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Lead: UNITOV

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Disclaimer

The TeNDER consortium consists of the following Partners.

No	Name	Short name	Country
1	UNIVERSIDAD POLITECNICA DE MADRID	UPM	Spain
2	MAGGIOLI SPA	MAG	Italy
3	DATAWIZARD SRL	DW	Italy
4	UBIWHERE LDA	UBIWHERE	Portugal
5	ELGOLINE DOO	ELGOLINE	Slovenia
6	ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	Greece
7	VRIJE UNIVERSITEIT BRUSSEL	VUB	Belgium
8	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	HOPE	Belgium
9	SERVICIO MADRILEÑO DE SALUD	SERMAS	Spain
10	SCHON KLINIK BAD AIBLING SE & CO KG	SKBA	Germany
11	UNIVERSITA DEGLI STUDI DI ROMA TOR VERGATA	UNITOV	Italy
12	SLOVENSKO ZDRUZENJE ZA POMOC PRI DEMENCI - SPOMINCICA ALZHEIMER SLOVENIJA	SPO	Slovenia
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[1] **R:** Document, report; **DEM:** Demonstrator, pilot, prototype; **DEC:** Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.

[2] **PU:** Public; **CO:** Confidential, only for members of the consortium (including the Commission Services).

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1. EXECUTIVE SUMMARY

This deliverable defines the general protocol of the TeNDER pilots, integration approach, responsibilities, timelines, detailed locations and success criteria. The result is a comprehensive pilot plan, ensuring that components, features and perceptions are tested in cycles to support a high-quality outcome. A detailed pilot execution and evaluation plan has been designed to guide the pilots. Guidelines have been produced to support all partners in the execution and evaluation of the pilots following a common, shared framework contained in the research book, that includes expected success criteria and timelines. In addition, the responsibilities and locations have been defined for each pilot. Moreover, this deliverable defines the general protocol of recruitment of each end user involved in the field work, with specific sections for each scenario, and the general methods of the pilots.

Section two further describes the purposes of this deliverable, defining the protocol of interaction with participants.

Section three describes the integration approach with technology, by reporting an overview of devices and technical procedures that will be used in the pilots.

Section four reports the trial protocol and background, including both the general criteria for the recruitment and the specific criteria for each disease and scenario.

Section five reports the methods that will be applied in the pilots.

Finally, section six describes the safety measures for the pandemic due to COVID-19 in the pilots.

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2. INTRODUCTION

PURPOSE, CONTEXT AND SCOPE OF THIS DELIVERABLE

The TeNDER project is developing an integrated care ecosystem for assisting people with chronic conditions of Alzheimer's, Parkinson's and Cardiovascular Diseases through the use of affect based micro tools. These micro tools will be able to recognize the mood of a person and thus adapt the system's probes to the person's needs via a multi-sensorial system, even in the most severe cases. Moreover, theymatch with clinical (from Electronic Health Records EHRs or from Electronic Medical Records EMRs) and clerical patient information, while preserving privacy, monitoring the ethical principles, providing data protection and security, with the result of an increased quality of life.

The main purposes of the clinical pilots are involving real end users in all the phases of the TeNDER ecosystem in order to assure that the needs and wishes of patients, caregivers, and healthcare or social care professionals are included at all times in the co-design process. Thus, it will be granted that the TeNDER system supports the improvement of quality of life for the patient and her/his family and also the improvement of working conditions of all health care and social care providers involved in the supply chain, taking into account a multi-disciplinary environment and constraints. The aim of this deliverable is to define the pilot protocols, in order to create a shared framework between all researchers involved in the project. The working conditions of professionals should cover in priority: work time management, quality of data/information exchange and multi-disciplinary coordination. Furthermore, TeNDER pilots will identify improved models for collaboration and organization among different stakeholders involved in caring of elderly people suffering of Alzheimer's, Parkinson's or CVD.

PROTOCOL OF INTERACTION WITH PARTICIPANTS

Order of interaction with participants

- Information sheet and explanation Informed consents for data and/or image recording (signed).
- Entry interviews to determine individual baseline for both intervening and control group.
- Quality of life surveys.
- Interaction with TeNDER functionalities/devices by disease and scenario.
- Exposure to the lab with sensors (if applies).
- Assessment of technology and functions by participants.

Protocol of interaction with technology

- Let participants to freely use the technology. Pay attention to the time it takes for them to find their way and eventual difficulties, but don't forget to reassure them in the process and offer the support of the researchers if needed. Do not do it for them!
- Identify the "routes" they take when using the technology.
- Ask them for their free first impression on technology and gather all their comments or suggestions all over the testing process.
- Ask them if they understand it and if they know how to use TeNDER technology.

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- Ask them to perform concrete tasks, like entering their personal information, including a new professional or caregiver, or a medical appointment in the calendar. Receive input on what to keep and what to improve.
- Make sure that their walkthrough includes all the relevant screens to be tested.
- Pay special attention to accessibility aspects: can they use it? What has to be adapted or improved regarding accessibility?
- Go beyond usability dimensions and ask for improvement suggestions in general. Try not to influence the participants when they offer their sincere opinions. Repeated opinion requests might be useful to identify the real needs and opinions of the end users. New opinions can lead to innovation. They are thus all important to us.

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3. INTEGRATION APPROACH

INTRODUCTION

Note: The TeNDER system is mostly modular, meaning that most of the peripheral sensors can be replaced with a sensor with the same interface (e.g., USB 3.0 connection requirement) depending on the cost of each scenario.

SYSTEM INSTALLATION

1) Description of system components and accessories.

The general functionality of the TeNDER setup is to collect data from multiple sensors and send them to the TeNDER cloud through RabbitMQ. RabbitMQ is the most widely deployed open-source message broker.

One of the central components of the TeNDER setup is the Mini-PC (or Mini-PC light depending on which scenario is chosen) in which HeTra is installed. Most of the sensors are connected using the local area network (LAN) through an HTTP GET method utilizing their wireless connectivity.

2) Hardware installation procedures. (each respective partner)

PILOT 1 (Spain, Madrid): under the responsibility of SERMAS, UPM will support the installation and de-installation phases of the devices at home and day-care centre environments for Pilot 1. UPM will also support SERMAS with technical aspects of piloting. Safety measures for the COVID-19 situation regarding the installation and de-installation phases (section 6) will be viewed in regard to epidemiologic situation in Spain and under the provisions of the authorities and institutional guideline according to the situation.

PILOT 2 (Spain, Madrid): under the responsibility of APM, UPM will support the installation and de-installation phases of the devices at home, day-care centre and rehabilitation room environments for Pilot 2. UPM will also support APM with technical aspects of piloting. Safety measures for the COVID-19 situation regarding the installation and de-installation phases (section 6) will be viewed in regard to epidemiologic situation in Spain and under the provisions of the authorities and institutional guideline according to the situation.

PILOT 3 (Rome, Italy): under the responsibility of UNITOV, DW will support the installation and deinstallation phases of devices at home and hospital settings in pilot 3. Moreover, DW will support UNITOV in monitoring of devices and acquired data after the installation of devices. Safety measures for the COVID19 situation regarding the installation and deinstallation phases are reported in section 6.

PILOT 4 (Bad Aibling, Germany): UPM together with DW and CERTH will support SKBA in the installation and setup of the various system configurations in the hospital setting. This service can be remote or in person, whatever the COVID-19 situation requires. Although in-person support is preferred as it allows direct reaction to possibly occurring problems, every partner will undertake all necessary steps (e.g., dedication of responsible people, structured availability...) to safeguard smooth functioning. The rights and wellbeing of the participants will prevail over all other considerations, especially the protection against COVID-19 infections.

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PILOT 5 (Slovenia): under the responsibility of SPO, ELG will be in charge of the installation and de-installation phases of the devices at home and day-care centre environments for Pilot 5. ELG will also support SPO with technical aspects of piloting. Safety measures for the COVID-19 situation regarding the installation and de-installation phases that are reported in section 6 will be viewed in regard to epidemiologic situation in Slovenia and under the provisions of the authorities and institutional guideline according to the situation.

The central components of TeNDER are:

- **Mini-PC [1]:**
- **Mini-PC light.**

Two types of PCs have been chosen to cope with the TeNDER needs while

All sensors that communicate with the Mini-PC through a HTTP GET method should first be connected to the LAN. These sensors are:

- **Sleep sensor [2]**
    - The Withings Sleep Analyzer was chosen due to:
        - It allows us to capture sleep data through Withing API.
        - It monitors the heart rate, respiration rate, sleep state and also has apnea detection.
        - It doesn't require other devices to run (only a wireless connection).
        - It stores data on secure cloud positioned in the EU.
- **Fitbit Band Versa 2 [3]**
    - The Fitbit band was chosen due to:
        - The possibility of creating apps (code) that can be inserted directly in the band. This allows to control the data flow.
        - It permits us to create a TeNDER scenario that includes only the band and the smartphone, skipping the pc.
        - It allows extracting raw measurements from the accelerometer which enables us to permit a procedure called re-association, which consists in matching the patient's band with the skeletons detected by the depth sensor, avoiding use of sensitive information while improving accuracy by using multiple modalities (skeletons, acceleration, patient's location).
- **Xiaomi Mi3 [4]**
    - Low price.
    - Water and dust resistance.
    - Long battery life.
    - Compatible with the position tracker system.
    - Allows direct measurements transfer trough Bluetooth (no cloud services are required).
- **Position tracker**
    - It connects directly to the local wireless connection (no additional device is required).
    - It measures the signal strength of all Bluetooth devices and sends it to the cloud.
    - Cloud is located in the EU.
    - Cloud supports API integration into the HeTra.
- **Aqara Hub**

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  - It is used as a gateway for the Environmental sensor and the binary sensor.
  - It connects to the local wireless connection.
  - The EU version of this device sends data by default to a Cloud located in the EU.
- **Environmental Sensor**
  - It connects to the Aqara Hub.
  - It measures the temperature and humidity of the environment.
  - It sends the temperature and humidity of the environment to the TeNDER cloud.
- **Binary Sensor**
  - Place at the entrance door, windows or other objects (box/drawer with pills).
  - It connects to the Aqara Hub.
  - It sends data on whether a door/window/object has been opened/closed.

The rest of the sensors are connected using a USB port:

- **Kinect Azure [5]**
  - It connects to the Mini-PC (Mini-PC light does not meet the Kinect Azure requirements).
  - It acquires RGB colour images and Depth images which are used to extract the skeleton using the body tracking SDK.
  - The skeleton data is sent to the TeNDER cloud.
  - This combined with Fitbit band and microphone we can infer fall detection.
  - This combined with Fitbit band we can identify the skeleton.
- **Real-Sense [6]**
  - It connects to the Mini-PC or Mini-PC light.
  - It acquires RGB colour images and Depth images which are used to extract the skeleton using the body tracking module.
  - The skeleton data is sent to the TeNDER cloud.
  - This combined with Fitbit band and microphone we can infer fall detection.
  - This combined with Fitbit band we can identify the skeleton.
  - Real-Sense requires the **body tracking module (for Real-Sense) [7]**
- **Microphone [8]**
- **Speaker [9]**

SOFTWARE INSTALLATION PROCEDURES

Note: The most automatic way (and at the same time the one that requires the less involvement from end-users) is to install the software side of the TeNDER system to create Windows Images and distribute them to the end-users by uploading them to the MAG Gitlab instance. Because this might not be available, the next best alternative is to provide instructions for installing the main components of TeNDER as follows:

1. **Mini PC (CERTH)**
   1. Installation script for Mongo (CERTH) [10]
   2. Installation script for HeTra (CERTH)
      a. Clone the HeTra repository from MAG Gitlab instance.
      b. Install or verify that the latest Visual Studio version is installed.
      c. Compile HeTra and execute the resulting binary.
2. Smartphones, Tablets (DW)
   1. **Mobile Application:**
      - Download App Mobile from PlayStore (android) or Apple Store (IOS).

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- Installation of the App on the smartphone or tablet.
- Registration.
- Login.

2. **Desktop Application**
   - Access to a dedicated host.
   - Installation of the App.
   - Login.

3. **System Validation (MAG)** After the installation procedure of the required tools and services in the Mini PC a validation test will be performed. The purpose of this test is to check the connectivity between the pilot site and TeNDER's central cloud infrastructure. The test script is provided by TeNDER GitLab (HeTra repository) and is designed to send dummy data to the cloud services and retrieve this data from the TeNDER's NBI interface.

BEFORE PILOTS

1. Users account creation (DW, MAG) All users should create a personal account on the TeNDER platform in order to have access only to data that is related to them based on their role. TeNDER platform provides this functionality by including an authorization and authentication server which is responsible for user management. Every user will create an account on the platform using the interface that is offered to his role (mobile app, web interface etc).
   1. Patients

      Pseudonymized system is foreseen for the pilot. After downloading the application from the store, the patient users are provided with a "pseudo-anonymize" code to continue registration. They will use this code to register. After registering they will have the possibility to choose the doctor(s) and caregiver(s).

   2. Caregivers

      The patient selects name, email of the caregiver in the app.
      Caregivers receive an email with links to download the app. They download the app and registers with the same email inserted by the patient. Once registered, the caregiver logs in and automatically finds the patient connected to his user.

   3. Professionals

      Doctors receive an email with a link to the platform and a temporary password for the first access provided by the user "Admin". The doctor user logs in for the first time, enters email and provisional password, once he logs in, he can enter his data in the profile section and change password.

2. Equipment configuration
   1. Associate band Bluetooth with user id/account (Local ELGO / Fitbit UPM).
   2. The procedure with the Fitbit is as follows:
      a. **Pre-configuration:** TeNDER is registered at Fitbit developer's website [11]:

TeNDER has developed an app to avoid regulatory uses, extracting only the information required for the project. The main goal is to extract the biological measurements, and also the acceleration information. In order to get access to the raw data in the bracelet, an application has been created using the Fitbit tools.

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Band install:

The code is created on both sides, the smartphone and the band. We use the online developer tool, previously described and upload the code as follows:

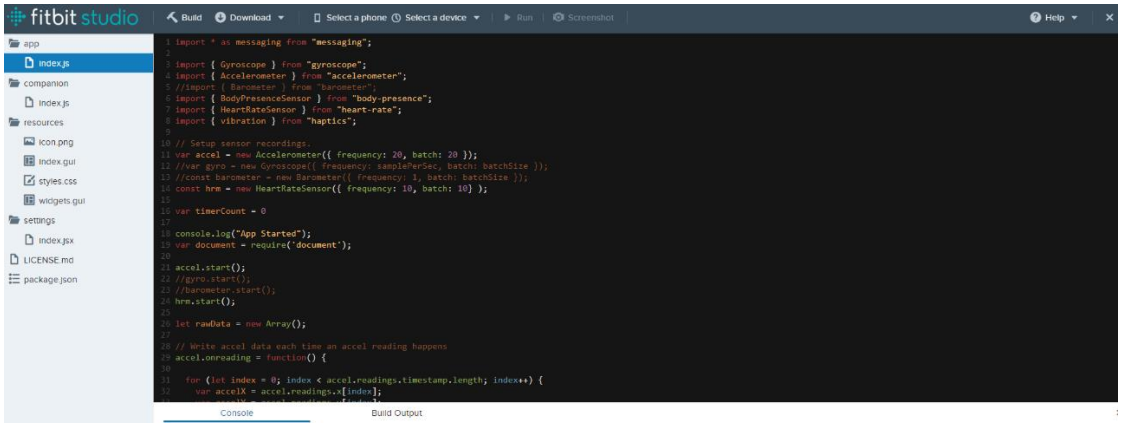

Figure 1 FitBit studio development

Once the code is uploaded at the Fitbit website, then both devices have to be connected to the PC. Once the devices are connected, the next step is connecting both the mobile phone and the band to the same wireless network as the computer with the Fitbit studio is connected.

In the following picture (2), it is observed how the acquisition is performed. On the left side, there is a screenshot of the app paired and with the app loaded, whereas the right side, shows the band when the software is being to be installed.

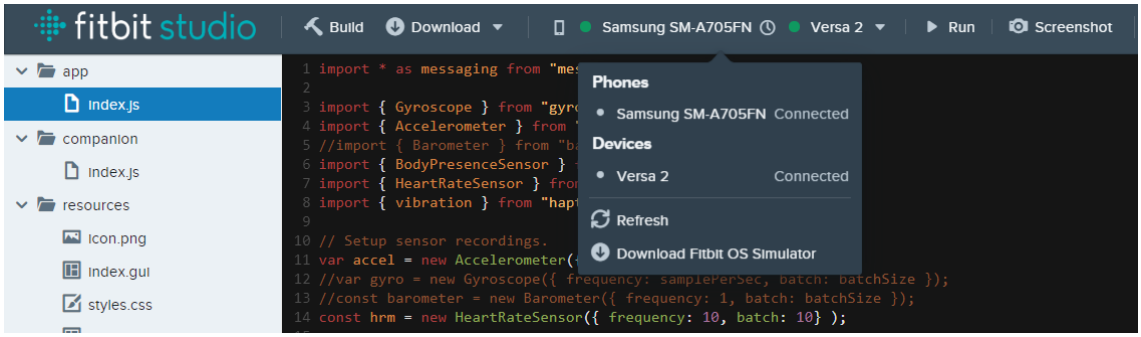

Figure 2 Fitbit examples of the smartphone (top left), fitbit band (rtop right) and software install (bottom).

b. Localization sensors association for pilot setup (ELGO)
c. Associate sleep sensor with user id/account (ELGO)
d. PC configuration (set mini-PC id or user credentials) (DW, MAG, CERTH)

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e. Note: We have decided to use an identification system one-to-one correspondence with each TeNDER setup. The person identification will be done using the association of the band and user id (and with the skeleton for fall detection through the camera).

DURING PILOTS

1. Patients (UPM):

Deployment of the devices at patient's home: Once the patient has followed the procedure of recruitment, information and consent agreement, the TeNDER partners proceed to perform the technical deployment. According to the patient needs and the definition of setups, the patient/caregiver will be informed of the procedure by technical experts. (In previous projects, the techniques used to visit the place to check possible locations of installation).

After the visit and the review of technical aspects, an appointment for the deployment is settled. The devices can include:

- Use of Mini-PC: The PC is going to be deployed in a strategic area of the place, avoiding intrusion. In the case of houses, the best location is near the router or in the living room. Depending on the type of device, extra operations are required to:
  - Connect the Depth sensor (through USB 3.0).
  - Pairing sensors that are connected via Bluetooth if required.
  - Ensuring that data collection is performed appropriately.
- This procedure uses to take around ~2hours, although it depends on the conditions of the place to deploy. Once it is finished, information about the operation of the system is provided to the user, making him/her understand that the last word is on their side.
- The configuration of the sensors, as well as the matching with the user created in the TeNDER subsystem are performed in the installation process.
- Use of a band: There are two bands considered in TeNDER. The first, the FITBIT Band. For this band, the TeNDER project team, led by UPM, has developed an app to collect the data from the TeNDER system. Therefore, TeNDER will install the app in both devices, the Fitbit band and the Xiaomi v3 band, and the patient will be informed about its use, as well as how to charge it, explaining at all time the type of information collected from this device. The Fitbit band has, therefore, the dependency of the smartphone for its normal operation. The patient will be instructed about its use.
- Use of Smartphone/Tablet
  - Digital behaviour analysis, serious games.
- Rehabilitation (CERTH)
  - Utilizing the skeleton inference module clinicians can evaluate the physical condition of the patients by quantifying angles and position of upper and lower limbs during predefined exercises. Up to three patients are being supported at the same time and inside the field of view of the camera.

2. Caregivers (DW)

- Use of Smartphone/Tablet.
  - Receives notifications and reminders (these functionalities will be better described in the next paragraph).
- Professionals (UBI)
  - Use of a web app.

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TeNDER ADDED VALUE TO USERS

1. Patient
   - Calendar: the patients can access the calendar and to see all his/her important events, social events, recommendations, reminders for medical appointments, reminders of medication.
   - Sleep Analyzer: the patient can visualize data and information regarding the sleep trend
   - Reminder: the patient can visualize all the reminders. There are three different types of reminders:
     - Reminder for medical check-up
     - Reminder for medical examinations
     - General reminder
   - QoL: Three types of questionnaires are submitted to the patient (pre/post pilot):
     - SF-36
     - Usability
     - User experience questionnaires
   - Safety and wellbeing: the patient can visualize the history of his emotional state or any falls
   - Communication between roles. A health professional is able to send personalised recommendations to a patient based on the information (graphics) provided by TeNDER.
   - Alerts: When some event of special interest is triggered: Fall down, leaving the house.These function will be extended for in the project lifetime.
   - Recommendations: recommendations for health condition improvement and adherence: health conditions, exercising, reminders on medication.
   - Recommendation of events of interest and social recommendations: That connects the social workers with the patients through TeNDER.

2. Caregiver
   - Alerts: Patient Localization: the caregiver receives an alert and immediately intervenes or calls for help.
   - Report: Weekly or monthly patient status/trend report
   - Calendar: the caregiver can visualize all of the patient's information and events, including medical appointments (and the ones of my patient if these are available), social events and recommendations.
   - Reminder: the caregiver visualizes all reminders and he can add a new reminder
   - QoL: Two types of questionnaires are submitted to the caregiver:
     - Usability
     - User experience questionnaires
   - Safety and wellbeing: the caregiver can monitor the emotional state of the patient and fall detection.
   - Social Communication: the caregiver can access a messaging service and contact the patients or doctors. He can see the history of conversations.

3. Professionals
   - Summarization graphs: the professional can view descriptive reports/graphs on the progress of the patient's treatment, the path taken, and have a general view of the medical condition.

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- Link to Reminder: the professional observes the recommendations that the system provides to his/her patients and checks prescribed routine exercise and have a track record, track the progress of the patients.
- Calendar: the professional can access a calendar and see all events, including medical appointments (and the ones of my patient if these are available).
- QoL: Two types of questionnaires are submitted to the doctor:
    - Usability
    - User experience questionnaires
- Safety and wellbeing: the professional can monitor the emotional state of the patient and fall detection.
- Social Communication: the professional can access a messaging service and contact the patients or caregivers. He can see the history of conversations.
- Link to Sleep Analyzer: the professional can visualize data and information of patient regarding user sleep trend.

GOALS:

- **For the first wave of pilots:** TeNDER ambition is to collect data for algorithms training. Some of the modules will be tested (i.e., the fall detection, the festination, real-time alerts creation).
- **For the second wave of pilots:** TeNDER system will be tested as a whole, with the full integration of all modules (Low-Level Subsystem) and all functionalities.
- **For the third wave of pilots**: TeNDER will be validated as a whole.

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4. TRIAL PROTOCOL AND BACKGROUND

BACKGROUND

With an increasingly growing population in Europe, cognitive impairments as well as heart diseases are a major social and health issue. According to the WHO in a 2018 report [12] dementia, including Alzheimer's disease remains one of the biggest global public health challenges our generation is facing. In the same time, other reports from the same organization suggests that Cardiovascular disease (CVD) represented the 31% of all global deaths in 2016, and it is deemed as the leading cause of premature death (37% of all deaths under the age of 70) and disability in Europe and worldwide (WHO) [13]. Moreover, the number of people living with dementia worldwide today is estimated at 44 million, set to almost double by 2030 and is likely to rise to about 152 million by 2050. Cognitive impairment, however, is a disabling comorbidity that represents a major challenge for HealthCare Systems and it is frequent in people affected by other diseases such as Parkinson's with 1.2 million people affected in Europe [14]. In the case of people who suffer Parkinson´s disease, they experience issues such as: 1) loss of judgment, 2) alterations in behavior, 3) sudden mood changes and 4) difficulties in planning and organizing, which are symptoms far less known in comparison with the symptoms related to motion alteration. Alzheimer's, Parkinson's and Cardiovascular diseases, mainly found in senior people as multi-morbidities have an estimated cost for the EU economy of more than EUR 196 billion a year [15] and a trillion US dollars at worldwide level with forecast estimation double by 2030. Therefore, this considerable concern is moving public authorities (National Health Systems NHSs), policy makers, researchers and private businesses to join forces to develop holistic solutions to extend autonomy of people affected by these diseases while maintaining, or even improving, their Quality of Life (QoL): to face this challenge, TeNDER aims to create an integrated care ecosystem for assisting people with chronic diseases of Alzheimer's (AD), Parkinson's (PD) and comorbidity with Cardiovascular Diseases (CVD) through the use of affect based micro tools.

RESPONSIBILITIES AND LOCATIONS

Pilot 1 by SERMAS-FIIBAP

SERMAS is in charge of Pilot 1. The Madrid Heath System (SERMAS) is the administrative and management structure that integrates almost all public hospital, primary care centres, emergency services and every public health service of the Madrid Regional Public Health System. FIIBAP has the legal capacity to handle the financial and administrative aspects of the Emergencies Services involved in research projects, including all issues relating to project management, including the employment and payment of additional personnel, purchase of equipment and consumables, etc. The Foundation depends of the Healthcare Coordinator General Directorate within SERMAS. The EC contribution will be directly handled by FIIBAP as an entity of SERMAS.

In Pilot 1 the TeNDER project will be carried out in the Primary Care System, where the participants will be recruited by the multidisciplinary health team, composed of general practitioners, community and family nurses and social workers, mainly. The participants will be the users and professionals of the Primary Care

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Health Centres. The TeNDER System will be placed in the context of primary care and the tools will be installed in patients' homes and day care centres.

Pilot 2 by APM

APM is in charge of the Pilot 2. Asociacion Parkinson Madrid is a non-profit patients' association that take care of people affected by Parkinson´s Disease and their families. The Association provides therapies to patients suffering from Parkinson into the rehabilitation centers and at home. The Pilot 2 will be carried by Asociacion Parkinson Madrid (Calle Poeta Esteban Villegas, 12, Madrid, Spain). The recruitment of patients and caregivers will be performed at APM using the own patient's database. The recruitment of sociohealth professionals will be done among the Asociacion Parkinson Madrid hired workers by the APM researchers.

The pilot 2 includes: Home settings, Rehabilitation Room settings and Day Care Centre. In Parkinson's Disease, motor rehabilitation is a fundamental treatment. With the TeNDER system, the aim is to measure the performance and evolution of the motor function in the rehabilitation room so that therapists can monitor the performance of the patients during the sessions and their evolution over time. In this way they can make decisions about treatment strategy. Therapist and patient can be connected in terms of their rehabilitation therapies through the TeNDER system. In turn, the system will be able to make automatic recommendations according to the performance. Day care centres and Covid 19 in the first wave: even though the deployment of the TeNDER system is also planned at the APM´s Day Care Centre., unfortunately, due to the COVID19 pandemic situation, this service is closed. It is certain that it will not be available to the project during the first wave of the pilot.

The Association has tried to reopen the day care centre on two occasions, in July 2020 and October 2020. But the fear that the pandemic has caused among the elderly population with Parkinson's Disease has caused them to refuse to return to this type of service where they live closely with other people and also have meals without masks. The day care centre used to have between 30 and 40 users per week. At present, the Madrid Parkinson's Association cannot guarantee when the day care centre will open and there are even doubts as to whether it will be able to open again. Since the health criteria associated with the COVID-19 and economic viability criteria will be taken into account. Initially, we assure that the day care centre will not be able to participate in the first wave of the pilot. As soon as the day care centre opens, it will be made available to the TeNDER project again. In order not to lose end users who test the TeNDER system the Association will increase the sample planned in the Rehabilitation Room scenario.

The Day Care Centre scenario will be deployed in the 2nd and 3rd waves, if the health situation regarding COVID-19 allows this. The recruitment will be done in the only specialized centre in Madrid in Parkinson´s Disease that belongs to APM. Patients who assist to the centre 2, 3, 4 or 5 days per week, could be recruited.

Pilot 3 by UNITOV:

The department of Biomedicine and Prevention of University of Rome “Tor Vergata” (Via Montpellier 1, Rome, Italy) is in charge of Pilot 3. The Pilot 3 will be carried out by the University of Rome “Tor Vergata” (UNITOV) in collaboration with the Institute of Research and Scientific Care Santa Lucia (SLUCIA), Department of Neuropsychology (Via Ardeatina 306-354, Rome, Italy). The recruitment of patients and caregivers will be performed at SLUCIA and the recruitment of professionals will be performed at SLUCIA and at UNITOV. User’s data will be collected at SLUCIA, on responsibility of UNITOV. The Pilot 3 will include home setting and hospital setting.

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Pilot 4 by SKBA

Schoen Clinic Bad Aibling (SKBA) is in charge of Pilot 4. SKBA is a neurological rehabilitation hospital located in Bavaria, Germany (Kolbermoorer Str. 72, 83043 Bad Aibling) and thus serves as clinical setting. The SKBA hospital and the SKBA Alzheimer's Therapy Centre (ATC), which is located nearby, will serve as study locations. Study conducts and recruitment of patients (AD, CVS, PD), caregivers, and health and other professionals will be performed by scientific personnel of SKBA. The hospital scenario comprises hospital rooms for CVD and PD patients, and apartments for AD patients who are accompanied by their caregiver. The TeNDER system will be placed to support hospital care, foster communication and provide easy information access, including professionals and caregivers closely in the patient`s care continuum.

Pilot 5 by SPO:

Spominčica - Alzheimer Slovenija (SPO) is in charge of Pilot 5. Pilot 5 will be carried out by SPO in collaboration with the Department of Neurology, University Medical Centre of Ljubljana. The piloting population will be represented by patients and carers that are members of SPO, and users of SPO activities. The recruitment in Day Care Centres will be done in 2 centres in Ljubljana, due to COVID-19 new reality, SPO is investigating the possibility to perform pilot in full time care centres. If the health situation regarding COVID-19 in Day Care Centres will allow it, the patients will be recruited and involved in testing for 2-8h/day and 1-5 days/week in the Day Care Centre. The recruitment of the professionals will be from the Department of Neurology, University Psychiatric Clinic of Ljubljana, Community Healthcare Centres, Day Care Centre professionals and SPO Expert Board members. User data will be collected by SPO, on the responsibility of SPO.

GENERAL PROTOCOL

Five different pilots will run simultaneously according to the validation strategy defined for the co-design process. The pilots were chosen to compare results among diverse National Health Systems (NHS) including well demarcated European Mediterranean and Central European zones. These pilots will co-design, assess and validate the TeNDER toolbox services in several well-defined scenarios, being the scope of this deliverable the detailed planning of the first wave of the pilots.

The expected timeline of the first wave was M13-M18. Nevertheless, due to several conditions presented during the pandemic caused by Covid-19 (activity of health care center, patients´ homes and hospital limited or interrupted, leaving non-urgent check-ups for later, restriction of patients/professionals allowed to access to hospital, rehabilitation centers and day care centers, etc.) the timeline of the first wave will be delayed (M15-M20).

TeNDER involves the dedicated contribution from end-user entities and medical bodies in TeNDER to analyse the available technologies. Further we will collect needs and requirements of each specific category of end-users in terms of services solution characteristics, interfaces and contents as well as current fields of interaction among the involved actors: health and other professionals, caregivers and associations, local authorities in the pilot countries. State of the art literature has been analysed, compiled and reported to illustrate and align the needs and constrains for users in the categories defined.

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Table 1 Summary Pilot Table of the waves of pilots.

Pilot (country)	Pilot 1 (Madrid region, Spain)	Pilot 2 (Madrid city, Spain)	Pilot 3 (Rome, Italy)	Pilot 4 (Bavaria, Germany)	Pilot 5 (Slovenia)
User partners	**SERMAS**	**APM**	**UNITOV**	**SKBA**	**SPO**
Diseases covered	AD, PD, CVD	PD	AD, PD	AD, CVD, PD	AD
Scenarios involved	Primary care, Homes and Day Care centers	Homes and Rehabilitation room.	Homes and Hospital	Hospital	Homes and Day Care centers
Stakeholders	Patients Caregivers (formal and informal) Professionals: Social professionals (social worker), Health professionals (GPs and nurses) and Administrative staff	Patients Caregivers (formal and informal) Professionals: Social professionals (social workers, speech therapists, music therapists, occupational therapist and Administrative staff. Day Centre workers pending of the reopen of the service). Health professional: phycologist and physiotherapists	Patients Caregivers and Family Professionals: Health professionals (Cardiologist, Clinical Neurologist, GP, Neuropsychologist/Psychiatrist, Radiologist, Pharmacologist, Pharmacy. Administrative staff	Patients Caregivers (formal and informal) Professionals: Health professionals (Physicians, movement scientists), Social professionals (therapists) Administrative staff	Patients Caregivers (formal and informal) Professionals: Social professionals (social worker), Health professionals Administrative staff
Users					
Patient	380 (534 with control group)	95 (133 with control group)	60 (84 with control group)	100 (140 with control group)	100 (140 with control group)

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Caregivers	290	80	60	60	80
Professionals	66	25	32	31	20
Number of end users involved (every month)	>60	>15	>10	>20	>20

TeNDER will provide 4 different scenarios according to the patients' pathways (home, day-care centre, rehabilitation centre/rooms, and hospital). Finally, TeNDER will seek a concrete measurement for a quality-of-life shift of people using the TeNDER system, measuring pre- and post-piloting assessment of quality of life, with the involvement of different care stakeholders, ranging from caregivers, social workers, patients, health professionals and support staff dealing with clerical information. The different scenarios in the project will have different technologies (micro-services) and interfaces, suitable for the different stakeholders identified, as indicated in the following Figure.

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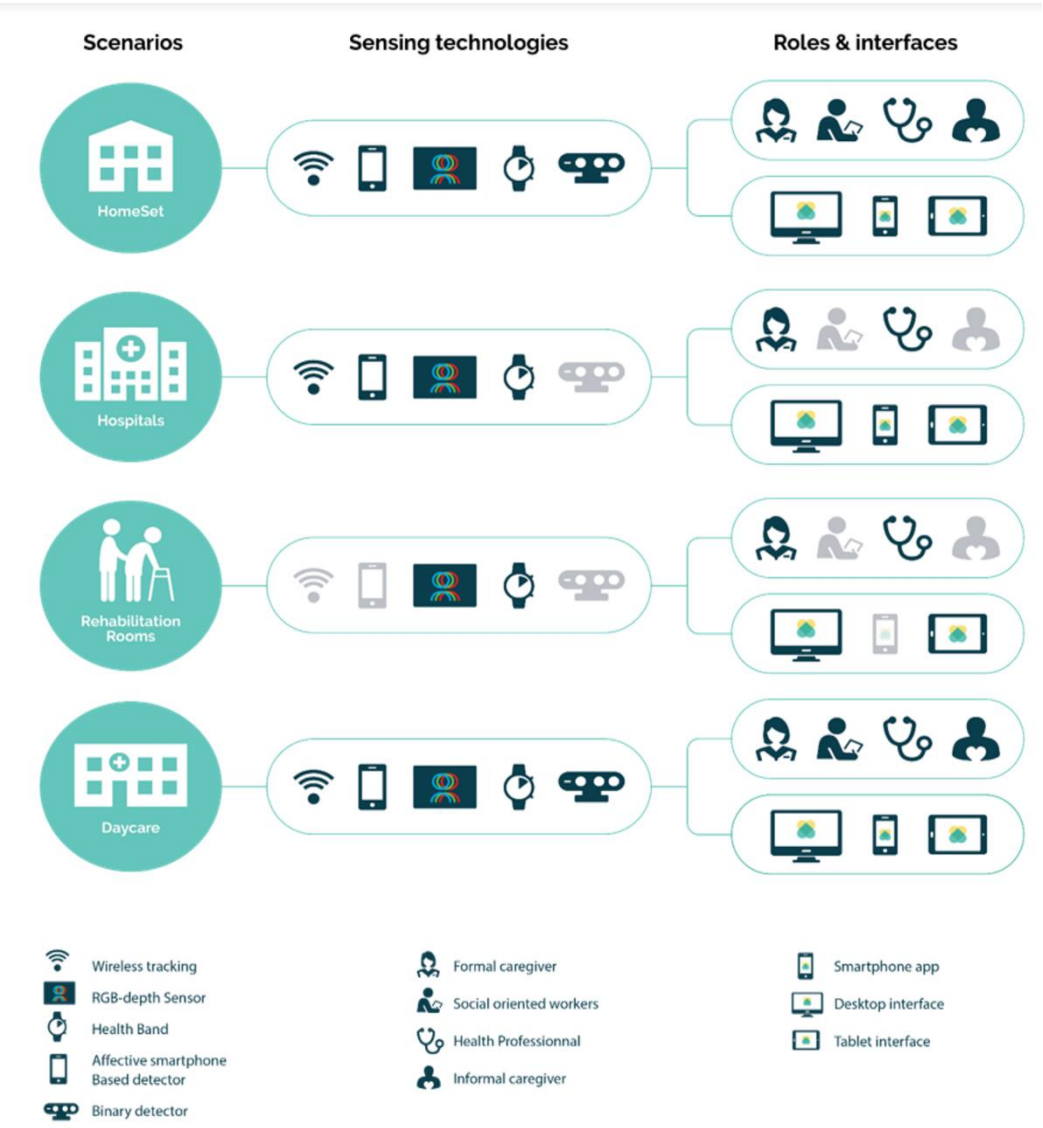

Figure 3 TeNDER nutshell of technologies and the corresponding scenarios

Table 2 Technologies and functionalities in first wave of TeNDER pilots

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Pilot (country)	Pilot 1 (Madrid region, Spain)	Pilot 2 (Madrid city, Spain)	Pilot 3 (Rome, Italy)	Pilot 4 (Bavaria, Germany)	Pilot 5 (Slovenia)
User partner	**SERMAS**	**APM**	**UNITOV**	**SKBA**	**SPO**
Technologies assigned	Application for smartphone/ tablet Mini PC (low-end) Smartphone Tablet Smartband (Fitbit/ Xiaomi MiBand 3) Binary Sensors (for pill case) Localization sensor Sleep tracker Different accessories, e.g. cables	Application for smartphone/table Mini PC Mini PC (low-end) Smartphone Fitbit Band Versa2 Smartband (Xiaomi Mi3) Binary sensor (for pill case) Microphone Speaker RGB Camera/ Kinect Different accessories, e.g. cables	Application for smartphone/table Mini PC (low-end) Mini PC (high-end) Smartphone Fitbit Binary sensors Microphone Speaker Localization sensor Sleep tracker Environmental sensors RGB camera/ Kinect Tablet Different accessories, e.g. cables	Application for smartphone/ tablet Mini PC (high- and low-end) Speaker Fitbit Microphone Sleep tracker Kinect Different accessories, e. g. cables	Application for smartphone/tablet Mini-PC (low-end) Smartband (Fitbit/ Xiaomi MiBand 3) Localization sensor Microphone Sleep tracker Speaker Different accessories, e.g. cables Smartphone Tablet
Functionalities to be tested	Medical examination/ daily plan schedule Calendar with notifications Activity and room level localization	Calendar with notifications Physical activity Drug adherence Sleep quality Safety and security at home due to motor problems (falls or	Medical examination/ daily plan schedule Calendar with notifications Fall detection Temperature detection	Medical examination/ daily plan schedule Calendar with notifications Nocturnal activities (quality of sleep)	Medical examination /daily plan schedule Calendar with notifications Nocturnal activities (quality of sleep) Emotional state detection

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	Nocturnal activities (quality of sleep) Sleep quality Drug adherence Safety and security at home Emotional state detection Physical activity (steps)	loss of balance, freezing) Measurement motor state and evolution (Skeleton identification). (Balance, march, corporal position, stiffness, coordination).	Humidity detection Apartment level localization Apartment presence Room level localization Emotional detection Festination Freezing Loss of balance Confusion and disorientation Doors, windows/leave house Sleep quality Personal calendar Physical activity Bio-measurement Skeleton identification	Emotional state detection Activities and room level localization Skeleton identification Fall detection Biomeasurements Physical activity (steps) Loss of balance	Room level localization Apartment level localization Apartment presence Fall detection Biomeasurements Physical activity(steps)

Recruitment of participants will be done without discrimination based on gender, assuring that at least 40% of the participants of each gender are represented, by presenting data compared by gender, by assuring to include the differential gender derived needs of end users.

The trial protocol requires the recruitment of patients affected by AD, PD, CVD, heterogeneously represented by gender (40% representation), with an age ≥60 years.

Case studies will be subjected to a proportional randomization in the second and third waves of pilots that will lead to the creation of two arms (research groups) matched by gender, age and stage of the disease: 1) the control group and 2) the experimental group (the user management based on electronic information sharing and monitoring by technological devices).

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In the first wave of pilots, the control and the experimental groups of patients, matched by gender, age and stage of disease will be created. The inclusion in experimental or control group will be performed according to the patient's final decision to actively participate to TeNDER project. This approach has been proposed as a part of the mitigation plan for the pandemic due to Covid-19: in addition to common reasons for a denied consent to participate, all end-user partners involved have highlighted some difficulties in the recruitment phase due to the fear of contagion during the installation phase of devices and due to the reduced access to day care center, rehabilitation room, and in some cases also in hospital and day hospital. During the Covid-19 outbreak in Europe, healthcare systems began postponing and scaling down some aspects of routine non-infectious diseases management (including neurodegenerative diseases and CVD) and outpatient visits. Although there are no data available yet on this issue, it is likely that many patients with non-infectious diseases management (including neurodegenerative diseases and CVD) have decreased access to outpatient visits and one-on-one clinical advice, and, in some cases, there may be a shortage of medicines. Further, some patients may be reluctant to seek care due to fears of infection in healthcare settings [16].

All these aspects linked to the pandemic due to Covid-19 lead to a significant reduction of potential users involved in TeNDER project in all countries involved. Therefore, in order to reach the number of expected users, we decided to include in the experimental group all patients that fulfill the inclusion/exclusion criteria and that decided to actively participate to the project. On the other hand, patients that fulfill the inclusion/exclusion criteria but denied the consent to participate to the project, will be included in the control group.

PATIENTS RECRUITMENT

General Inclusion criteria

- Age ≥ 60 years.
- Understand local language.
- Have a caregiver or reference person.
- Able to move and walk in their homes.
- Sufficient cognition capabilities to take informed decisions.
- Acceptance to participate and have signed the informed consents.
- Compliance with scenario setting.

General Exclusion criteria

- Patients whose caregiver is unwilling to participate / assist; Patients / caregivers are unwilling to work with the technologies used in this project.

General inclusion and exclusion criteria for disease

Patients will be classified according the disease in AD group, PD group and CVD group.

In cases of mixed pathology, the patient will be included in the group of the pathology that mainly influences the clinical aspects.

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The patient will be allocated to the trial-groups according to the main diagnosis which is the reason for hospitalization or examination. In cases of mixed pathology, the patient will be included in the group of the pathology that mainly influences the clinical aspects. The evaluation and decision are made by the trial investigator. In order to take care of the possible confounding effects, further diagnoses will be recorded, as well, and adjusted for in the final statistical analysis.

Table 3 General inclusion/exclusion criteria in Alzheimer's disease or dementia group, in Parkinson's disease group, in Cardiovascular diseases group.

	Alzheimer's (AD) or Dementia	Parkinson's (PD)	Cardiovascular diseases (CVD)

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Inclusion criteria	-Persons expressing subjective cognitive compliant and MMSE score of 19 to 28 pts, or having diagnosis of disease-causing dementia (with MMSE score of 19 to 28 pts) or Diagnosis of Alzheimer's according to NINCDS-ADRDA criteria [17]).	- Confirmed diagnosis of Parkinson's disease. All patients will provide a report with an assessment from the neurologist.	Patient that presents one of the following: - Cardiovascular failure grade II-III NYHA [18] - Coronary heart disease: both stable and acute coronary artery disease (ACS) with or without ST elevation - Atrial Fibrillation - Cardiac Pacemaker Carrier - Cerebral Stroke
Exclusion criteria	- Advanced stages of the disease (for example Alzheimer's disease: avoid GDS 6-7).	-Parkinsonism secondary to vascular disease, treatment, etc. -Parkinsonism syndromes (Multiple System Atrophy (MSA) Progressive Supranuclear Palsy (PSP), Corticobasal Syndrome (CBS) - Dementia with Lewy bodies (DLB)	- ACS less than 4 weeks ago -Severe aortic stenosis.

Hospital scenario: inclusion and exclusion criteria for AD patients

All Patients will undergo a complete medical investigation including a medical history, neurological examination, Mini Mental State of Examination (MMSE), a neuropsychological examination, a complete neuropsychiatric examination and eventually neuroimaging (for example MRI or PET scan).

Inclusion criteria

- Age ≥60 years;
- Patient with Alzheimer Disease accordingly to the NINCDS-ADRDA criteria [17] or diagnosed dementia with MMSE score of 19 to 28;
- Agree to use the provided devices;
- Understand local language;
- Ability to walk (with or without walking aids) or able to use wheelchair;

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- Compliance with scenario setting.

Exclusion criteria

- Patients with acute stroke in the previous six months (Hachinski scale score > 4);
- Pyramidal and or Extrapyramidal signs at neurological examinations;
- Patients' whom informal carer (family care giver) is not willing to participate/assist;
- Patients/carer is unwilling to work with technologies used in this project;
- Advanced stage of disease.

Hospital scenario: inclusion and exclusion criteria for PD patients

All Patients will undergo a complete medical investigation including a medical history, neurological examination, Mini Mental State of Examination (MMSE), a neuropsychological examination, a complete neuropsychiatric examination and eventually neuroimaging (for example MRI or ^{123}I FP CiT SPECT).

Inclusion criteria

- Age ≥60 years;
- Patients with confirmed diagnosis of Parkinson Disease accordingly to the criteria by United Kingdom Parkinson's Disease Brain Bank (UKPDSBB) criteria or according to a neurological assessment [19];
- Both Patients and Caregivers agree to use the provided devices;
- Understand the local language;
- Ability to walk (with or without walking aids) or able to use a wheelchair;
- Compliance with scenario setting.

Exclusion criteria

- Patients with secondary parkinsonisms;
- Patients' whom informal carer (family care giver) is not willing to participate/assist;
- Patients/carer is unwilling to work with technologies used in this project;
- Advanced stage of disease.

Hospital scenario: inclusion and exclusion criteria for CVD patients

Inclusion criteria

- Age ≥60 years;
- Patient that presents one of the following:
  - Cardiovascular failure grade II-III NYHA;
  - Coronary heart disease: both stable and acute coronary artery disease (ACS) with or without ST elevation;
  - Atrial Fibrillation;
  - Cardiac Pacemaker Carrier;
  - Cerebral Stroke;
- Both Patients and Caregivers agree to use the provided devices;

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- Understand local language;
- Ability to walk (with or without walking aids) or able to use wheelchair;
- Compliance with scenario setting;
- Preserved language comprehension and communication skills.

Exclusion criteria

- Patients' whom informal carer (family care giver) is not willing to participate/assist;
- Patients/carer is unwilling to work with technologies used in this project
- ACS less than 4 weeks ago;
- Severe aortic stenosis;
- Severe visual or hearing impairment.

Home and Day care centers scenarios: inclusion and exclusion criteria for AD patients

Inclusion criteria

- Age ≥60 years;
- Persons expressing subjective cognitive compliant and MMSE score of 19 to 28 pts, or having diagnosis of disease-causing dementia (with MMSE score of 19 to 28 pts) or Diagnosis of Alzheimer's according to NINCDS-ADRDA criteria [17]);
- Agree to use the provided devices;
- Understand local language;
- Ability to walk (with or without walking aids) or able to use wheelchair;
- Compliance with scenario setting.

Exclusion criteria

- Patients with acute stroke in the previous six months (Hachinski scale score > 4);
- Patients' whose informal carer (family care giver) is not willing to participate/assist;
- Patients/carer is unwilling to work with technologies used in this project;
- Advanced stage of disease.

Home, Rehabilitation and Day care centers scenarios: inclusion and exclusion criteria for PD patients

Inclusion criteria

- Age ≥60 years;
- Patients with diagnosed Parkinson Disease;
- Both Patients and Caregivers agree to use the provided devices;
- Understand local language;
- Ability to walk (with or without walking aids) or able to use wheelchair;
- Compliance with scenario setting.

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Exclusion criteria

- Patients with secondary parkinsonisms;
- Patients' whom informal carer (family care giver) is not willing to participate/assist;
- Patients/carer is unwilling to work with technologies used in this project;
- Advanced stage of disease.

Home scenario: inclusion and exclusion criteria for CVD patients

Inclusion criteria

- Age ≥60 years;
- Suffering from Cardiovascular Disease one of the following
  - Coronary heart disease;
  - Heart failure (Classification NYHA, stage II/IV or self-reported) [18];
  - acute coronary syndrome;
  - been a coronary catheterization for stent placement;
- Both Patients and Caregivers agree to use the provided devices;
- Understand local language;
- Ability to walk (with or without walking aids) or able to use wheelchair;
- Compliance with scenario setting.

Exclusion criteria

- Patients' whom informal carer (family care giver) is not willing to participate/assist;
- Patients/carer is unwilling to work with technologies used in this project;
- Patients who have had a heart attack less than 4 weeks ago;
- Poor life expectancy (<6m);
- Aortic stenosis.

CAREGIVERS RECRUITMENT

Inclusion criteria

- To be able to consent and to comply with at least one of the following requisites:
  - To be employed by a public or private company or directly by the patients to provide direct care and thus support daily activities.
  - To live with and/or take care of a relative (or other close relationship) affected by Parkinson's disease or Alzheimer's disease or/and others dementia or CVD
  - To provide logistic support to a family member or a close friend affected by Parkinson's disease or Alzheimer's disease or/and others dementia or CVD.
- Express readiness in the use of technologies to use the devices

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Exclusion criteria

- Caregivers not able to consent.
- Caregivers not aware of the daily needs of patients.

PROFESSIONALS RECRUITMENT

Inclusion criteria

To be able to consent and to be qualified and working in a medical or social area specialized in the care or support of Parkinson's, Alzheimer's or/and dementia and cardiovascular diseases (including general practitioners, nurses, social workers and others).

Exclusion criteria

- Not working as a professional involved in the care or support of AD, PD, CVD patients.
- Working practice and environment not connected to Alzheimer's', Parkinson's' and other dementias.
- Conflict of interest.
- Not to be able to consent.

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5. METHODS

Three waves of pilots will follow a first phase of initial definition. As mentioned in Deliverable 2.3, the first two waves of pilots will implement the TeNDER system with a revision of the proposed solutions based on users´ evaluations.

The third wave will allow the final TeNDER system evaluation.

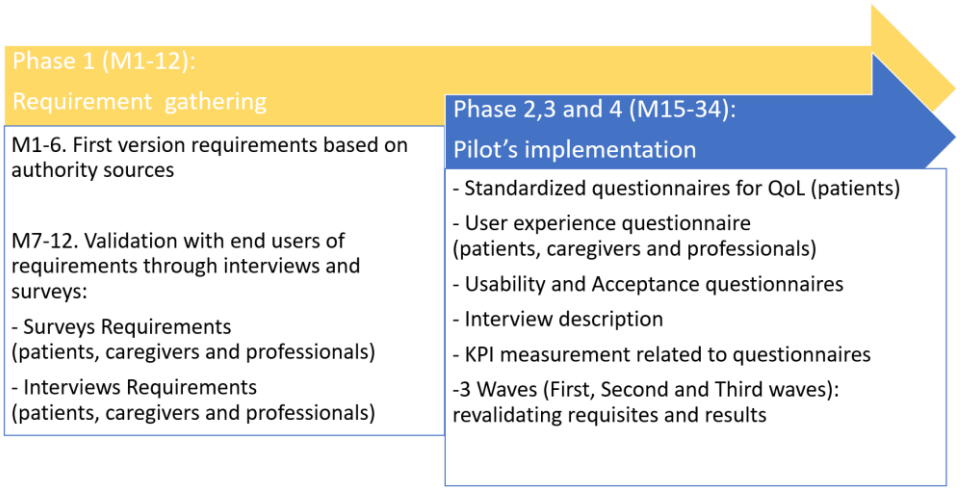

Figure 4 TeNDER Phases

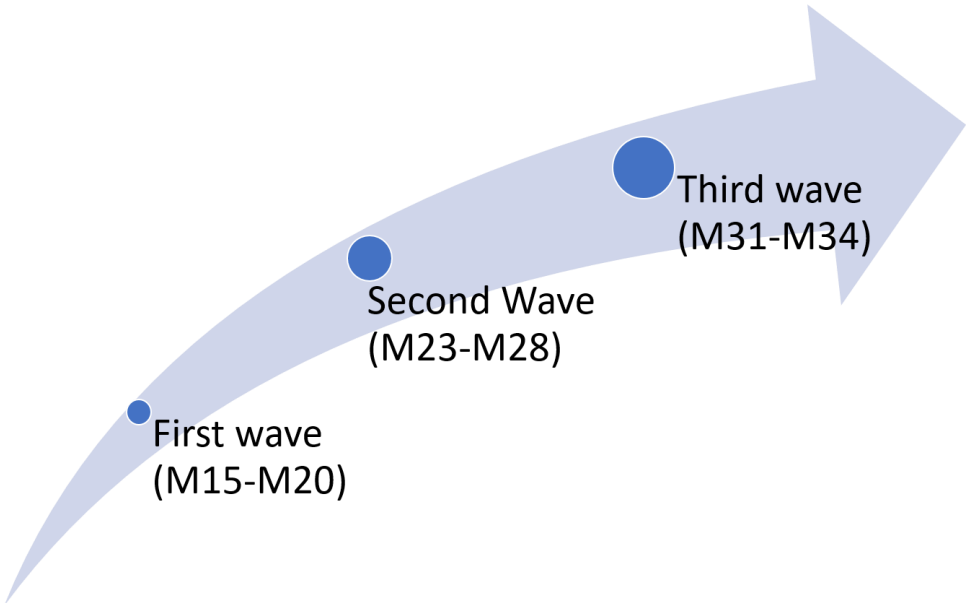

Figure 5 . Waves (First, Second and Third waves): revalidating requisites and results.

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Patient

The project will measure its success through benchmarking with Improvement physical well-being / QoL (measured by SF-36) and Improved interaction paradigms (User Experience Questionnaire).

All patients involved undergo a QoL measurement by using SF-36 after the recruitment, at baseline. In addition, patients undergo an initial assessment of their perceived autonomy, at baseline, by performing the "Autonomy Questionnaire", a section of the User Experience Questionnaire of patients (UEQ patient) reported in the Deliverable 7.1. Then, the TeNDER system will be implemented according to each scenario.

The patient management based on electronic information sharing and/or monitoring by technological devices will be applied for a period between 45 days - 2 months for each patient (with their respective caregiver and professionals) in home setting.

In the hospital setting the treatment time (system use) will be dependent on the length of the hospitalisation. In each wave at least one patient will be equipped with the TeNDER system for the use at home after the hospitalisation to get a 45 days-2 months data set.

In the day care centre/rehabilitation room setting the expected length of monitoring is 2-8h/day in 1-5 days/week, for a 45days- 2months data set.

However, this period could vary due to the needs of the participants or the project itself and it can be influenced by several aspects, including the impact on the facilities of the pandemic due to Covid-19.

At the end of the monitoring, in each patient The User Experience questionnaire will be performed in order to assess the relevant information linked to the reaching of KPIs, including the impact on patient's life of each functionality tested, evaluated by "Modular set function questionnaire" section of UEQ patient. The UEQ patient has been reported in Deliverable 7.1.

The SF-36 and the "Autonomy Questionnaire" of User Experience Questionnaire measurements, performed at the end of the monitoring, will be compared to the baseline assessment.

The expected KPIs are:

- Improved physical well-being / Health related QoL (measured by SF-36) of 15% (~7-8 points).
- Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate.
- Improved perceived QoL and the autonomy of the patient respectively by 15% and 10%.
- The QoL evaluation should be performed at least in 3 different health conditions.
- 10% increase in autonomy.
- Patient satisfaction of speed-up attention perception (>90% Questionnaires satisfaction).

In addition, an initial usability assessment has been defined for the first wave of pilots, as reported in Deliverable 7.1.

At the baseline, all users will undergo an Affinity for technology assessment. After the monitoring, all patients will undergo a Usability assessment, both Quantitative by using System Usability Scale, and Qualitative by using 3-opened questions elaborated by the consortium.

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The Usability assessment will be implemented during the project and next steps concerning the Usability and Sustainability assessment will be implemented in Task 6.2.

Caregivers

As a horizontal objective, TeNDER will identify models for collaboration and organization among different stakeholders (i.e. health professionals involving therapeutic personnel, social workers and caregivers). The project will measure its success through benchmarking with Improvement perceived QoL and Improved interaction paradigms (User Experience Questionnaire) in caregivers.

All caregivers involved undergo a Perceived QoL measurement, a section of User experience questionnaire of caregiver (UEQ caregiver) after the recruitment, at baseline. In addition, all caregivers undergo an evaluation regarding the satisfaction about the care of the patient, included in UEQ caregiver. Then, the TeNDER system will be implemented according to each scenario.

The patient management based on electronic information sharing and/or monitoring by technological devices will be applied for a period of 45 days-2 months. In the hospital setting the period is dependent on the patient`s length of hospitalisation.

At the end of the monitoring, in each caregiver The User Experience questionnaire will be performed in order to assess the relevant information linked to the reaching of KPIs, including the impact on caregiver's life of each functionality tested, evaluated by "Modular set function questionnaire" section of UEQ caregiver. The UEQ caregiver has been reported in Deliverable 7.1.

Therefore, the perceived QoL/ Question regarding the satisfaction about the care of the patient (included in UEQ caregiver) measurements, performed in the caregiver at the end of the pilot, will be compared to the baseline assessment.

The expected KPIs are:

- Improved physical well-being / Health related QoL (measured by perceived QoL) of 15%.
- Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate.
- Carer satisfaction of speed-up attention perception (>90% Questionnaires satisfaction).
- 10% increase in satisfaction of relatives.
- Time saving for carers in waiting while patient is going to be attended (>10%).

In addition, an initial usability assessment has been defined for the first wave of Pilots, as reported in Deliverable 7.1.

At the baseline, all users will undergo an Affinity for technology assessment. After the monitoring, all caregivers will undergo a Usability assessment, both Quantitative by using System Usability Scale, and Qualitative by using 3-opened questions elaborated by the consortium.

The Usability assessment will be implemented during the project and next steps concerning the Usability and Sustainability assessment will be implemented in Task 6.2.

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Professionals

The project will measure its success through benchmarking with Improved interaction paradigms (User Experience Questionnaire) during the entire period of the project.

Particularly, User Experience Questionnaire measurements (UEQ professional) will be performed during each wave in all professionals involved. The social and health professionals will improve their working conditions since they will optimize their time management and use high quality data collected by all stakeholder inputs, interaction and sensors. This analysis will provide the healthcare professionals with additional information and pertinent feedback on demand to make more accurate and informed decisions in relation to older adult's health care. This makes the health professional an informed consultant, who, assisted by the ICT-based interventions outcome, better supports the older adults, in a personalised way, in achieving his/her optimal quality of life.

All professionals involved undergo a "Working conditions Questionnaire" measurement, a section of User experience questionnaire of professionals (UEQ professional) after the recruitment, at baseline.

Then, after the end of each wave of pilots or at the end of the involvement of the professional in the wave, in each professional the UEQ professional will be performed in order to assess the relevant information linked to the reaching of KPIs. The UEQ professional has been reported in Deliverable 7.1.

Therefore, the questions regarding the working conditions (included in UEQ professional) measurements, performed in the professional at the end of the pilot, will be compared to the baseline assessment.

The expected KPIs are:

- Improvement of working conditions of health and social care providers and professionals by at least 10% (measured with questionnaires).
- Reduction of average number of visits to the hospital at least 12%.
- Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate.
- Reduction of time in access to clerical patient information at least 10%.

In addition, an initial usability assessment has been defined for the first wave of pilots, as reported in Deliverable 7.1.

At the baseline, all users will undergo an Affinity for technology assessment. After the end of each wave of Pilots or at the end of the involvement of the professional in the wave, all professionals will undergo a Usability assessment, both Quantitative by using System Usability Scale, and Qualitative by using 3-opened questions elaborated by the consortium.

The Usability assessment will be implemented during the project and next steps concerning the Usability and Sustainability assessment will be implemented in Task 6.2.

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6. SAFETY MEASURES FOR COVID-19

The protocol concerning the safety measures to reduce transmission of COVID-19 will be described and implemented throughout the entire project. In fact, the safety measures, including both individual and environmental measures, are subordinate to European and national directives and should be applied on the responsibility of each institution and facility involved in the project. Obviously, both European and national directives are subject to changes based on changes of circumstances regarding COVID-19 transmission in each country.
Therefore, as necessary, the safety measures for COVID-19 in TeNDER project will be integrated and updated. TeNDER partners involved in the pilots will take all the necessary protection measures to ensure that we are adequately protecting staff and partners from those risks to their health or safety that cannot be avoided or sufficiently limited by adopting organisational measures, technical measures and, ultimately, individual protection measures. All the above measures shall be taken simultaneously if the working conditions so require.

PILOT 1

Home setting and day care centres:

The safety measures to reduce transmission of COVID-19 in the home scenario involve mainly patient's and caregiver's compliance with the individual safety measures and the updates defined by the Ministry of Health, Consumption and Social Welfare, Government of Spain [20].

Within the development of the pilot in the home of the participants there are 2 moments of risk of transmission of the COVID-19. On the one hand, that of the installation and uninstallation phases of the devices; and on the other hand, the home visit of the professionals and researchers involved who go to the participants' homes to collect data on the experience of use. In both cases and during these visits, the following preventive measures will be taken:

- Minimize visits as much as possible: only make the visits strictly necessary to develop the project.
- Minimize the number of visitors: only the number of people strictly necessary to develop the work will go.
- No visits in case of suspicious symptoms: those who have scheduled a home visit and present symptoms compatible with Covid-19, will not go to the home.
- No visits in case of have had close contact with a person who has tested positive for Covid.
- Hygiene recommendations must be followed at all times to reduce the risk of contagion:
    - Hand washing with hydroalcoholic gel before and after the visit.
    - Previous disinfection of the material that is going to be introduced in the house.
- Wear the necessary personal protective equipment throughout the visit to reduce the risk of contagion:
    - Wear protective masks (FFP2/KN95).
    - Use disposable gloves.
- Provide a safe environment for everyone in the house:
    - Keep a minimum distance of two metres between people.
    - Work in ventilated environment (where is possible).
- Measures to be followed by users:
    - Wear protective masks (FFP2/KN95).

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- Maintain a distance of at least 2m from visitors.
- Minimize the number of people sharing space.

Pilot 2

APM have deployed a safety protocol since 1st of June 2020 in order to avoid the infections by COVID-19 in its action environment. APM must follow the updates defined by the Madrid Region (Community of Madrid (https://www.comunidad.madrid/servicios/salud/2019-nuevo-coronavirus) and Ministry of Health, Consumption and Social Welfare, Government of Spain [20].

The concrete measurements in every scenario during the pilots in TeNDER project are described in the following:

Home setting

PROFESSIONALS who visit homes:

It must be ensured that all personnel visiting a home have specific and up-to-date information and training on the measures to be implemented (e.g. adequate hand washing as the main measure of prevention and control of infection; use of hydro alcoholic gel; steps to put on and take off protective equipment properly, etc.).

In addition, each entity will guarantee the correct supply of the material, providing the workers:

- Surgical masks. Morning and afternoon working day will be delivered two, morning working day only one. Shorter intervals when required by circumstances, e. g. frequent change between patient rooms, soaked mask, visible stains.
- Disposable gloves. Sufficient number to use a different pair of gloves with each user and that there is a spare in case of accidental breakage.
- Hydro-alcoholic solution able to destroy SARS CoV-2.
- Protective glasses.
- Plastic bags for waste disposal.
- Spray with virucidal solution to spray the shoes just at the moment of entering the home.
- On the first day that the professionals go to a home, they will inform the member about the new COVID-19 protection regulations.

Recommendations:

General preventive hygiene measures

- It is essential to reinforce personal hygiene measures in all areas of work and against any exposure scenario. To this end, the necessary means will be provided so that the professionals of the TeNDER project can clean themselves properly following the following recommendations:
- Hand hygiene is the main measure for the prevention and control of infection (with soap and water for at least 20 seconds and more recommended for 40 seconds or with hydro alcohol). Hand hygiene should be carried out before putting on personal protective equipment and after its removal, as well as before and after each home visit.
- The gloves must always be changed with each member and hand hygiene must be carried out after removing them and before putting on new ones.

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- Once the gloves have been disposed of, the professionals will put them in a bag that they will close and throw away in the rubbish when they leave the house. They will carry bags to dispose of the waste individually.
- They will cover their nose and mouth with a handkerchief when coughing and sneezing, and dispose of it in one of the plastic bags they will take with them for this purpose and which they will throw away outside the home. If tissues are not available, use the inside of the elbow to avoid contaminating the hands.
- Avoid touching your eyes, nose or mouth.
- Avoid rings, bracelets, etc.
- Wear your hair up so as not to touch your face, avoid using creams on your face.
- If the professional wears glasses, remember to disinfect the glasses.
- Keep a physical distance of 2 metres as much as possible (even if you are wearing a mask).
- It is important to stress the importance of adapting information and training to the measures that the Ministry of Health updates, which requires continuous monitoring.
- Ideally, you should go to the home visit with a negative PCR test, or instead a serological/rapid test (consult the corresponding risk prevention department).

Preventive material hygiene measures:

- Have equipment users and maintenance personnel follow all recommendations outlined by health authorities to reduce the risk of transmission of COVID-19, including proper hand washing, use of appropriate hand sanitizer, use of face masks as well as the provision of appropriate PPE.
- Consult the equipment manufacturer for instructions on cleaning the equipment. Equipment instructions are expected to include validated cleaning and disinfection or sterilization procedures.
- Do not use disinfectants, including atomised foggers, sprays or other types of cleaning agents, on any component of electrical equipment made of any type of material: plastic, insulation, paint, metal, etc. unless specifically instructed to do so by the manufacturer of the electrical equipment.
- Among the recommendations, it is normally advisable to moisten (not soak) a lint-free cloth (microfiber) with hot water containing a pinch of soap, clean extremely gently and then dry the device.

Preventive measures when visiting homes (the measures will be implemented according to the national and European regulation):

In Public Transport:

- The use of a mask
- When travelling by bus, public transport, metro or train, keep a safe distance from your fellow travellers (whenever possible).
- In the case of public buses, the driver will ensure that the capacity is controlled and that interpersonal distance is respected.

In the street:

- It is compulsory to wear a mask on the street.
- Keep interpersonal distance when walking in the street.
- Specific steps to be followed by TeNDER professionals
- The greeting will be cordial, but without touching or kissing the member or the relative, neither when arriving nor when leaving.

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- The professional, when he arrives at the home and at the doorway, will disinfect the sole of his shoes with virucidal spray, wash his hands with water and soap for at least 20 seconds (or hydro alcohol), put on gloves, a gown or jacket that isolates the outside of his street clothes and protective glasses. He will collect the material he needs and leave the backpack at the entrance of the house. The mask will be worn at all times. Just before you start touching any device or surface in the house, you will protect your gloves with hydro-alcoholic gel.
- As a general rule, try to touch objects as little as possible.
- If at any time it is necessary to write something down, the professional will use his pen and the partner will use his own.
- You will wash your work clothes every day (we recommend washing at 60 to 90 degrees or at 40 degrees in a long programme with an oxygenated detergent).

Order of placement and removal of PPE at homes:

Placement of PPE

1. The mask always on
2. Hand hygiene
3. Disinfect soles with virucidal spray
4. Putting on gloves
5. Putting on protective glasses
6. Hydro alcohol on hands with gloves before starting any activity
7. Mask (it is not necessary to change it at home, we recommend one in the morning and one in the afternoon, in case of reduced working hours only one per working day)

Removal of PPE

1. Hydro alcohol in the gloves
2. Remove protective glasses
3. Remove gloves
4. Disinfect your hands immediately after removing your gloves, after the removal of the PPE.

PARTICIPANTS with Home Visits

- All members to be visited by a TeNDER professional must be provided with a mask. As far as possible, an attempt will be made to maintain interpersonal safety distance.
- If there is a family member or caregiver in the home they should maintain the same preventive measures, i.e. wear a mask, wash their hands and maintain safe distance.
- Members must ensure that their homes are kept clean.
- Members must allow the use of the toilet for professional in case he/she needs it.

Rehabilitation room setting

PROFESSIONALS who visit Rehabilitation Centre

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- At the entrance to the association all TeNDER professionals will disinfect their hands with hydro alcohol and also the soles of their shoes on the mats at the entrance with virucidal.
- The professional will wash his hands and if he has to handle anything, he will put on his gloves.
- The greeting will be cordial, but without touching or kissing the partner or the relative, neither when arriving nor when leaving.
- As a general rule he will avoid touching his face.
- At the end of the visit to the rehabilitation room, the gloves will be removed and/or hands washed with soap and water or hydro alcoholic solution.
- Used gloves and mask used during the day will be discarded and hands washed with soap and water before leaving the centre.
- Wash used clothing (60–90-degree wash recommended).
- Follow the recommendations in the section 'Preventive Measures for General Hygiene'.

PARTICIPANTS who attend Rehabilitation Centre

- Rehabilitation groups will gather an adequate number of attendees in relation to the space available, so that interpersonal safety distance can be maintained.
- Sealed groups have been designed to reduce the number of interactions with different people as much as possible and thus avoid the spread of infection. It will also facilitate the traceability and identification of the people who maintain contact. Space and timetables have been organised in such a way that the different groups do not have contact with each other. This type of group is called a "bubble" to make it easier to understand and refer to it.
- Bubble" groups: the same times are kept, on the same days of the week; the people attending are always the same and the same therapist (as far as possible). In such a way that the risk of contagion is limited to people who are in the same therapeutic group.
- Bubble groups will also include members' companions who will be waiting in the corresponding waiting rooms.
- To avoid contact between the different groups, a map of the premises has been drawn up with authorised movement flows, waiting areas and defined treatments. In this way, two differentiated common areas have been set up to meet the capacity requirements according to the interpersonal distances involved. Zone 2, which contains a waiting room and adjoining toilets, will be used by the groups at the entrance to the premises. These groups will remain in zone 2 until the group that had previously entered leaves the premises. When this happens, the group waiting to receive their therapy will move to Zone 1, which will be disinfected after the previous group has used it. Zone 1 consists of a waiting room and bathrooms. This way the two groups will not cross and it will give enough time for the areas to be disinfected.
- In order to avoid contact between the therapy groups, the therapists will organise the exit in such a way that interpersonal distance can be maintained in the waiting areas and corridors. Once the distance between the rooms is assured, the therapist will allow the users to leave.
- Members and users must leave the room when indicated without delay.
- The therapy rooms (tables, chairs and the required utensils) will be disinfected after the passage of each group.

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Pilot 3

Hospital setting

The Hospital setting of the Pilot 3 will be performed in SLUCIA hospital, mainly in day-hospital environment. Therefore, the compliance with AntiCOVID-19 national regulations defined by The Italian Ministry of Health will be on responsibility of SLUCIA hospital.

Hand sanitizer dispensers have been installed in each room of SLUCIA hospital. For each person that enter in the facility (including both patients and caregiver or chaperone), is required to wear a sterile mask provided by the facility, after the removal of his/her mask and after a properly disinfection of hands.

Then, each patient undergoes a triage assessment (day-hospital or emergency triage according to needs) in which there is a section regarding COVID-19. The triage aims to assess the possibility of a potential contact with a COVID-19 or the presence of characteristic symptoms in the last 14 days. Moreover, the triage aims to evaluate if the patient needs additional precautions (for example in case of immunodeficiency disorders or in case of patients suspected for COVID-19 infection). Then, after the evaluation of triage assessment, the physician will define the COVID-19 risk and the precautions to be taken for the visit.

A similar assessment is performed also in caregivers. Due to the limitation of access in sanitary structures, the access of caregiver inside the visit-room is limited to essential (just one caregiver for each patient, as necessary) and it's allowed just in case of low risk of COVID-19 infection.

Home setting

The safety measures to reduce transmission of COVID-19 in the home scenario involve mainly patient's and caregiver's compliance with the individual safety measures and the updates defined by Italian Ministry of Health.

The main issue about COVID-19 spreading concerning TeNDER in home setting regards the installation and uninstallation of devices phases.

Installation and deinstallation of devices at home: safety measures for COVID-19 situation.

Technicians involved in the installation and deinstallation of devices at patient's home will work adopting safety measures in order to reduce COVID-19 transmissions.

Technicians will:

- wear protective masks (FFP2/KN95);
- wash their hands with hydro alcholic gel;
- use disposable gloves;
- work in ventilated environment (where is possible).

Moreover, both technicians and who lives in home will declare that they:

- are not in quarantine;
- have not suspicious symptoms for Covid 19 (for instance fever, cough, shortness of breath, chills, muscle pain, headache, sore treat, new loss of smell or taste);
- have not tested positive for Covid 19;
- have not been in contact with people who tested positive for Covid 19.

Installation and deinstallation of devices at hospital: safety measures for COVID-19 situation.

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Technicians involved in the installation and deinstallation of devices at hospital will work adopting safety measures in order to reduce COVID-19 transmissions.

Technicians will:

- wear protective mask (FFP2/KN95);
- wash their hands with hydro alcoholic gel;
- use disposable gloves;
- work in ventilated environment (where is possible).

Moreover, technicians will declare that they:

- are not in quarantine;
- have not suspicious symptoms for Covid 19 (for instance fever, cough, shortness of breath, chills, muscle pain, headache, sore treat, new loss of smell or taste);
- have not tested positive for Covid 19;
- have not been in contact with people who tested positive for Covid 19.

Pilot 4

Hospital Setting

Special measures for risk minimization for CoVID-19 in SKBA:

In Germany, partners only conduct "face-to-face" interviews if the local corona rules and the specific regulations in the SKBA facility allow this according to the guidelines of the Robert Koch Institute [21]. At SKBA, the general situation regarding Covid-19 and the potential risks arising from it are constantly evaluated and immediate action is taken if necessary. The frequency of the risk evaluation is adapted to the risk level (daily, weekly, biweekly). The measurements will be defined, implemented an controlled by physicians specialised in hospital hygiene and hygiene experts. This includes restricting visits to the hospital (in whole or in part), wearing a face mask at all times, washing hands / using hand disinfection when entering the hospital area or intervening with patients, and maintaining safe distances (min. 1.5 m) from others. If possible, the staff also work from home and conduct the interviews by telephone. In addition, weekly/biweekly general Covid-19 testing is required of each staff member in order to work in the facility. If an employee has had contact with a person who has tested positive for Covid-19 or has been in a high-risk area, he/she must immediately follow the quarantine regulations and can only enter the facility if he/she has tested negative for Covid-19 twice. The second test can hereby be taken no earlier than 5 days after re-entry into the country or exhibition. In addition, it is necessary to wear an FFP2 mask at the facility at all times until day 14. Similar actions will take place if the employee himself is tested positive. In addition, all initial contact persons of the last 2 weeks must be contacted. If the rate of people infected with Covid-19 in a particular region rises above 50 per 100,000 people, lockdown measures are implemented. Employees who are not relevant to the system are not allowed to enter the SKBA facility during this time and must work from home.

If the risk is estimated too high, the clinic will close the Alzheimer's therapy centre or minimize the admission of non-Covid-19 and non-emergency patients to the hospital.

According to these guidelines, interviews take place in ventilated environments. The researchers will only contact the participants if they have a negative test result for Covid-19 that is not older than one week. In addition, the researchers will wear protective equipment such as a face mask and follow the hospitals

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hygiene guidelines for washing hands and using hand disinfection. In addition, a safe distance of minimum 1.5 meters to the participants will be maintained at all times.

All equipment used in the TeNDER testing will be disinfected according to the specifications of the hygiene experts of SKBA, e. g. exposure time of disinfectant.

Furthermore, both participants and researchers will explain that:

- they have not tested positive for Covid-19;
- they have no suspicious symptoms of Covid-19 (fever, dry cough, fatigue, pain, sore throat, headache, loss of taste and smell, etc.);
- they have not been in contact with people who tested positive for Covid-19 in the last 2 weeks;
- they are not quarantined.

The measurements described above will be adapted according to the change of the COVID-19 situation. All employees involved in the TeNDER project agree to strictly follow the protective measurements set by the hospital management and the hygiene experts.

Pilot 5

Day-care setting

SPO will follow protocol "SARS-CoV-2 Infection Control Plan (COVID-19) - protocols for the operation of institutional care providers", defined by government of Slovenia. The general measurements will be adapted according to the change of the COVID-19 situation.

The day-care setting is planned to take place at two locations at Ljubljana, including full time care services. Both institutions have own protocols and follow the general guidance from NIJZ (National Institute of Public Health [22]) and Slovenian Ministry of Health provisions and general and institutional rules for mitigation of COVID-19 risk spreading. Due to COVID-19 restrictions, day-care centres are closed, SPO will search and try to have an agreement that it will be possible to include their full-time care residents in testing, if the situation will allow. All the rules and guidance form Slovenian government, Ministry of Health, NIJZ and institution, where the testing will take place, will be followed.

Home setting

The safety measures to reduce transmission of COVID-19 in the home settings will follow guidance from NIJZ (National Institute of Public Health [22]). To ensure patients', family members' and caregiver's safety, individual safety measures and the updates will be checked through piloting. Before the first visit and also before/when performing the testing, SPO researcher and/or the technician that will be in face-to-face contact with the participant, will explain to the participant, that they are not positive for COVID-19, don't have any symptoms (high temperature, dry cough, fatigue, pain, sore throat, headache, loss of taste and smell, etc.as listed form NIJZ), have not been in contact with COVID-19 positive person and have not be quarantined the last 14 days, neither is one of his/her family member.

We will monitor of possibilities: (1) if the participant is infected by COVID-19 during the testing; (2) if the participant is in close contact with a person that is infected by COVID-19; (3) if the researchers or technical partner that is in contact with participants is infected with COVID-19; (4) if the researchers or technical partner that is in contact with participants is in contact with a person that is infected by COVID-19.

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If not generally disabled or hospitalized, the participant (patient, caregiver, professional) or the researcher of TeNDER, infected with COVID-19, may continue with the participation/conducting the study by remote participation for the duration that is prescribed in each Member State, or the institution. Thus, if possible, web-based or phone-based conversations may continue. The same applies to the people that were in close contact with a COVID-19 positive person.

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