D8.1
Experimentation Protocols

Dementia Ambient Care: Multi-Sensing Monitoring for Intelligent Remote Management and Decision Support

Dem@Care - FP7-288199

Deliverable Information

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Abstract (for dissemination)		The purpose of this document is to describe the current experimentation protocols of the three pilots to be conducted in Lab-based, Nursing-Home based and Home-based environments (T8.2-T8.4). It presents updated plans for piloting and motivates the changes based on analysis made in T8.1 "Evaluation Protocols and Methodology", as foreseen in the Description-of-Work.

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Executive Summary

This deliverable details the experimentation plans of the Dem@Care project in terms of planned sample sizes and participant characteristics, duration of deployment, privacy protection, sensor installation specifications, and clinical objectives, for the pilots that will take place in the three countries (France, Ireland, Sweden) and in different environments (operational scenarios): the lab-based pilot, the nursing-home based pilot, and the home-based Pilot.

In the first section, the concept and the goals of WP8 "Pilot, Evaluation and Clinical Validation" are stated, in order to contextualise the perspective of the work package within the Dem@Care project. This section is followed by a description of the initial experimentation plans for each country as they had been originally described in the DoW. As this document goes on to describe, these plans evolved over time into three site-based pilots in order to allow researchers to focus on the selected themes of enablement, diagnosis and safety.

Following this, the updated experimentation strategy is presented, illustrating the strengths of having three test sites deployed to, and also how the sophistication of the systems deployed to the sites will be developed in an incremental fashion. The analysis in T8.1 has shown a better approach for experimenting and evaluating than that originally foreseen in the DoW, and the current deliverable describes the motivation for certain changes made to the original DoW.

The last sections give a detailed overview of each experimentation protocol with its primary theme. The topics discussed in each chapter are: evaluation strategies, current state of development, pilot sites, clinical objectives, privacy protection, descriptions of the clinical scenarios, and sensor specifications for the experimentation protocol at the lab-based, nursing home-based and home-based environments.

Abbreviations and Acronyms

DoW	Description Of Work
WP	Work Package
PwD	Person with Dementia
Tx.x	Task x.x
Mx	Month x
DCU	Dublin City University
CHUN	Centre Hospitalier Universitaire de Nice
LTU	Lulea Tekniska Universitet
ADL	Activity of Daily Living
IADL	Instrumental Activity of Daily Living
ICT	Information and Communication Technologies
EHPAD	Etablissement d'Hébergement pour Personnes Agés Dépendantes (Nursing Home)
BPSD	Behavioral and Psychological Symptoms in Dementia
NPI	Neuropsychiatric Inventory
IR	Infra Red
CDR	Clinical Dementia Rating scales
Pilot@Lab	The pilot phase of the project as performed in the lab setting
Pilot@NursingHome	The pilot phase of the project as performed in the nursing home setting
Pilot@Home	The pilot phase of the project as performed in the home setting

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1 Introduction

WP8 aims to validate and assess the Dem@Care technology through three phases of evaluation, during which system prototypes will operate in different environmental contexts (lab-based, nursing-home based, and home-based environments). The first evaluation phase ("pilot") tests the system using initially short and then long multi-sensor recordings. This first phase will focus on the usability, functionality and reliability of the developed algorithms, as well as on fine-tuning them in order to maximize their performance.

The second evaluation phase will mainly focus on the Dem@Care's user-interface qualities, and on the evaluation of its suitability, accuracy, and maturity for deployment with a population of older adults with dementia.

The third evaluation phase will report the overall efficacy and impact of Dem@Care system, including clinical considerations related to improving the quality of diagnostic information, and improving the quality of life for persons with dementia and their caregivers.

The experimentation protocol will be designed in accordance with the the clinical requirements delineated by WP2.

Task 8.1 defines the evaluation methods for use in the pilot phase, and will make updates and adaptations to these with the advent of new information and insights afforded by the iterative evaluation cycles. For each site, a protocol has to be developed covering different aspects of themain themes (enablement, diagosis and safety).

The objective of the deliverable D8.1 "Experimentation protocol" is to detail the planned pilots to be conducted in the three different environments (Lab-based, Nursing-Home based and Home-based). Accordingly, this report provides a description of the clinical objectives (diagnosis, enhancement, enablement/support of PwD and their caregivers), as well as the participants (Dem@Care system and end users), the phase duration, evaluative strategy, privacy protection and sensor installation specifications required for successful implementation and performance of the pilots, which are being elaborated upon in collaboration with WP2 partners.

1.1 Experimentation Plans in the DoW

This section describes the pilots as they were initially planned in the DoW of the Dem@Care project for each country. A description of each pilot was provided along with an initial

experimentation plan in terms of site settings involved, number of participants, and the project duration.

Pilot for Assisted Living in Sweden

The initial pilot conducted in Sweden will include tests with 5 participants in a clinical setting and tests in 5 homes of people with dementia in Luleå, for a period of one to two days. In the second pilot, the tests will take place in the homes of 5-10 participants in Norrbotten (3-5 weeks), while for the final long-term pilot, 15-30 users diagnosed in the regional healthcare system with mild to moderate stage dementia, will be tested in total, in homes in Norrbotten and Västerbotten (3 to 6 months). The pilots will be carried out in collaboration with the Norrbotten regional health council for the E-health Innovation Centre. This will allow for the assessment of the complete Dem@Care system (wearable and static sensors) with these users. These users will have the usability-tested Dem@Care system installed in their homes for a period of no less than three months, in order to evaluate the impact on quality of life of the provided closed loop services. Collaboration with clinical experts on dementia from the regional health council in Norrbotten, the University hospital in Lulea and dementia researchers at the LTU Health Science department will ensure the reliability of these results.

Pilot for Assisted Living in France

The initial pilot in France will involve short-term testing (between 1 to 1 1/2 hours) in the memory consultation center/homes in Bordeaux (15 participants) and in the memory consultation center/day care hospital in Nice (15 participants). These pilots will consist of monitoring persons with dementia using the Dem@Care technology in order to provide a brief overview of their health status during consultation (cognition, behaviours and function), and to correlate the Dem@Care system data with the data collected using typical dementia care assessment tools. The second pilot consists of 1-2 weeks of testing duration, and it will involve 24 participants in a nursing home in Bordeaux, and 6 participants in a day care center in Nice. The main goals will be to assess aspects of the wearable technology (suitability, accuracy, security, fault tolerance, operability and attractiveness). The third pilot will involve long-term tests (3 to 6 months) of 15 participants in their homes in Bordeaux and 25 participants in a day care center/nursing home in Nice.

Pilot for Assisted Living in Ireland

The deployment of a range of sensors, including wearable, physiological, activity-based, and location-based, will not only require pilot trials in real homes or care residences but also require testing in the research labs, working with prototypes to ensure accuracy and performance. In this task we replicate what is done in T8.2 (Sweden) and T8.3 (France) and we extend that testing into a University-based community flat which is a realistic, though unoccupied, showroom of a modern 3-bedroom apartment available at Dublin City University precisely for work such as this. The fully-furnished community flat is a teaching facility used within the University to teach nursing students how to attend to the healthcare needs of clients in the community setting and has a typical apartment layout and facilities – kitchen, living room, bedrooms, bathroom, and balcony. Hence, for the first pilot, the Dem@Care system will be deployed in this setting for system testing for a period of a month and will involve role playing by 5 actors/students that will be assessed against observed senior readings. The second pilot will involve 5 participants in real homes in Dublin (1 to 2 months), while for the third pilot, 5 more participants will be selected and added to the ones of the second pilot, and testing will take place for 6 months. These real deployments will be selected from contacts within the Memory Works clinic in DCU, which supports people with dementia in living more independently.

1.2 Updated Experimentation Strategy

The updated experimentation strategy is to have three pilot types (lab, nursing-home, home) to gather information about persons with dementia at different stages of their illness, by firstly focusing on improving the early detection of relevant symptoms of dementia, secondly on supporting participants in order to preserve their autonomy and cognitive functions, and thirdly on coping better with dementia-related impairments.

The three pilots will feed results into each other as described in the following sections, and will be incrementally expanded to cover more functionality and sites. Overall, the number of test users has been increased compared to what is described in the DoW, and multiple sites will be used more than described in the DoW, for reaching more test users and for identifying variations between countries.

The staging and expansion of the pilots are summarized in Table 1 and Table 2 below.

Table 1 Functionalities to be evaluated, per scenario, site and pilot

	ENABLEMENT & SAFETY					CLINICAL ASSESSMENT
	SLEEP	**EXERCISE**	**MOOD**	**EAT**	**SOCIAL**	
LAB						P1N P2N P3N
HOME	P1D P2D P3DL	P1D P2D P3DL	P2D P3DL	P1D P2D P3DL	P1D P2D P3DL	P1D P2D P3DL
NURSING HOME	P1L P2LN P3LN	P1L P2LN P3LN	P1L P2LN P3LN	P1L P2LN P3LN	P1L P2LN P3LN	P1L P2LN P3LN

Pi: Pilot i, i=1:3 ;
PiD: Pilot I, Dublin
PiN: Pilot I, Nice
PiLN: Pilot i, Lulea, Nice
PiDL: Pilot I, Dublin, Lulea

Table 2 Number of test users, per pilot and operational scenario

	P1	**P2**	**P3**	**TOTAL**
LAB	150			
HOME	5	5	5	15
NURSING-HOME	5	10	15	30

1.2.1 **Lab-based Pilot**

The Lab-based pilot is going to be used as a reference site to test Dem@Care technologies and to acquire clinical knowledge about the behaviour of dementia patients and interaction with Information Communication Technologies (ICT). The acquired expertise will be used to

drive deployment of ICT solutions in terms usability, functionality and reliability in the Nursing-Home and Home pilots.

The three themes of enablement, diagnosis and safety permeate the three protocols. The lab-based research is primarily concerned with diagnoses.

1.2.2 Nursing Home-based Pilot

For the nursing home, functionality will be limited to the exercise, mood and sleep domains for Phase 1 since in this environment these are seen to be the prioritised domains. For this environment, personalisation is less fundamental than for the home-based deployment, since the enabling, person-centred approach is more appropriate for use in older adults with early stage dementia. For later stage dementia such as individuals in a nursing home, it is likely that more care decisions will lay in the hands of the clinician.

1.2.3 Home-based Pilot

The DCU site will engage directly with "lead user" participants in order to facilitate a rolling iterative design process and expedite the final design of a workable prototype. We have access to a community apartment, which can be used to pilot the Dem@Care sensor system, with younger participants at the outset. The apartment's purpose is to troubleshoot the system before it is deployed with the more vulnerable dementia population. The Dem@Care @Home pilot will then take place in the private homes of the lead users, who will be older adults with dementia, and their caregivers. Systems will be deployed to participants' homes on a rolling basis until up to 15 participants are engaged with the Dem@Care system, for as long a duration as the participants are happy to engage. This means that instead of a strictly phased approach, participants will enter the project on a rolling basis. All participants will be recruited via the Memory Works clinic at DCU.

The home-based pilot is primarily concerned with the theme of enablement. Within enablement, there are 5 functional domains, as defined in D2.2; sleep, Activity of Daily Living (ADL) such as eating, physical activity, mood and social interaction. These five areas will be investigated in the final versions of both the home and nursing home deployments. For phase 1 of the research, social interaction is omitted, since the analysis is not yet sufficiently developed. Additionally functionality is limited on the ADL domain since this also represents a technical challenge. As such, entering the first phase of the home and nursing home based deployment, the "toolbox" of available areas in which to offer support to participants will

comprise mood, sleep, exercise & physical activity, and to a certain extent, eating and ADL. These domains, their related sensors and supporting analytic tools will be deployed iteratively as their prototypes have been released by technical partners. This allows us to offer a (limited) personalised service to participants from the start of deployment.

1.2.4 **Motivation for changes**

Analysis in T8.1 has shown a better approach for experimenting and evaluating than what was foreseen in DoW.

The numbers of participants have been increased for stronger statistical power and improvement of validity. Furthermore, a larger sample allows testing a wider variety of technical devices for discovering possible limitations. Clinical and technical requirements can be modified or deleted according to obtained test results.

Task 8.1 has identified a need to change the test user recruitment process also. The experimentation protocol originally followed a phasic approach, which would have been sensible with regards to the technological development of the project. However, within the @Home and the @Nursing home scenarios, a qualitative, multiple case study approach is being taken, and therefore it makes more sense to deploy to individuals on a rolling and incremental basis. Instead of recruiting a set & separate sample of participants to be involved in each phase, we have decided to recruit two lead users at the start of the project for the @Home pilot, and to deploy to additional (up to 15) homes as the project progresses. This approach allows us to deploy for longer durations in the home, allowing a more in-depth qualitative investigation of the long-term efficacy of the system. The use of lead users also allows us to take a co-design, person-centred approach to the development of the system for use in the @Home scenario, which emphasises enablement and person-centred care. The approach is also being adopted by the @Nursing home deployment, for similar reasons. Validation will be assessed in a qualitative manner, investigating the use of the system in all 15 homes during the third piloting stage of the project. This methodology follows ethnographic principles of validation, deploying to homes for a long period of time and investigating the efficacy of the system via interview. To further consolidate the validation methodology, this approach can be taken in conjunction with a pre-post, statistical analysis of participant wellbeing & functioning during and after the deployment.

2 Pilot@Lab: Experimentation protocol

2.1 Evaluation strategy

The Lab-based pilot aims to collect data for the first evaluation phase (usability, functionality, and reliability of Dem@care technologies) of Dem@Care system in a controlled environment, and to implement an objective assessment of autonomy, and goal-oriented cognitive functions at different stages of the Alzheimer's disease. The data collection will be conducted in an experimental room equipped with home appliances, where participants will have to perform predefined activities of daily living. The setting will include video sensors (ambient and wearable), audio sensors (ambient and wearable), accelerometers and physiological sensors for recording all forms of activities, and software modules for event recognition, as well as for extracting other biomarkers that could support the detection of dementia at early stages and on-going tracking of the dementia disease state. This pilot will provide complementary objective information for clinical practitioners, and help them to better assess the difficulties of participants in activities of daily living compared to the current rating scales based on interviews used in clinical practise.

2.2 Experimentation protocol status

The experimental protocol described below was submitted to the French Ethical Committee on February (M4), and final approval was obtained on April (M6) (for more details see D2.4 Ethical Approval Procedures and Documentation).

2.3 Pilot sites

Lab-based pilots will be conducted in the Memory Center of Nice Hospital and Bordeaux Hospital.

2.4 Lab-based pilot objective

The Lab-based pilot is focused on the improvement of assessment tools for the diagnosis of Alzheimer's disease at early stages, through short-term tests proposed during a standard memory consultation. This pilot consists of monitoring the health status (behaviour, cognitive abilities, physical activity) of persons with and without dementia using the Dem@Care

technology. Pre-defined clinical scenarios conducted in an experimental setting, equipped with daily objects, are described to each participant. Each clinical scenario is conceived to assess certain functions and abilities and to be representative of daily situations in order to provide an ecological assessment of the participant's abilities.

The primary aim of this pilot is to define and compute quantifiable metrics extracted from the completion of clinical scenarios specially conceived to assess the level of autonomy of older people. Secondary aims of this pilot are to assess the impact of cognitive decline and behavioural disturbances (i.e. apathy) on speaking and voice sound characteristics during specific vocal directed tasks. This pilot also enables the assessment of 1) the participants' acceptance of the new assessment method based on Dem@Care technology during a standard memory consultation in clinical setting, and 2) the participants' acceptance of Dem@Care system for a daily use in their home surroundings (see Appendix II: Acceptability form filled by the patient).

2.5 Study context

The Lab-based Pilot is a non-randomized multi-centric study. Participants will be recruited during a medical consultation at Memory Center of Nice. Three groups of participants will be targeted: healthy control participants (HC), patients with Mild Cognitive Impairment (MCI) and patients with Alzheimer's Disease (AD). 150 participants aged over 65 years will be involved in this pilot (50 persons in each group). The inclusion period is scheduled for a duration of 9-12 months. The total duration of each visit is about 3 hours: 30min for medical consultation, 1 hour for ecological assessment (i.e. clinical scenarios recorded with Dem@Care technologies), and 1 hour 30 min for the clinical consultation with the neuropsychologist). At the end of the medical consultation, having collected the clinical information, the ecological assessment (Lab-based Pilot experimentation) is initiated by the physician. According to the experience, i.e. if the participant is experiencing difficulties, the duration of the protocol can be made shorter as appropriate.

2.6 Privacy protection

In order to disseminate findings based on the participants' data, either in scientific journals or at conferences, participants have to indicate their consent. To this end participants should

receive a written report outlining the aim of the study. The participant's informed consent to participate in the study and have their data published if appropriate is provided by the signature of this report. For all communication, the identity of individual participants will not be divulged, and will be presented only using anonymous code. All images will be altered to protect the identity of the person. For example, faces or names on signage will be blanked and the participant's agreement to share these images will be sought prior to any sharing. (See D2.4: "Ethical Approval Procedures and Documentation").

Only anonymous data, stored on a secure server with password access, will be made available to named researchers on the Dem@Care project who request such data. The data will be transferred securely in these instances and shared only with the requesting consortium members, only for the purposes of analyses relevant to the Dem@Care project.

2.7 Clinical scenario description

The ecological assessment is divided into three steps conducted in an experimental setting equipped with daily objects and ambient Dem@Care technology.

- The first step (Step1, S1) called "Directed Activities" is conducted by a clinician, who details step by step the different activities to do by the participant. This step is divided into two parts. The first part (S1_P1) has as objectives, characterizing participants' gait in mono and dual tasks, and the impact of cognitive activity on gait (e.g., walking speed, step length, stops during the walking exercise done in dual task). The second part (S1_P2) is based on vocally-directed tasks: one task consists of repeating a sentence after the clinician (this task is repeated with three sentences), and the other is an articulation control exercise done to evaluate the neuromuscular mechanism of speech production.
- The second step (Step2, S2) called "Semi-directed Activities", consists of assessing the autonomy of the participant. The participant has to organize himself/herself and correctly perform a list of Instrumental Activities of Daily Living (e;g., managing finance, using phone, preparing tea) within a timeframe of 15minutes. For this step, the participant is alone in the experimental setting and can refer to the instruction sheet of paper with the IADLs to perform at any time.

- The third step (Step3, S3) called “Discussion with the clinician” is divided into two parts. The first part (S3_P1) is a directed discussion during which the clinician assesses the episodic memory of participant through questions related to events and activities of Step2 (S2). The second part (S3_P2) consists to assess the verbal fluency and mood of participant using a picture that the participant has to describe (with the picture in the eyes) and then to involve a discussion about their interests for the activity represented. This part is done with two different pictures.

A full description of each step and its constituent tasks are given in the Appendix (see Appendix I: “Lab-based protocol in CHUN”).

2.8 Sensor Specifications

The experimental setting is equipped with ambient audio-video sensors: ambient RGB video cameras (n=2 or 3, one used during all steps, and two located in the specific side of the experimental setting only to be used duringstep 2), RGBD Kinect ® (n=2, only used during the Steps 1 and 2), ambient microphone (n=1, used during all Steps). During this pilot, wearable sensors are also worn by the participant and clinician: one wearable RGB camera and one wearable still image camera SenseCam® worn by the participant used during all Steps, wearable microphones (n=2, one worn by the participant used during all Steps, and one worn by the clinician only used during the Steps 1 and 3), accelerometers devices (Wireless Inertial Measurement Unit, not available at this stage of development) and one physiological sensor (Philips DTI-2, no available at this stage of development). Specification of all sensors used has already been described in the D2.3 “Training Data Collection and Annotation”.

3 Pilot@Nursing-Home: Experimentation protocol

3.1 Evaluation strategy

The nursing home-based pilot aims to evaluate the usability, functionality, and reliability of the Dem@Care sensor system to gather data that can support the person with severe dementia to manage daily life activities. The expectation is that both wearable and ambient sensors will be used and the test will start with few sensors that have been verified to work reliably. Step-wise, new sensors and functions will be introduced based on the outcome and experience of using the first sensors. The approach will be similar to a 'living lab' approach where the development of the Dem@Care system is process-oriented and the users, persons with dementia, their family members, and health professionals can contribute to understanding and improving the usability and functionality of the system. Testing with a small number of individuals with dementia will be performed over a longer time period and when necessary they will be replaced by new participants as appropriate for a multiple-case design.

The ambient sensors will primarily be installed in the living areas of the persons with dementia, but wearable and ambient sensors will be developed to also cover common areas with other people at the nursing home, including outdoor premises. The sensor-based support may focus on any of up to five areas of daily life that have been chosen for initial prioritisation in the second piloting phase. These five areas are: exercise & physical activity, sleep pattern, eating and ADL, social interaction, and mood. For these five areas, the focus is on using sensors and combinations of sensors that can collect data about emotional status, physical activity, sleep and night time behaviour, and eating behaviour.

The aspect of individualization of the system, to specifically cater for the needs of the individual with dementia, is important and will be part of the evaluation of usability and functionality. We do not expect that each participant will need to use all functions of the system.

As in the Nursing-home-based pilot, the emphasis will be placed on triangulating data from different sensors understanding how this information can be interpreted, and how it corresponds with other sources of information as observations. The goal is that sensor information will add to the understanding of the personal needs of each person with dementia and that this information will improve the quality of the support given in the nursing home.

3.2 Experimentation protocol status

The description of Nursing home based pilots is currently in discussion, and no experimental protocol has yet been submitted to Ethical Committee evaluation.

3.3 Pilot sites

Nursing-Home based pilots will be conducted in nursing homes of the municipalities of Boden, Luleå, and Piteå, Sweden, and also in Valrose EHPAD of Nice and potentially another nursing home**.** These tests may later be extended to other sites in both countries according to the availability of resources and initial results.

3.4 Nursing-Home based pilot objectives

The aim of the Nursing home pilot is in the first pilot to evaluate the usability, functionality, and reliability of the Dem@Care multi-sensing monitoring system to gather data that can support clinical staff to enable the person with severe dementia to manage daily life activities with improved wellbeing. In a later stage of the nursing home pilot also impact on the care of the person with severe dementia will be assessed.

One of the major challenges in the care of persons with severe dementia is to support the person who displays 'Behavioural and Psychological Symptoms of Dementia' (BPSD). Behavioural symptoms can be for example aggression, wandering or apathy, and examples of psychological symptoms include depression, anxiety and hallucinations. There is evidence from research and from clinical experience that a person-centred approach to care has an ameliorative impact on BPSD. The core features of person-centred care approach are to strive to systematically understand the *individual* needs of the person with dementia and to try to understand how they experience their daily life. Based on this understanding, support will be provided and systematically evaluated. Person-centred care of persons with severe dementia uses today the skills of staff to observe the person's behaviour, and the Dem@Care system will provide additional tools in the assessment of the person and evaluation of care support through the multi-sensoring monitoring system. This includes information on mood, physical activity, sleep pattern, and eating.

The objective of the Nursing-home based pilot is therefore to answer the following research questions:

- Is the multi-sensoring monitoring system usable for supporting a person-centred care approach for persons with severe dementia in nursing home setting?
- Can a tailored approach to monitoring provide personalised, adaptable, supportive feedback to the care staff for their support of individuals with BPSD?
- Can the use of multi-sensoring monitoring data in a person cantered care approach, over time have an impact on the wellbeing of the person with dementia with BPSD?

In order to answer the research questions we will offer a comprehensive assessment that follows and develops the use of the multi-sensoring monitoring system. This mean that only robust and previously-evaluated technical devices will be used, and stepwise, new functions will be introduced. This process will be adapted to the individual needs of each participant and the evaluation process will follow the work strategies of person-centred care. In this process the sensor data will be aggregated and analysed by clinicians and care staff to allow a sophisticated analysis of the person-with-dementia's functional, psychological and physical wellbeing. The use of the multi-sensoring monitoring system to support a person-centred care approach will be compared with the work with the more traditional care approach wherebystaff have to rely on their own skills of behavioural observation.

3.5 Privacy protection

The privacy protection in the nursing home pilot will follow the procedures outlined in the national ethical applications described in D2.4 and the ethical guidelines that will be outlined in D2.5. These include that all participants and their relevant family members have to provide their written informed consent to participate in the pilot and the evaluation process.

A specific ethical challenge in this pilot, beside the general problem of attaining informed consent with participants who have severe dementia, is the indirect participation of other residents, visitors and clinical staff when ambient sensors are placed in common living areas and outdoor premises. There must be a way of informing the group of potential indirect participants of the ongoing testing, and ways of omitting data and information concerning this group. For all communication, the identity of individual participants will be protected, and

presented only in an anonymous manner. All images will be altered to protect the identity of the person. For example, faces or names on signage will be blanked and the participant's agreement to share these images will be sought prior to any sharing.

Only anonymous data, stored on a secure server with password access, will be made available to named researchers on the Dem@Care project who request such data. The data will be transferred securely in these instances and shared only with the requesting consortium members, only for the purposes of analyses relevant to the Dem@Care project.

3.6 Clinical scenario description

In the Nursing-home pilot the Dem@Care multi-sensoring monitoring system will be deployed in four nursing homes at the start of the pilot, three in Sweden and one in France. At each nursing home setting the multi-sensoring equipment will be deployed with two participants in their living area. In all a minimum of 8 participants will be involved for a limited time period at any time of the test and successively be replaced by new participants. Over the whole evaluation period of pilot one and two additional test sites will be added according to availability of resources and the results of the evaluation. Depending on these circumstances it is estimated that approximately 40-50 participants in nursing homes will have tested the Dem@Caremulti-sensoring monitoring system during the whole time frame of the project.

For each participant that is included in the project a structured clinical assessment will be conducted to achieve an understanding of the participant's health profile, and to identify functional areas in their lives which could benefit from receiving technological support. These areas have previously been defined by WP2 based on clinical experience andliterature review, and are, sleep, eating and ADL, physical activity and exercise, social interaction, and mood (c.f. D2.2). The assessment will follow the structure of the Neuropsychiatric Inventory (NPI) and inclusion criteria for the participants is that they have some degree of BPSD and that the clinical staff are experiencing caring problems with the person with dementia.

Following the clinical assessment, the researchers will deploy a personalized sensor set from the Dem@Care multi-sensor monitoring toolbox. The system will then undergo a process of refinement, using a co-design methodology, with researcher, clinical staff and participant developing and refining the system until it is of optimal benefit and minimal intrusion. This

refinement process will start with deploying a limited number of robust tested equipment and gradually introducing additional functions based on the co-design process. Data will be aggregated, securely stored and analyzed. Feedback of the aggregated data will be provided to their caregivers to include in the person centered caring process and to the researchers for evaluation purpose.

The researcher will work together with the clinical staff of each nursing home to ensure the reliability of the data that is collected, that ethical guidelines are followed, and to ensure that the system is being maintained.

For comparison purposes, in pilot 2, for each participant that will have a Dem@Care multi-sensor monitoring system deployed another participant will be recruited that will receive the same person-centred care but without the support of the system. This control group is anticipated to be the same number as the group that will test the equipment. The evaluation will be based on a method for multiple case studies.

3.7 Sensor specifications

The sensors deployed for each individual case will depend on the needs of the subjects involved and will be selected from the Dem@care multi-sensor monitoring toolbox. Important aspects of the nursing home monitoring system is the possibility of monitoring mood, physical activity, location, eating, and sleep pattern. We list here a list of potential sensors, keeping in mind that each individual deployment will have a subset of this and that the co-design approach may change priorities.

As with the other pilot settings the nursing homes may be equipped with ambient audio-video sensors including ambient RGB video cameras, RGBD Kinect ® 3D cameras, and ambient microphones. Passive IR sensors may be used to collect data on room occupancy and usage and the transit between different living areas. Various wearable sensors may also be worn by the participant. To measure bodily movement and limb movement and record general actigraphic data, an actigraph sensor we will be used measuring skin conductance will be used. Sensors for room temperature and skin temperature will be considered to be introduced in a later stage of the test.

Other environmental sensors may be deployed to collect data about the participant's interaction with, and usage of, objects around the home. This will carried out using devices

such as contact switches to identify events such as the opening and closing of doors, cupboards and drawers, and the use of kitchen appliances. Pressure mats may be used to record when the subject is in bed, or sitting on their couch, for example. Sensors indicating the use of toilet facilities may be considered as well as sensors collecting information about their sleep quality.

4 Pilot@Home: Experimentation protocol

4.1 Evaluation strategy

Individuals with dementia and their caregivers will be introduced to the Dem@Care project with an assessment interview, which aims to identify the functional area(s) with which the PwD could benefit from support. This assessment interview spans both qualitative and quantitative investigation. Participants will be interviewed about their acceptance of ICT and assistive technologies, and their views on its effectiveness. They will be asked about their dementia-related experiences since receiving a diagnosis, and about any functional decline they may have experienced. Following this the researcher will achieve a basic understanding of the individual's profile, and the areas with which they experience difficulty. Based on this understanding the researcher can consult the assessment document, which is a collection of related psychometric tools and questionnaires, allowing a more in-depth analysis of the individual's difficulties. Each individual will receive scores on the relevant tools as their baseline measurements. The individual's clinical dementia rating (CDR) score also serves as a baseline measure.

With a baseline in place, then, Dem@Care researchers move towards the evaluation phase. Evaluation will have two main phases; ongoing assessment, and the exit interview.

Before any participant interaction takes place, the system will be deployed firstly in a test apartment at DCU to ensure there are no technical or compatibility issues. Following this short testing phase, the sensor system can be said to be technically evaluated and appropriate for deployment in the homes of the participants.

On-going assessment entails the sensor-based monitoring of the individual in their home environment. Following the assessment interview, the toolbox approach will allow individuals to choose the useful, acceptable sensors they are happy to have deployed to their home. The function, purpose & potential benefits of each sensor will be described in detail to each participant, and should they express any reservations about them, a demonstration will take place. If they are still at this point unhappy to continue with the sensor in question, an alternative will be offered, if available. If this is also unacceptable, this aspect of system monitoring will be abandoned for this participant. The collection of deployed sensors will send data to a central home hub, where data will be aggregated, analysed and stored to

provide regular feedback to the stakeholders. These data demonstrate trends in parameters over time, super-threshold levels of functioning, and problematic events, e.g. falls, episodes of wandering. For example, if an individual is receiving support in the social realm, the system will aggregate social data over time. These data will be summarised for the clinician and for later statistical investigation. One evaluation strategy involves examining these data over time and detecting decline, stasis or improvement. For each participant, this represents a case-study level description of how their functioning in this area has been maintained during the deployment. Obviously there is no comparison condition here, so these data will remain purely descriptive. For some areas, namely sleep and mood, questionnaires are administered at time points during deployment, and these results can be analysed to detect clinically meaningful change over time for that individual.

Second, intermittent and final exit interviews can be used to assess end point functioning and technology use & acceptability of the participants. By conducting further interviews, qualitative analyses can illustrate any changes in attitudes towards technology use and also the individual and their caregiver's experiences since deployment, as well as their general wellbeing in this period. Those tools used to more quantitatively evaluate their problematic functioning areas at entry interview can be repeated, to provide a quantified measure of comparison of pre- and post-deployment.

All interviews follow the format of the Neuropsychiatric Inventory, assessing all relevant functional areas. Since the individuals engaged in the private home deployment have a higher overall level of functioning, it would be inappropriate to use the NPI as our evaluation strategy. Conversely, for individuals being evaluated in the lab and nursing homes, using the NPI is appropriate to evaluate functional status. Therefore it would be extremely difficult to arrive at a common evaluative strategy. The private home deployment will employ the NPI framework in its interviews, therefore, to achieve some common thinking about evaluation.

One characteristic of the @Home site is its specific methodology of evaluation. In the lab and nursing home case-control comparisons will be used to further evaluate the efficacy of the system. Since the private home represents a multiple case study design with a qualitative, ethnographic emphasis, the use of case controls would not be appropriate. Private home deployment will focus upon qualitative evaluation, and pre-post comparisons of participant functioning.

Finally, the clinicians involved in the deployment will also be interviewed at exit to better understand their perceptions of the Dem@Care system, its effectiveness, and ways in which it could be improved.

If the private home deployment at DCU is successful, the private system has the potential to be exported to private homes at the CHUN and LTU sites, dependent on resources and exportability. This represents another mode of evaluation of the private system.

4.2 Experimentation protocol status

The experimental protocol has recently been approved by the DCU ethics committee, and is available in full detail in the assessment document (Appendix 2: DCU Ethical Approval Procedure Documentation, in the submitted deliverable D2.4: Ethical Approval Procedures and Documentation). The experimentation protocol for phase 1 involves 2 lead users having a personalized sensor system deployed to their homes. Since phase 1 represents an early point of the project, the "toolbox" of available sensors and supporting data integration & algorithms may not be fully available at this point. The available system modules will be deployed as required and acceptable to participants. Across all three phases, 15 individuals will eventually be deployed to, with differing levels of completeness in line with the level of development completed by the technical partners.

4.3 Pilot sites

Home-based pilots will be conducted in Dublin. Later these experiments could be reproduced in other sites according the availability of resources and initial results. It is hoped that a small number of homes will be accessible to deploy the private home sensor system in Luleå.

4.4 Home based-pilot objectives

The aim of the Pilot@Home phase of the research is to assess the deployment and use of sensor technology to maintain and enable independence of the individual with dementia living at home in the community. The increase in the average lifespan across the world has been accompanied by an unprecedented upsurge in the incidence of dementia, with high costs associated. The high cost associated with formal care means that it is economically important to develop a personalised home-based system to support independent, sustainable and

integrated living for the individual with dementia, while improving quality of life and the wellbeing and efficacy of their families. Using the DCU apartment, we can firstly assess the compatibility of sensor technologies and triangulate resulting data, employing the help of student participants. This done, the sensors will be deemed ready for use in the community, with older adults suffering from dementia. Our main research questions are;

- Is a home-based multi-parametric monitoring system acceptable by the person with dementia and their families?
- Can a tailored approach to monitoring provide personalised, adaptable, supportive feedback to the person with dementia, their families and clinicians?
- Can the data we collect over long periods of time indicate deterioration, improvement, stasis or risk of future deterioration in the wellbeing of the person with dementia?
- Do multi-sensor technology deployments contribute to the wellbeing and promote the independence of the person with dementia living at home in the community?

Multi-parametric monitoring of activities, lifestyle, and behaviour can help the clinician to monitor the person with dementia remotely and make informed clinical decisions. It can help the PwD's family to gain an insight into the wellbeing and potential deterioration, in general and cognitive health, of the person with dementia. Multi-parametric monitoring leads to an aggregation of relevant biopsychosocial metrics. These metrics can comprise useful feedback to the person with dementia themselves, enabling reflection on activities and behaviours, and empowering them to manage their own lifestyles. We will offer a comprehensive assessment in order to shape an adapted home-based monitoring system for the person with dementia, who will choose aspects of their lives to be focused upon, depending on their personal problematic areas, and on the sensors which they and their families find acceptable for use. The sensor data will be aggregated and analysed by clinicians to allow a sophisticated analysis of the person with dementia's functional, psychological and physical wellbeing. Individuals with dementia living in the home do not receive significant technological formal intervention at present and the results from this project will inform further research and clinical practice on the efficacy, cost-effectiveness and benefits of a home-based tailored sensor system.

4.5 Privacy protection

The privacy of the participants is paramount in the researcher's concerns. We may wish to share findings based on the participants' data upon completion of the study, either in scientific journals or at conferences. Participants will receive a written report outlining the principle findings of the study also. The identity of individual participants will not be divulged, and will be presented only using pseudonyms. Participants may wish to volunteer a selection of images from the study for research and teaching purposes. All such images will be altered to protect the identity of the person or any place contained. For example, faces or names on signage will be blanked and the participant's agreement to share these images will be sought prior to any sharing.

It could be said that the wearing of visible sensors could also threaten the privacy of the individual. No participant will be asked to wear a sensor with which they are not comfortable, and all participants will be frequently reminded that they can withdraw from the research or alter their sensor set at any time. The continuously interactive and co-design nature of the study means that participants will have many opportunities to raise concerns about their privacy, or potential disinclination towards certain sensors.

All data will be kept confidential and anonymous at all times, and if the family caregiver wishes to withdraw from the project, the dyad's data will be withdrawn also. The data will be rendered anonymous and all identifiers removed and replaced with a code with no record retained of the code's relation to the identifiers. The data will be kept in a locked cabinet and on encrypted computers. All participants will be assured of strict confidentiality within the limitations of the law during all stages of the research. The signed consent forms will be immediately detached from any other captured information. Dem@Care consortium members will have access to the data upon request. Only anonymous data, stored on a secure server with password access, will be made available to named researchers on the Dem@Care project who request such data. The data will be transferred securely in these instances and shared only with the requesting consortium members, only for the purposes of analyses relevant to the Dem@Care project.

The data will be stored in a secure, locked facility for 5 years at the School of Nursing & Human Sciences, DCU. Aside from the named researchers, no one will have access to the data. Data will be shredded and destroyed after 5 years.

4.6 Clinical scenario description

The Pilot@Home involves deploying the Dem@Care technology to the homes of 12-15 participants, as personalized according to their individual profiles, and assessing their acceptability. Participants will first undergo a structured clinical interview in their home to indicate technological experience, comfort levels with technology, to achieve an understanding of the participant's health profile, and to identify functional areas in their lives which could benefit from receiving technological support. These areas have previously been defined in a top-down fashion by WP2, and are as follows; sleep, eating and ADL, exercise and physical activity, social interaction and mood (c.f. D2.2). The clinical interview will first ascertain that participants are experiencing some functional difficulty in their lives (as this is a significant part of the differential for a dementia diagnosis) and will also point the researcher in the direction of what these specific difficulties may be. For instance, during the interview, the participant may indicate difficulties in their sleep and social routine. The interview will be followed by a clinical assessment, the contents of which are directly dependent on the outcomes of the interview. If the researcher has reason to believe that the participant is having difficulty in the areas of sleep and social routine, for instance, the assessment will involve a structured investigation of functioning in these areas, using validated and published scales and questionnaires.

Following the clinical assessment, the researchers will create a personalized sensor set from the Dem@Care "toolbox" and propose their use to the participant and their families, assessing their initial acceptability. The system will then undergo a process of refinement, using a co-design methodology, with researcher and participant developing and refining the system until it is of optimal benefit and minimal intrusion. This refinement process will take place with 10 participants in version 1. Following sensor deployment, data describing the individual's activities in their predefined functional areas of interest will be aggregated to different devices, securely stored and analyzed at a later stage. Feedback concerning the individual's wellbeing will be provided to the individual, their caregiver, and also the clinician/researcher, as defined in other WPs.

Following the data collection period, the individual will undergo an exit interview to assess their experiences with the sensor technologies, and their psychosocial wellbeing will be assessed using published, validated scales and questionnaires. The researcher will visit

intermittently during deployment to ensure that the system is being maintained and successfully gathering data, and will be available for consultation by the participants at any time.

4.7 Sensor specifications

As stated above, the actual set of sensors deployed for each individual case will depend on the personal preferences of the subjects involved, in order to ensure they remain comfortable and at-ease during the data collection period. We list here the complete list of potential sensors, keeping in mind that each individual deployment will have a subset of this.

As with the Pilot@Lab scenario, the Pilot@Home setting may be equipped with ambient audio-video sensors: ambient RGB video cameras, RGBD Kinect ® 3D cameras; and ambient microphones. The number of each device used will depend on which areas of the home are to be monitored.

Passive IR sensors may be used to collect data on room occupancy and usage and the transit between areas of the home. Environmental lux sensors may be used to measure the brightness of the rooms.

Various wearable sensors may also be worn by the participant. To provide a visual record of the participant's activities, we will use a wearable RGB video camera (GoPro) and a wearable still image camera (ViconSenseCam Revue®). To measure bodily movement and limb movement and record general actigraphic data, we will use accelerometers (DCU/Tyndall Rev3 Wireless Inertial Measurement Unit) and physiological sensors (Philips DTI-2).

Other environmental sensors may be deployed to collect data about the participant's interaction with, and usage of, objects around the home. This will carried out using devices such as contact switches to identify events such as the opening and closing of doors, cupboards and drawers, and the use of kitchen appliances. Pressure mats may be used to record when the subject is in bed, or sitting on their couch, for example.

The Revue SleepClock may be used in the participant's bedroom as a means of collecting information about their sleep quality.

5 Conclusions

This report presents the current planning for Dem@care prototypes at each of the three types of pilot sites envisioned: lab-based, nursing home-based and home-based environments (T8.2-T8.4), as they have been discussed in the clinical requirements of WP2 (See D2.2). For each pilot, the report describes clinical objectives (diagnosis, enhancement, enablement/support of PwD and their carers), the number of participants, the observation period, the privacy protection with reference to the D2.4, evaluative strategies, and the sensors that could be used.

Furthermore, this document describes the experimentation protocols as well-suited for multi-case evaluation designs targeting functionality, usability and reliability qualities, during the three-cycle development of the Dem@Care system, The three sites can now be used in synergy, to involve higher numbers of participants, in turn enabling a more comprehensive validation process and the evaluation of cross-site differences,and comparisons between potential technical devices.

During each main cycle of development and evaluation, a co-design approach will be followed. This approach closely matches agile methods for iterative system development.

However well-designed an evaluation strategy is, results from each evaluation stage will necessary lead to critical assessment of the overall evaluation strategy, and minor adaptions for the following evaluation stages.

Next steps will refine the methodology adopted for assessing health status and disease progress, and the contextual data collected for assessing the cost-effectiveness of the Dem@Care approach in each environment (T8.1). This work will be included in the deliverable D8.2 (Evaluation Protocols) that is due to month M16. Then a future deliverable D8.3 will report data on user (examples: indicators of quality of life, health status), technical (example: number of activities recognised), and clinical assessment of the Dem@Care approach based on the feedback and observations acquired via the first pilots described in this deliverable.

Appendices

A.1. Appendix I: Lab-based protocol in CHUN

File attached: Appendix-I_CHUN-Pilot@Lab_protocol-1.pdf

A.2. Appendix II: Acceptability form filled by the participant

This form is filled in by the participant at the end of assessment.

File attached: Appendix-II_Acceptability-Form_french(1).pdf

2012

NUMBER OF THE STUDY
12- PP-01

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SEVENTH FRAMEWORK PROGRAMME

dem@care

SUMMARY

[PROTOCOL OF BIOMEDICAL RESEARCH]

" Ecological assessment of autonomy and apathy in Alzheimer patients at mild and moderate stages, as well as in normal control participants "

Table of contents

1 Summary

Cognitive symptoms are the core feature of Alzheimer's disease. Besides these problems, behavioral and psychological symptoms (BPSD), and an impairment of activities of daily living (IADL) are frequently encountered and usually show an impact on autonomy maintenance, prognostic and care during the prodromal and early stages of the disease.

Such symptoms are noticeable before the diagnosis of dementia and their occurrences as well as their intensity increase with the evolution of the disease.

Apathy, initially defined as a reduction of motivated behaviors, is the most frequently observed BPSD. Apathy is clinically defined by a significant reduction or complete loss of interest, initiative capacity and emotional blunting. Accordingly, apathy is characterized by diminished goal-directed cognitions and behaviors.

Behavioral and psychological assessment relies essentially on neuropsychiatric scales. These are used to gather precise data regarding patient's clinical state from interviews with the patient, the career or from clinical impressions during the consultation. From their apparent simplicity they have made their way into daily clinical practices, yet neuropsychiatric scales are reportedly biased by the assessors' subjectivity.
However, some tools whose allow simple, fast and objectively valid assessments are not widely used.

Hence, the use of ICT such as actigraphy (wearable device assessing locomotion activities), automatized audio-video recognition and signal analysis from events, may be of interest in addition to current assessment methods.

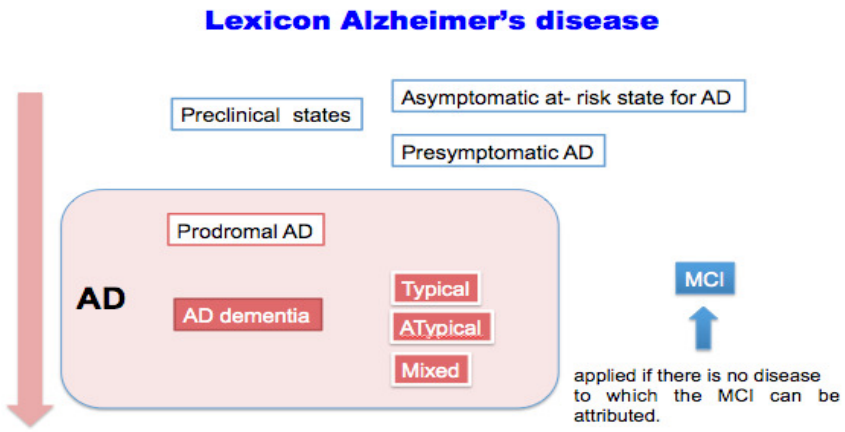
The aim of this study is to implement an objective assessment of goal directed activities and autonomy in an experimental design including predefined actions. The setting includes video cameras RGB (ambient and wearable)/ RGBD (Kinect), microphones (ambient and wearable), accelerometers and Galvanic Skin Response sensors for recording and computer-based recognition of events using audio-video data, and accelerometers data respectively as well as automatically extracting biomarkers for supporting detection of dementia at early stages and supporting ongoing tracking of the dementia disease state.

The following population will be included: patients with Mild Cognitive Impairment (n=50), patients with Alzheimer's disease (n=50) and normal control participants (n=50),

This work will provide further objective information for clinical practitioner in order to detect behavioral disturbances such as apathy.

Alzheimer disease and related disorders: a predementia and a dementia phases

As today the diagnostic label of Alzheimer disease is restricted to the clinical disorder that starts with the onset of the first specific clinical symptoms of the disease, and encompasses both the prodromal / predementia and dementia phases



Dubois & al, Lancet, Neurology, 2010

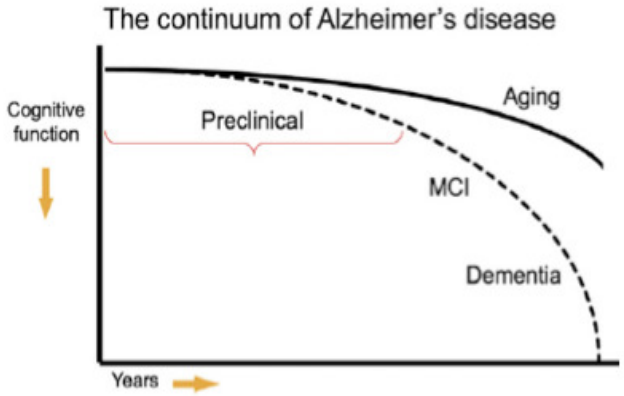


Fig. 1. Model of the clinical trajectory of Alzheimer's disease (AD). [1]

National Institute on Aging and Alzheimer's Association Workgroup

A better assessment needed for soft functional and behavioral signs:

In the research field of independence in functional abilities, it is accepted that persons with MCI commonly show mild problems in functional tasks which they used to perform previously such as paying bills, preparing a meal or doing grocery shopping. Nevertheless they generally maintain their independence in daily functioning, with minimal assistance. It is acknowledged that these functional criteria are challenging issue in order to detect these subtle ground truth functional changes when using classical assessment scales.

2 Aims of the study

2.1 Primary aim

To differentiate early stage Alzheimer's disease from healthy control participants using actimeter and audio-video data analyses obtained during the completion of a standardized scenario of daily living oriented activities.

2.2 Secondary aims

a) Differentiate early stage Alzheimer's disease or related disorder from patients with mild to moderate stages of the disease.

b) To assess the impact of behavioral disturbances, in particular apathy, on the completion of the proposed activities of daily living.

c) To assess the impact of cognitive decline on speaking behavior and voice sound characteristics

d) To assess the adjunct feasibility of the actigraphy coupled with an audio-video setting to a normal memory consultation.

e) Estimate the acceptability of this evaluation method by the participant during a standard consultation in a memory center

f) To assess the participants' acceptability to introduce a follow-up monitoring system based on the use of ICT within their own house

3 Study description

3.1 Population

It is a non-randomized multicentric study involving 3 diagnosis groups of participants:

DIAGNOSIS GROUP	INCLUSION AND NO INCLUSION CRITERIA
Normal Control group : n=50	**Inclusion criteria** • Male or Female ≥ 65 years • Subjects were not accompanied by an Alzheimer subject recruited for the study; • Subjects without any serious motor disability; • Subjects without global cognitive impairment with MMSE> 27. ***Special cases:*** May be included: Subjects with no schooling aged from 50 to 79 years with MMSE> 22/30, and for over 80 years MMSE> 21/30 (standards of Kalafat, 2003) (Folstein et al. 1975), or arguments in favor of the following diagnosis: probable Alzheimer's disease according to the criteria of the NINCDS-ADRDA and / or major depressive episode according to DSM-IV-R; • Subjects affiliated to a social security system; • Signature of informed consent. **No inclusion Criteria** • Inability to perform the protocol due to a locomotor disability; • Prescription of a new psychotropic medication (hypnotic, anxiolytic, antidepressant, antipsychotic) within the previous week of the assessments; • Patient under guardianship;
Predementia **MCI Patients group : n =50**	**Inclusion criteria** • Male or Female ≥ 65 years • Subjects with a diagnosis of MCI according to the criteria of the National Institute on Ageing and Alzheimer's Association group (Albert MS, 2011), or predemential Alzheimer's disease stage (B. Dubois, 2010) • Subjects with a score of 0 to items of "tremors" and "muscle stiffness" of the UPDRS III • Subjects with no criteria for major depressive episode according to DSM IV-R; • Subjects affiliated to a social security system; • Signature of informed consent. **No inclusion Criteria** • Failure to complete neuropsychological tests because of sensory or motor deficits; • Prescription of a new psychotropic medication (hypnotic, anxiolytic, antidepressant, antipsychotic) within the

	previous week of the assessments; • Patient under guardianship;
Dementia **AD patients group : n=50**	**Inclusion criteria** • Male or Female ≥ 65 years • Subjects with a diagnosis of Alzheimer's disease according to NINCDS-ADRDA (McKhann et al. 1984) or Alzheimer's typical or atypical (B. Dubois et al. 2007) • MMSE score ≥ 16 • Subjects with a score of 0 to items of "tremors" and "muscle stiffness" of the UPDRS III • Subjects with no criteria for major depressive episode according to DSM IV-R; • Subjects affiliated to a social security system; • Signature of informed consent. **No inclusion Criteria** • Inability to complete neuropsychological testing because of a sensory or motor deficit; • Prescription of psychotropic medication (hypnotic, anxiolytic, antidepressant, antipsychotic) in the week preceding the assessment; • Patient Trust under curatorship or judicial protection

3.2 Course of the study

The course of the study is the following:

- Inclusion period = 9 months
- Data analyses =3 months
- Length of the study = 12 months
- Duration of the visit = 2 to 3 hours with 25 minutes in the experimental room.

4 Design

4.1 Overview of the protocol course

PART	DESCRIPTION	TASKS
MEDICAL CONSULTATION (T1)		
Medical consultation	- Medical consultation with the physician	➢ **Interview** ➢ **MMSE and UPDRS test (see Part6)** ➢ **Inclusion criteria checking** ➢ **Signature of the consent for the participant to Dem@Care @Lab Protocol** ➢ **E-CRF filling up**
ECOLOGICAL ASSESSMENT IN THE EXPERIMENTAL ROOM (T2) ***(Recording Session, see Part 4.2)***		
Preparation/ Explanation time (PrEx1)	- The assessor enters with the participant inside the experimental room and gives an overview about the assessments. - The participant is equipped with wearable devices, and ambient sensors are launched.	-
Step 1 (S1) Directed activities	- The assessor is with the participant inside the experimental room, and asks them to do different activities.	**(Description see Part 4.2.1)** ➢ **S1_P1. Physical directed tasks** - S1_P1.1. Walking (mono-task) - S1_P1.2. Counting backwards (mono-task) - S1_P1.3. Walking and counting backwards (dual task) ➢ **S1_P2. Vocal directed tasks** - S1_P2.1. Sentence repeating task - S1_P2.2. Articulation control task

Preparation/ Explanation time (PrEx2)	- The assessor asks the participant their difficulty to perform IADLs in the daily life. - The assessor explains to the participant the rules of the Step 2, and shows where each IADL has to be performed. - At the end of the explanation time, both the assessor and participant leave the room. Then the participant enters alone inside the experimental room with the instructions sheet of paper to perform the Step 2.	-
Step 2 (S2) Semi directed activities	- The participant is alone inside the room and has to perform the Step 2 following the instructions given during the (PrEx2). - The participant leaves the room when he/she feels that he/she has accomplished the Step 2, or after a time frame of 15minutes the assessor prevents that the Step 2 is finished.	**(Description see Part 4.2.2)** ➢ **List of IADLs to perform**
Step 3 (S3) Discussion with the clinician	- The assessor is with the participant inside the room. - Between the S3_P1, and S3_P2, the assessor checks that all activities were well achieved. In case of unaccomplished task(s), the assessor asks the participant to perform the related activity in order to confirm that it was due to an omission and not to any praxis difficulties.	**(Description see Part 4.2.3)** ➢ **S3_P1. Directed expression** ➢ **S3_P2. Free expression and discussion** - S3_P2.1. Verbal description of a picture - S3_P2.2. Free discussion from the picture about the interests of the participant
Preparation/ Explanation time (PrEx3)	- End of clinical scenario: sensors are stopped	-

CLINICAL CONSULTATION WITH A NEUROPSYCHOLOGIST (T3)		
Clinical Consultation	- Clinical consultation with a neuropsychologist	➢ **Battery of neuropsychological and neuropsychiatric tests (see Part 6)** ➢ **E-CRF filling up**

4.2 Tasks description during the ecological assessment

4.2.1 Step 1 (S1) Directed activities

TASK	DESCRIPTION
S1_P1. PHYSICAL DIRECTED TASKS	
S1_P1.1. **Walking** **(mono task)**	- *The as*sessor asks the participant to walk 4 meters across the room, to turn and then to come back (total walking distance: 8m)
S1_P1.2. **Counting backwards** **(mono task)**	- *The participant is standing and t*he assessor asks *him/her* to count aloud backwards*:* -> From 305 to 285 (to change tens and hundreds) one by one; or -> From 20 to 0 if they make counting mistakes after 2 attempts of the previous backwards counting.
S1_P1.3. **Walking and Counting backwards** **(dual task)**	- The assessor asks the participant to walk and count *aloud backwards simultaneously:* -> From 305 until the end of the walking tasks; or -> From 20 to 0 for participants who don't manage to count backwards from 305 to 285 during S1_P1.2

S1_P2. VOCAL DIRECTED TASKS	
S1_P2.1. **Sentence repeating**	- The participant is asked to repeat a short sentence after the assessor. -The assessor reads aloud a sentence. The participant repeats the sentence. The action is done once by sentence. Three sentences must be repeated. <u>*Sentences:*</u> - *Sentence 1.* "La montagne est enneigée en ce mois de mars" - *Sentence 2."*Le chien a fait une longue promenade ce matin." - *Sentence 3.* "Le schtroumpf grognon est très content aujourd'hui."
S1_P2.2. Articulation control	- The participant is asked to pronounce repeatedly a predefined diadochokinetic "Pataka" token as rapid as possible stopping this action upon a sign by the assessor. The assessor will stop the action in 10sec.

4.2.2 Step 2 (S2) Semi-directed Activities

4.2.2.1 Preliminary information

- **Clinical scenario choice**
  - This part of the protocol is proposed to participants with a MMSE≥16.
  - For the patients with MMSE≤21/30 <u>and</u> ≤2/3 to words at recall, the planification task of the scenario will be removed: the patient will have to perform the 11 activities following the given order.

- **Instructions given to the participant (clinical scenario with planification task)**

"Your task is to perform this list of 11 activities in a logical manner within 15 min. These 15 minutes represent a typical morning period of everyday life":

- Read 1 article and answer the three questions written below
- Water the plant
- Answer the phone at …h…
- Call the psychologist to confirm the appointment afterwards
- Find on a bus map the line that takes you to the train station
- Pay the phone bill (check writing)
- Leave the room when you are finished with all the activities
- Prepare the drug box for tomorrow according to the prescription
- Watch the TV

- Prepare a hot tea
- Establish the account balance

You have to carry out these 11 activities in a logical manner according to the following instructions:
- Water the plant just before leaving;
- Call the psychologist, who will take 10 minutes to arrive;
- Establish the account balance and write the check for the phone company before the phone call.

4.2.2.2 Task description

IADL	DESCRIPTION
Read 1article and answer the three questions written below	- Three articles are proposed to the participant (Topics: Collection Cars; Cooking; Sightseeing). The three articles have the same words number and level of difficulty. Below each articles, the 3 following questions are asked. - Q1/ What is the topic of the article? - Q2/ What is the percentage of French interested in the … (Collection Car / Cooking / Sightseeing, text adapted to the article topic)? - Q3/ Who is interviewed? - The participant has to read 1article and writes the 3 good responses.
Turn the TV	- The TV is turn off. The participant has to take the remote control and turns on the TV.
Establish the account balance	- Three bills (Electricity/Gaz/Phone) are proposed. The account balance is given. - The participant has to establish the amount balance after having taken into account the three bills.
Pay the phone bill (check writing)	- Three bills (Electricity/Gaz/Phone) are proposed. The participant has to pay the phone bill by check. - The check is well completed if the amount, order (i.e. Phone Company), date and signature are right.
Answer the phone …h…	- The phone is scheduled to ring 10 minutes after the entering of the participant inside the room. - During this task, the assessor explains that there is a mistake on the phone bill: the amount was wrong. Consequently, it is expected that

	the participant corrects his/her phone check and correct account balance (tasks normally established before the phone call according the constraint). <u>Discussion during the phone call:</u> [Assessor]:- "Allo Mr/Mrs …?" [Participant]: - "Yes" (or something else) [Assessor]: - "Allo Mr XXX from the phone company. I call you to inform that following a technical problem there is a mistake on your phone bill. The amount was doubled, so you just have to pay half of your bill. Please accept our sincere apologies for the inconvenience. Have a good day."
Call the psychologist to confirm the appointment afterwards	- The participant has to call the psychologist. Two phone numbers are proposed to the participant (1 visit card of the hair dressing,+ 1 visit card of the CHUN with phone number of a psychologist). - According the constraint, the participant has to call the psychologist within the 5 first minutes.
Find on a bus map the line that takes you to the train station	- A real bus map is showed to the participant with the indication of the current location of the participant. - The participant has to write on a sheet of paper located next to the bus map the bus lines to take for the itinerary (From Hospital to Station train). Two itineraries are accepted.
Prepare the drug box for tomorrow according to the prescription	- 4 types of drugs are proposed to the participant. - The participant has to respect the posology prescribed (2 types of drugs at different moment of the day) and the date (day and moment of the day).
Prepare a hot tea	- The participant has to switch on the electric kettle. - The participant has to pour the hot water on the glass containing the tea bag.
Water the plant	- The participant has to take the water can, and water the plant nearby.
Leave the room when you are finished with all the activities	- The participant has to leave the room when he/she feels that all activities are performed and achieved.

4.2.3 Step 3 (S3) Discussion with the clinician

TASK	DESCRIPTION
S3_P1. DIRECTED EXPRESSION	
Questions about the read article	- The assessor asks the same questions than the ones asked on the read article: - Q1/ What is the topic of the article? - Q2/ What is the percentage of French interested in the … (Collection Car/Cooking/Sightseeing, text adapted to the article topic)? - Q3/ Who is interviewed?
Questions about the course of the Step 2 (S2)	- The assessor asks the participant information about the course of S2: During the semi-directed activities: - Q1/ Did you achieve all the 11 activities as specified on the sheet? - Q2/ Did you think having respected all the constraints?- - Q3/ Before starting the activities, did you know how to organize them (for participant with planification tasks); or Did you have any strategy to do this task (for participant without planification tasks)? - Q4/ Did you face any difficulties? If Yes, specify - Q5/ Can you recall the order of the achieved activities?
The assessor checks with the participant the good achievement of IADLs performed during the Step 2 (S2)	
S3_P2. FREE EXPRESSION AND DISCUSSION	
Verbal description of a picture (S3_P2.1); and **Free discussion from the picture about the interests of the participant (S3_P2.2)**	(S3_P2.1) The assessor shows to the participant one picture representing daily activity. The assessor asks the participants to give a verbal description of the picture in a few sentences. (S3_P2.2) The assessor asks if the participant likes doing this activity and why. The activities (a1) and (a2) are done with two different pictures (one picture representing a banquet table; the other picture represents a couple of older people (back) walking on the mountains).

5 Experimental data collection

5.1 Assessment of the Step 1 (S1) Directed Activities

5.1.1 Description

Location
Inside experimental room / controlled environment
Duration
5 min max
Sensors included
Compulsory: - 1 ambient RGB video camera (front Point Of View (POV)) - 2 RGBD Kinect sensors (front and lateral POV) - 2 Wearable microphones (1 for assessor + 1 for participant) No compulsory: - 1 wearable RGB video camera - 1 SenseCam - 1 Ambient micro - Accelerometer specifically - Wireless Inertial Measurement Unit (WIMU) - 1 Galvanic Skin Response sensor

5.1.2 Measurements and sensor needs

Clinical aim: **Gait assessment and impact of a cognitive activity on gait performance**	
Clinical requirement ➢ **Gait assessment**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Walking speed (Obs. period: mono task walking activity/dual task)	• Video camera/Kinect sensors (granularity level: People localization) • Accelerometer WIMU (high time resolution)
• Step length (obs. period: mono task walking activity/dual task)	• Kinect sensor (granularity level: body part detection, local motion)

	• Accelerometer WIMU (high time resolution)
• Dynamical balance during the walking (e.g., people trajectory study) (obs. period: mono task walking activity/dual task)	• Video camera/Kinect sensors (granularity level: People localization) • Accelerometer WIMU (high time resolution)
• Walking speed instantaneous (obs. period: mono task walking activity/dual task)	• Video camera/Kinect sensors (granularity level: People localization) • Accelerometer WIMU (high time resolution)
• Stopping displacement during the walking (yes/no) (obs. period: mono task walking activity/dual task)	• Video camera/Kinect sensors (granularity level: global localization) • Accelerometer WIMU (high time resolution)
Clinical requirement ➢ **Vocal biomarkers extraction for cognitive load assessment**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Voice features indicative of speech fluency e.g. pause rate, speech rate, vowel duration • Voice features indicative of articulation control (e.g. voicing onset time) (obs. period: mono-task cognitive activity/dual task)	• Wearable audio sensor
Clinical requirement ➢ **Explore the time of latency [stimulation, response] of the Part 1 (Explore sensitivity of this measure for assessing the apathy)**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Time of latency between the end of instructions (stimulation) and the beginning of the task (mono & dual) (response) (Obs. period: mono-task walking activity/mono-task cognitive activity/dual task)	• Wearable microphone (one for participant, and one for assessor) • Fusion: audio (worn by assessor and participant) & Video/Kinect/accelerometer data specific to the participant (to define the beginning of walking activity & cognitive activity)
Clinical requirement ➢ **Assessment of mutual influence of cognitive activities an motor activities**	
Expected measurements & data	**Sensor needs**

(Observation period of collected data)	
• Voice features indicative of speech fluency and articulation (obs. period: mono-task cognitive activity/dual task)	• Wearable microphone
• Correlation between walking speed instantaneous and the vocal features (obs. period: dual task)	• Fusion microphone/ video camera/ Kinect/ accelerometers sensors
• Difference of measurements between mono-task and dual tasks enable to measure impact of the cognitive activity on the gait performance and impact of the motor activity on the cognitive performance.	
Clinical requirement ➢ **Assessment of the verbal reaction time and the impact of cognitive load imposed by the sentence recall task on speech fluency**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Verbal reaction time (time interval between the end of assessor's speech and the beginning of participant's speech) • Voice features indicative of speech fluency e.g. pause rate, speech rate, vowel duration (obs. period: sentence repetition task)	• Two wearable microphones, one for the participant, one for the assessor
Clinical requirement ➢ **Assessment of the level of the participants' control over the neuromuscular mechanism of speech production**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Diadochokenetic rate (DDK), i.e. the mean number of tokens per second. • Speech regularity, e.g. similarity between spectral and prosodic features measured at different occurrences of the token. • Voicing onset time statistics (obs. period: articulation control task)	• Wearable microphone
Clinical requirement ➢ **Explore stress level during this part**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Stress level (Obs. period: the different part of the Step 1)	• Galvanic Skin Response sensor

5.2 Assessment of the Step 2 (S2) Semi-directed Activities

5.2.1 Description

Location
Inside experimental room / controlled environment
Duration
15 min max
Sensors included
Compulsory : - 3 ambient RGB video camera (front POV; Coffee Zone POV; Office Zone POV) - 2 RGBD Kinect sensors (front and lateral POV) - 1 wearable RGB video camera - Accelerometers - 1 wearable microphone (for the participant) - Environmental sensors No compulsory: - 1 SenseCam - 1 ambient micro - 1 Galvanic skin response sensor

5.2.2 Measurements and sensor needs

<table>
<tr><td colspan="2">Clinical interests:
Assessment of functional and cognitive abilities during a clinical scenario representing daily living activities</td></tr>
<tr><td colspan="2">Clinical requirement:
➢ Cognitive abilities assessment (ability to organize several activities)</td></tr>
<tr><td>Expected measurements & data
(Observation period of collected data)</td><td>Sensor needs</td></tr>
<tr><td>• Activity recognition system (macro context)
Data collected for each activity listed:
-> Omitted (yes/no)
-> Repetition number
-> Completed(yes/no)
-> Period ([begin, end]) during which the participant has oriented behaviour to do the activity

(obs. period: activity recognition process during S2)</td><td>• Video camera (ambient & wearable)/Kinect sensors
Granularity level:
->People localization (tracking person/ Orientation)
-> Posture recognition
-> Interaction with objects (local motion)
-> Body part detection)

• Contact sensor or ambient Audio sensor (e.g., TV turning on/off; electric kettle on/off)

• Fusion video camera/Kinect/contact/audio sensors</td></tr>
<tr><td colspan="2">Clinical requirement:
➢ Explore functional abilities for the completion of specific activities</td></tr>
<tr><td>Expected measurements & data
(Observation period of collected data)</td><td>Sensor needs</td></tr>
<tr><td>• Action recognition system (micro context):
(Perform the way for doing one activity)
-> Hands trajectories (way to interact with objects)

(obs. period: during the execution of a specific activity)</td><td>• Video camera (ambient & wearable)/Kinect sensor
-> Body part detection
-> local motion
-> Posture recognition

• Accelerometers (high time resolution)
-> local motion</td></tr>
<tr><td>Speech fluency and mood (Apathy) exhibited during the reading aloud and the phone conversation tasks. (obs. period: during the phone conversation activities)</td><td>• Wearable microphone</td></tr>
<tr><td colspan="2">Clinical requirement:
➢ Explore stress level during this part</td></tr>
<tr><td>Expected measurements & data
(Observation period of collected data)</td><td>Sensor needs</td></tr>
</table>

• Stress level(Obs Period: during all the Step 2)	• Galvanic Skin Response sensor
Clinical requirement ➢ **Explore ability to organize with efficiency the different activities**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
Total distance walked (obs. period: during all the Step 2)	• Accelerometer
• Trajectory of the participant inside the room (between the different zones of interest) (obs. period: during all the Step 2)	• Video camera (global localization)

5.3 Assessment of Step 3 (S3) Discussion with the clinician

5.3.1 Description

Location
Inside experimental room / controlled environment
Duration
10 min max
Sensors used
Compulsory: - 1 ambient RGB video camera - 2 wearable microphones (1 for assessor + 1 for participant) No compulsory: - 1 wearable RGB video camera - 1 ambient micro - 1 SenseCam - 1 Galvanic skin response sensor

5.3.2 Measurements and sensor needs

Clinical interests: **Memory assessment & Verbal fluency/Apathy assessment**
Clinical requirement ➢ **Vocal biomarkers extraction for cognitive load assessment**

Expected measurements & data (Observation period of collected data)	Sensor needs
• Voice features indicative of speech fluency e.g. pause rate, speech rate, vowel duration • Voice features indicative of articulation control (e.g. voicing onset time) (obs. period: S3_P1and S3_P2)	• Wearable microphone
Clinical requirement: ➢ **Assessment of the impact of cognitive load imposed by the picture description task on speech fluency**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Voice features indicative of speech fluency e.g. pause rate, speech rate, vowel duration (obs. period: S3_P2 Verbal picture description task)	• Wearable microphone
Clinical requirement: ➢ **Memory and self-appraisal assessment**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Responses to the questions form filled by the assessor (Obs. period: S3_P1)	• Wearable microphone (logged as a reference)
Clinical requirement ➢ **Explore stress level during this part**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Stress level (obs. period: during S3_P1 and S3_P2)	• Galvanic Skin Response sensor
Clinical requirement: ➢ **Verbal fluency and mood (Apathy) assessment**	
Expected measurements & data (Observation period of collected data)	**Sensor needs**
• Verbal reaction spontaneity (time between the end of assessor's speech and the beginning of participant's speech) (Obs. period: S3_P1 and S3_P2)	• Audio sensor (wearable), one for the participant, one for the assessor
• Involvement in the discussion (speech rate & total time of participant's speech) (Obs. period: S3_P1 and S3_P2)	• Audio sensor (wearable), one for the participant, one for the assessor

• Speech fluency (pause rate, vowel duration) (Obs. period: S3_P1 and S3_P2)	• Audio sensor (wearable), one for the participant, one for the assessor
• Mood: active vs. passive (prosodic features, i.e. pitch contour statistics, energy statistics) (Obs. period: S3_P1 and S3_P2)	• Audio sensor (wearable), one for the participant, one for the assessor

6 Clinical data collection

The following data are collected during either the Medical Consultation (T1) or the Clinician Consultation (T3).

Demographical characteristics	**Clinical characteristics**
• Gender • Date of birth • Education Level • Laterality • Size	• Diagnosis established the day of the recording session. Participant is assigned to one of this 3 categories: Healthy Control participants, Alzheimer's disease at pre-dementia stage, Alzheimer 's disease at dementia stage. • Cognitive abilities assessment - Mini-Mental State Exam (MMSE). - Frontal Assessment Battery (FAB). - Trail making test A and B. - Short Cognitive Battery. - The Free and Cued Selective Reminding Test. • Neuropsychiatric/Mood assessments - NPI - DSM-IV Criteria for depression - Apathy Inventory (AI) and diagnostic criteria for apathy. • Motricity abilities assessment - Part III of the Unified Parkinson's Disease Rating Scale (UPDRS) . • Autonomy assessment - Instrumental Activities of Daily Living for Elderly (IADL-E).

Questionnaire :

Acceptabilité du protocole expérimental dans une consultation standard

OBJECTIF DU QUESTIONNAIRE

Vous venez de participer à un protocole expérimental. Nous souhaiterions proposer cette évaluation de manière plus systématique lors de consultation standard. Ainsi nous aimerions connaître votre avis.

DEROULEMENT DE L'EVALUATION

- Q1/ L'ensemble des tâches vous a semblé :
  - Difficile
    0 (difficile) ●——————————● 10 (simple)
  - Pénible/Stressante
    0 (pénible) ●——————————● 10 (agréable)
  - Correspond à des situations de votre quotidien :
    ☐ Oui ☐ Non
- Q2/ Sur l'ensemble de l'évaluation, avez-vous trouvé :
  - L'environnement stressant ☐ Oui ☐ Non
  - La durée ☐ Trop longue ☐ Adaptée
- Q3/ L'utilisation de capteurs durant cette évaluation:
  - Vous a stressé ☐ Oui ☐ Non
  - A modifié votre attitude ☐ Oui ☐ Non
- Q4/ Globalement est ce que vous avez bien compris ce qui vous était demandé ?
  ☐ Oui ☐ Non
- Q5/ Avez-vous bien compris l'intérêt de cette évaluation ?
  ☐ Oui ☐ Non

AU FINAL

- Q6/ Seriez-vous prêt à participer une nouvelle fois à cette évaluation
  ☐ Oui ☐ Non
- Q7/ Autres commentaires :

  ……

Questionnaire :

Acceptabilité des capteurs pour une utilisation quotidienne

OBJECTIF DU QUESTIONNAIRE

Durant cette évaluation vous avez pu utiliser différents capteurs. Nous aimerions connaître votre avis quant à l'introduction de ces capteurs dans votre quotidien.

ACCEPTABILITE DES CAPTEURS

- Q1/ Accepteriez-vous de porter des capteurs pour suivre votre activité au quotidien :

☐ Oui ☐ Non

- Si oui : Pendant combien de temps

☐ En permanence (longue durée) ☐ Une semaine ☐ Une journée ☐ Occasionnellement

- Si non : Quels sont les motifs de votre réticence

☐ Trop intrusif ☐ Manque de confort ☐ Trop visible

☐ Trop contraignant ☐Autres (précisez)……..

- Q2/ Accepteriez-vous d'avoir des capteurs intégrés à votre domicile pour suivre votre activité au quotidien : ☐ Oui ☐ Non

- Si oui : Pendant combien de temps

☐ En permanence (longue durée) ☐ Une semaine ☐ Une journée ☐ Occasionnellement

- Si non : Quels sont les motifs de votre réticence

☐ Trop intrusif ☐ Manque de confort ☐ Trop visible

☐ Trop contraignant ☐Autres (précisez)……..

- Q3/ Autres commentaires : ……

DISCUSSION

- Q4/ Si des réunions d'information sur l'intérêt de ces capteurs vous étaient proposées, cela vous rassurerait-il quant à leur utilisation

☐ Oui ☐ Non

- Q5/ Si l'utilisation de ces capteurs devez-vous être prescrit par votre médecin, l'accepteriez-vous ☐ Oui ☐ Non