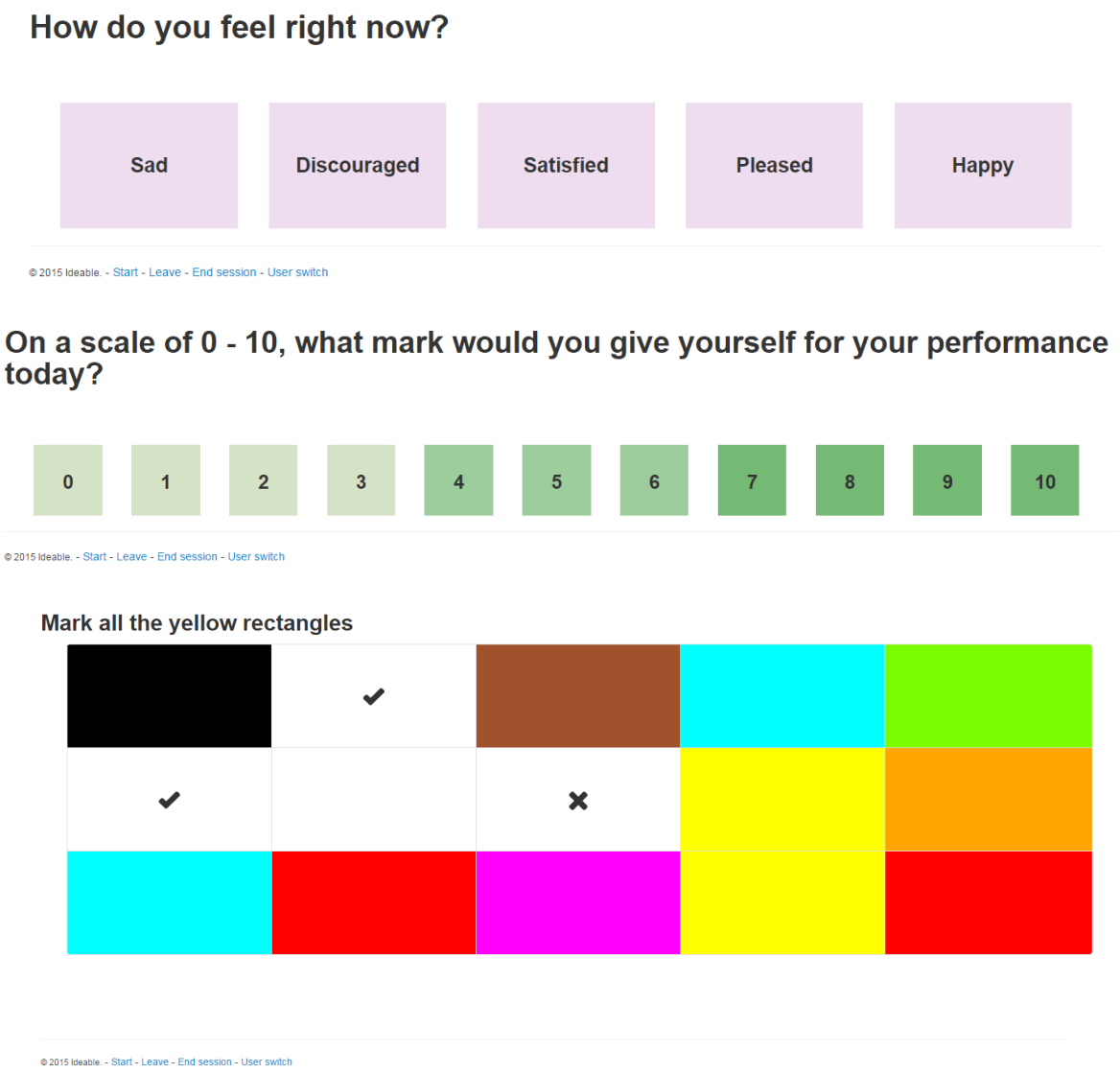

Figure 6 Cognitive stimulation tool - example

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technological device, a tablet. A psychologist and a technician will help the elderly to power-on the tablet, insert their personal data and use the start menu, recognize the icons necessary to start the application and learning how to manage lighting system and sensors.

The aim of a cognitive work-out is to train different mental capacities, i.e. language, calculating, memory, attention, executive functions, orientation. The exercises are drag & drop, multiple choice, quiz, memory games, paintings. In addition, the device will present alerts received from the rules engine for the end user to promote wellbeing, to play serious games, etc. The platform will also collect information about self-assesment, emotional status and daily activity in order to embrace all aspects of elderly wellbeing.

This meeting will last for an hour and the elderly will receive the booklet with the instructions to use that in their daily life. In conjunction with the training for elderly, the technicians will install the devices in their home.

5. RUNNING THE FIELD TRIAL TEST

The home of MCI older adults will be equipped with an intelligent system consisting of sensors and a lighting solution. For this part of the project, specialized technicians will be hired or appointed by each site responsible for the field trial tests. They will be specifically informed on the purpose of the project and will receive a detailed plan of the technological requirements for PETAL and the home planimetry that each subject involved in the field trial test provides to the local partner.

5.1 Equipment

In addition, the equipment that each house will have available for the trials will include the devices, the lights and the smart sensors described in the following sub-sections.

5.1.1 Tablet

Caregivers will interact through a web portalform both creating the rules through the Rule Editor, and end users will use a tablet to access the cognitive stimulation application (patients with MCI). In

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addition, the tablet will host the application used to receive alerts from the platform. A gateway will control the appliances in the house (e.g. lights, sensors, etc.). The tablet selected is the Samsung Galaxy A SM-T580 and the Lenovo Yoga 10" tablet. There will be one tablet available in each house involved in the PETAL field trials.

Further information at: https://www.samsung.com/it/tablets/galaxy-tab-a-10-1-2018-t580/SM-T580NZAEITV/ or https://www.pccomponentes.com/lenovo-yoga-tab-3-plus-101-3gb-32gb-negra

5.1.2 Smartwatch

Patients with MCI will also wear a smartwatch that will be used to measure the steps that they will be making during the day and also to provide information about the user heart rate. One smartwatch will be available in each house involved in the trials (and associated with the MCI patient).

Further information at: https://www.ebay.it/itm/LEMFO-LEM7-Bluetooth-Smart-Watch-2018-Uomo-Guarda-4G-WIFI-GPS-per-Android-iOS-/183192447490

5.1.3 Beacons

Beacons are hardware transmitters i.e. a class of Bluetooth Low Energy (BLE) devices that broadcast their identifier to nearby electronic devices (like smartphones, tablets and other devices) so that it is possible to perform actions when the user is in close proximity to the beacon. In particular, we will use the Estimote Proximity Beacons, placing one beacon in each relevant room of the houses included in the trials. Through such beacons we will know if a user (and which user) is inside that specific room.

Further information at: https://estimote.com/products/

Other beacons with accelerometer may give us information about the using of certain objects at home (doors, sticks, cupboards, etc.) https://minew.en.alibaba.com/product/60723843637-805129101/BLE_NRF52810_Module_bluetooth_Beacon_with_motion_Sensor.html

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5.1.4 Light-related devices

In the houses involved in the trials, we will basically use two types of illumination devices: three types of Philips Hue types of lights (also equipped with the bridge for controlling them), and the GREAT Luminaire.

5.1.4.1 Philips Hue "White and Colour" Lamps

The Philips Hue "White and Colour" lamps are bulb-based remotely controllable/programmable lights that can display different light colours, and also different light 'temperatures' (e.g. cold light vs. warm light). They have a E27 bulb, therefore it will be important to verify that this requirement is satisfied in the house(s) involved in the field trial. The Philips Hue Lamps are bought in a kit that, beyond three bulbs, also includes the bridge (between the lamps and the portable device) for controlling such lamps.

Further information about the kit is at: https://www2.meethue.com/it-it/p/huewhite-and-color-ambiance-starter-kite27/8718696592946

Figure 7 Philips Hue White ambiance and Philips Hue light stripe white and colour ambiance

5.1.4.2 Philips Hue Go Portable Lamps

The Philips Hue Go Portable Lamps are portable and remotely controllable lamps. They can be also controlled via the Philips Hue bridge. Further information at:

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https://www2.meethue.com/en-us/p/huewhite-and-color-ambiance-go-portablelight/714606048

5.1.4.3 Philips Hue LightStrips Plus

The Philips Hue LightStrips Plus offer a flexible, strip-based light solution that can also be controlled via the Philips Hue bridge. Further information about their specification is available at:

https://www2.meethue.com/it-it/p/hue-white-and-color-ambiance-base-lightstrip-plus-per-eu-regno-unito/7190155PH

5.1.4.4 GREAT Luminaire

The GREAT (Get REAdy for acTivity) is a standing-luminaire that Bartenbach developed for another AAL-project in cooperation with emt, a Swiss partner expert in electronics to influence the affective state of people with dementia. The goals were to activate or relax people in specific situations or to prepare them for upcoming actions. The GREAT luminaire homogenously illuminates a whole room with up to 25m^2. Further information about the GREAT luminaire is available in the PETAL Deliverable 3.3.a (Personalizable Lighting System).

For cost-based reason, there will be only one GREAT luminaire available in each house.

Figure 8 GREAT-luminaire

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5.1.5 Other Sensors

5.1.5.1 Philips Hue Motion Sensor

This sensor not only provides information about motion, but also measures light Level and temperature. The Context Delegate associated with this sensor (and which provides the gathered data to inform the PETAL Context Server about associated contextual updates) will run on the OpenHab gateway.

Further information on this sensor is available at:
https://www2.meethue.com/it-it/p/huesensore-di-movimento/8718696743171

5.1.5.2 Xiaomi Sensors + Kit for controlling Xiaomi sensors

The Xiaomi gateway serves as a hub for all Xiaomi devices, allowing the connection of various sensors

5.1.5.3 A gateway for receiving all the information and interacting with all devices

It will connect to all devices and centralize all the gathered information to send it to the rules engine. Apart from that, it will include a copy of those rules to be performed in real time and will contain an OpenHAB and MQTT server.

OpenHAB, the home automation framework that we will use in PETAL, is able to communicate (over a ZigBee network) with another set of sensors that will be used for the trials. In particular, such sensors are:

-Honeywell Gas detector, to detect gas leaks

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-Honeywell Smoke detector, to detect smoke

-Aqara Humidity, temperature and pressure sensor

-Mijia Door/Window Sensor

-Smart Socket (to remotely control devices)

Such sensors will be controlled thanks to the Xiaomi gateway (https://it.gearbest.com/alarmsystems/pp_345588.html), which serves as a hub for all Xiaomi devices.

Further information about Xiaomi sensors is at:
https://www.openhab.org/addons/bindings/mihome/#supported-devices

We intend to use Rigado gateway https://www.rigado.com/products/iot-edge-as-a-service/

5.1.6 Router

In each house involved in the trials a Wi-Fi router will be installed, providing Internet access within the house. Such router needs to have at least three Ethernet connections available.

Figure 9 Router example

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5.2 Team of experts

For each couple of subjects (MCI patients and their caregivers) a special team will be made available during the entire cycle of the field trial test. The team will be composed by a computer technician, a psychologist, or an equivalent doctor, and a contact person. The technician will handle all the technical part of the project (for example: internet Wi-Fi, Bluetooth connections, the configuration of tablets, sensors and lights system etc). The psychologist, or equivalent doctor, will be in charge of supporting the MCI patients and their Caregivers with special attention to their needs and difficulties. Finally, the contact person will supervise the entire cycle and will be in contact with the end-users for all possible questions and requirements that may rise up during Petal use.

6. Data Analyses

Generally speaking, the study design used for the field trials of PETAL is a prospective cohort study with a pre- and post-test to be conducted at 4 different sites. All data collected during the field trial test will be uploaded in clearly structured tables in Excel scoresheet by each site and, after their merge in a single database, will be analysed through sophisticate statistical programme. Two types of analyses will be performed at the end of the field trial test. One regarding the assessment PRE and POST and the other regarding the behaviour monitoring collected throughout the duration of the field trial. The aim of data analysis is to verify a possible correlation between the use of platform in daily life and improvement of neuropsychological and psychopathological weell-being of the elderly persons taking into account possible third impact factors that eventually could mask the effects of using the PETAL system. This is possible because the platform will also collect information about self-assessment of performance and emotional status of the elderly every time that the person uses the cognitive stimulation tool.

Although statistical analysis will be an essential element in the evaluation of the field tests, their

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validity needs to be put into perspective. Due to the very low number of cases, it is not to be expected that observable improvements can be confirmed by a significance test. Therefore, in addition to statistical comparisons of all observations, a case-by-case analysis will also be carried out that includes both quantitative and qualitative data and takes into account the particularities of each test person and test situation.

CONCLUSIONS

During the field trials phase the PETAL platform will be tested by primary and secondary end-users in a 'real life' setting. This will allow us to get their unique, and therefore invaluable, perspective on the day –to– day usage of our solution. To permit a comprehension of possible effects of our solution on the elderly with MCI and their caregivers, in the PETAL field trial two behavioral evaluation (PRE and POST) will be administered. Concomitantly, two types of training and the installation of the platform in elderly's flats will be carried out. Than PETAL system will be tested in the everyday life. The final aim of PETAL system is prolonging the autonomy of the elderly in managing their daily lives and providing caregivers with new systems for monitoring the elderly at distance.

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