Analysis of Requirements and Specifications for a Monitoring System to Support the Self-management of Dementia Patients at Home

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ABSTRACT

Telemedicine systems are nowadays making significant advances in healthcare by decentralising it, offering innovative services to patients and doctors worldwide, and making medical practice more efficient and cost-effective in a plethora of its subfields. There is although a field that has not yet been successfully coped with, even though it induces a significant burden, both socially and financially. This field includes patients suffering from dementia, as well as their carers, who run the risk of developing depression symptoms themselves and often face social withdrawal and heavy additional private costs. ALADDIN is a technology platform that intends to progress “state-of-the-art” in integration of existing technological solutions. In order to develop and validate an innovative monitoring system for health promotion, risk assessment, prevention and sustainable impact of self-management tools and education for patients suffering from dementia and their care-givers. In this paper the authors present the envisaged services of the ALADDIN platform, the user requirements and ALADDIN’s functional specifications.
prolonged home-based care of patients suffering from dementia involves the implication of informal carers who run the risk of developing depression symptoms themselves, a main issue in the home-care process of these patients is to relief distress in caregivers. Several psychosocial approaches have been proposed in this direction. The majority of the psychosocial interventions include psycho-education and/or supportive approaches in order to help caregivers to appropriately monitor the impact of the disease on cognitive, functional, behavioural and personality changes. An ICT enabled capability to remotely monitor the caregiver’s emotional and psychological status in parallel to the patient’s cognitive and behavioural status, can significantly aid towards the early detection of distress to the caregiver and the timely diagnosis of deterioration symptoms of the patient. Therefore, ICT can provide means to efficiently cope and improve self-management of the patient condition and ultimately help delaying institutionalisation of the patient. The focus of this approach therefore is on prevention and prediction through the early identification of risk factors rather than on medical interventions after symptoms and complications have developed [1],[7].

ALADDIN is a technology platform that aims to delay institutionalisation, improve the contact between doctor and patient, improve the caregiver’s services toward the patient, address the caregiver’s own possible problems with depression, and further personalise health care for each patient with more efficient data accumulation and processing, while in the same time avoiding unnecessary visits to clinics and reducing relative costs. It is a homecare system targeted specifically on early and moderate stage dementia patients, that will meet the aforementioned goals by addressing issues of prevention rather than intervention, focusing on quicker and more reliable information processing after the outbreak of the disease, but also on information processing for the extraction of patterns, the analysis and comparison of models and the foresight of adverse event implications, so as to develop methodologies and strategies to proactively cope with health promotion. Thus, ALADDIN is a holistic platform that can be used by clinicians in order to predict and prevent the expeditious advancement of dementia, to attend the development of the disease and to remotely assess the condition of both dementia patients and their carers. At the same time the platform aims to provide a set of tools for the self-management of the disease, and enhance empowerment and motivation of patients to actively participate in a variety of daily activities. The tools and methodologies that will be developed through the project will be validated through pilots that will be set-up in three clinical sites.

2. ALADDIN PLATFORM DESCRIPTION

ALADDIN aims to utilise state-of-the-art in ICT in order to develop an innovative integrated solution for the self-management of patients suffering from dementia, and develop innovative tools to support this procedure. This solution can be conceived as an integrated platform which will enable distant monitoring of patient status and facilitate personalised intervention and adaptive care for these patients. This platform will actually constitute a middleware solution that can be used on top of existing Hospital Management Systems, so as to increase their efficiency and provide the means for the formulation of strategies. The project also aspires to establish a network for assessing, communicating and appropriately managing information related to patients suffering from dementia, targeting the improved and sustained quality of self-management practices.

Figure 1 depicts the conceptual ALADDIN architecture and its main entities which aim to enhance patient and carer safety through the risk assessment and prediction mechanisms supported by the smart devices. The overall system comprises of three main subsystems:

- The web-based environment which incorporates the social networking utilities for the communication between patients with similar conditions, the communication with carers for sharing similar experiences, and the communication between the aforementioned and specialised medical personnel. Supplementary tools that are under consideration include, music therapy, physical exercises etc, through an interactive platform aiming to improve behavioural and psychological symptoms.

- The monitoring tools, which involve the development of smart devices for the conduction of remote psychometric tests (Mini Mental State Examination -MMSE or MBPC, CDR etc), along with video-conferencing utilities for the provision of a more thorough clinical image of the patient to the medical expert. Patient monitoring will include blood pressure measurements in order to avoid hypertension that is a relevant risk factor for cardiovascular events that could significantly worsen the progression of dementia, as well as body weight measurements to avoid malnutrition, a common problem with dementia progression due to poor appetite or food refusal, in order to allow an early intervention with appropriate alternative strategies (liquid integrators, multi-vitaminc etc). An electronic recorder of physical activity will also be included, with the double purpose to evaluate the patient’s daily activity and the quality of the patient’s sleep. The risk assessment and analysis tools, will retrieve, combine and process information from diverse resources, including psychometric tests, electronic health records and personal evaluations by medical experts as well as data from the monitoring devices.

- More analytically:
  - The ALADDIN monitoring platform will comprise portable devices (e.g. Tablet PC’s), designed to be used by both caregivers and patients with user friendly interfaces for both
The devices that are targeted towards the patients and their primary carers will be responsible for:
- Acquisition (either manual or automatic) of the data produced by monitoring devices (e.g. blood pressure monitor, weight scale etc.)
- Interfacing with patients for the conduction of the clinical examination (psychometric tests)
- Activation of a reminder for drug therapy compliance
- Secure communication with the Communication Server, and the wireless transmission via any available cellular network of the received clinical data.

The devices that are targeted towards the specialised personnel will be responsible for:
- Secure communication and interfacing with the Clinical Record Repository, for the acquisition of diagnostically critical information for the patient through their electronic record, including measurements from the monitoring devices along with the results of the clinical examination, in order to allow for the evaluation of the patient’s clinical status.
- Secure communication and interfacing with the Procedural Manager which will produce the adverse events’ prediction and risk assessment mechanisms, along with alarms in the case that certain pre-defined thresholds are exceeded.

The web environment incorporates all the social networking utilities for the communication between patients with similar conditions, the communication with carers for sharing similar experiences.

The Secure Communication Server will act as the intermediate between the Smart Devices of the patients and the clinicians and the various repositories. Since medical data are both critical and sensitive, the Secure Communication Server will make use of cryptography and encryption procedures, so that these medical data will not be tampered with.

The Authentication Server will be responsible for the user authentication via standardised procedures (user name and password), thus allowing for controlled access and user non-repudiation.

The Monitoring Data Repository contains data gathered by the monitoring devices of the subjects.

The Clinical Record Repository contains other diagnostically critical clinical data of each patient. Electronic Health Records (E.H.R.) of patients will be stored in this repository, with their data being utilised both by clinicians (individual access to these records) as well as from the procedural manager for the extraction of patterns.

The Interoperability / Interfacing Layer (IT) is responsible for the semantic articulation of the data between the repositories and the procedural manager, namely for the semantic federation of the peer data bases.

The Procedural Manager is the core of the analysis of the gathered data. It communicates with the Secure Database Server, is responsible for the pattern recognition and analysis, and should certain predefined limits be exceeded it is responsible for the identification of patient risk and for the production of certain alarms. These patterns will also be used for statistical analysis by the procedural manager, as input for the adverse events’ prevention and medical treatment strategy decision mechanisms and for the extraction of valuable scientific conclusions (in perspective it can be used for integration with genetic information processing unit for individualised therapy). The aim is to establish a semantic information organisation scheme for the available databases. Those patterns can be used for the detection and assessment of the adverse events and the accurate evaluation of the patient’s status and critical incidents related to their safety.

Semantic organisation of available data bases. The initial step towards the establishment of semantic data mining mechanisms in the context of the proposed project comprises the semantic organisation of the raw data contained in the available electronic health record (E.H.R.) databases.

Risk Assessment mechanisms. In the context of the envisaged system, intelligent data mining methodologies will be developed to establish robust, effective and computationally efficient methodologies for the imminent adverse events’ prediction and risk assessment.

3. USER REQUIREMENTS
Prior to the initial system design, questionnaires were handled to clinicians of the field and extensive discussions were made, in order to specify the actual needs in every-day dementia patient care, as perceived by active clinicians in healthcare centers in England (NHNN), Spain (Badalona Serveis Assistencials), Italy (University of Bologna) and Greece (Attika Psychiatric Hospital).

At the core of the User Requirements phase, before the actual device user requirements, three major issues were considered:
1. Patient Inclusion and Exclusion criteria
2. The selection of appropriate assessment scales
3. The identification of primary and secondary outcomes

3.1 Patient Inclusion and Exclusion Criteria
Patient inclusion and exclusion criteria were addressed first because of the apparent direct implications in the Pilot Study. Taking into account the heterogeneity among the clinical partners, it was decided not to limit the diagnostic inclusion criteria to dementia diagnoses but to include Parkinson disease as well. Consequently, in the pilot study will be recruited patients affected by:
- Alzheimer disease;
- Vascular dementia;
- Parkinson disease;
- Other neurodegenerative dementia;
- Mixed dementia (e.g.: Alzheimer and vascular).

As a result, the focus of the requirements’ analysis has been stated as the identification of common dementia features for Alzheimer’s disease, vascular dementia and Parkinson’s disease. Moreover, it has been decided that only patients with adequate functional capacity should be included in the study. Consequently at the inclusion each patient should be initially face to face screened with the Mini Mental State Examination (MMSE) and evaluated with the Barthel Index (BI). Each patient should report scores between 9 and 24 at the MMSE while the BI should be > 35.

Exclusion criteria are the caregiver absence, a caregiver unable to use technology at a minimum level, the presence of the disease in its terminal phase, severe medical conditions and other primary axis I diagnoses.

3.2 Assessment Scales
The incorporation into the monitoring system of some assessment scales raises the following issues: To train a non-qualified person in administering clinical instruments to his/her relative is neither
methodologically nor ethically correct, considering firstly that clinical instruments, such as the MMSE, have been created to be administered by specialized personnel and secondly that the caregiver is emotionally involved with the patients and consequently the caregiver administration of the instrument and the reported results could be biased by this involvement. There is also a copyright inconvenience as well, linked to the administration of an entire validated clinical instrument. Finally, the items included in the monitoring system should not be redundant and time consuming, to avoid compliance problems or poor quality data.

To avoid all these inconveniences it has been decided to include in the system only a small number of items from each of the most used and validated clinical instruments that, according to the literature and clinical experience, are the most predictive of a symptomatological worsening. This solution allows to avoid another problem linked to the possibility of generating a set of items without considering validated instruments as sources. In this case, the issue of the construct validity of each item raises. Construct validity refers to whether an item measures or correlates with the theorised construct that it purports to measure (“The selected item effectively measure what we want to?”) and it should be evaluated by statistical methods. The selection of items derived by previously validated instruments allows us to be sure of the construct validity of each of them.

### 3.3 Primary and Secondary Outcomes

The project’s core target is the avoidance of emergencies. A non institutionalized patient usually faces every day emergencies owed to his condition and its effects on his mental state, his physical state and to effects of the administered drugs. During the pilot we will evaluate both primary outcomes of the platform’s use and secondary, more indirect, outcomes.

Among the main concerns are predictions of adverse events, reactions and efficiency in case of an emergency, as well as the lessening of the need for frequent visits to the clinic. Through the early detection of clinical warning signs we will avoid severe emergency incidents and so alleviate some of the carer’s burden. As an indirect result of the previous, comes the quality of life of the patient and of course the lessening of the overall cost for the treatment of his condition. Regarding caregivers, our main concern will be the effects on their psychological burden and the indirect positive outcome will be the improvement on their quality of life.

The ‘emergency contacts’ should be recorded by clinicians. The detection of clinical warnings should be evaluated in terms of increased scores through a defined period of time (1 day), considering both single items and item clusters. In particular, the shift from a 0 score (¬No) to a 1 score (¬Yes) in single items and an increase of ≥2 in the score for each item cluster (cognitive cluster, aggressiveness cluster, etc) should be considered as clinical warnings. The possibility for clinicians to customize alarm thresholds will be considered.

Pre-trial data on each patient about the frequency of occurrence of such emergency contacts will be collected through a standardized form: when available pre-trial data of the 6 months before should be collected. Half of the sample will be treated as usual to evaluate the incremental benefit of our strategy: ten controls and ten patients should be included for each centre. Clinicians should have a record of the patient before the screening through the platform. Initial assessment of

1) socio-demographic features for both patients and care-givers, of
2) clinical features for patients and
3) physical and mental health features for the carers, should be carried out at the stage of the pilot study. Pilot centers should list the variables that clinicians should collect and have on their monitor. Moreover, a set of assessment scales should be administered face to face at baseline, after three months, after six months and at the end point (after nine months): For patients:
- Mini Mental State Examination (MMSE)
- Barthel Index (BI)
- Blessed Dementia Scale (BDS)
- Mattis Dementia Rating Scale (MDRS)
- Quality of Life scale for dementia (to be determined by clinical partners)

For carers:
- Quality of Life Scale (QoLS)
- Beck Depression Inventory (BDI)

### 3.4 User Requirements for the ALADDIN Monitoring System

The display requirement is to be at least 12inch. The system will be always-on tablet PC with a docking station to facilitate connection. It should include instant touch screen for an easier use by elderly patients. The system should have a permanent connection. Concerning mental evaluation tests, the system will include two kinds: Tests for the Patient and Tests for the carers. The patient-related tests will be implemented into both a patient-assisted-by-caregiver version and a caregiver-only version. Patient should be always assisted by caregiver during the writing out of the tests. Daily physical measurements will also be included in the system if technically possible, such as blood pressure and actigraphic evaluations. Body weight will also be measured and recorded, considering that weight loss is a common problem associated with dementia that sometimes precedes cognitive decline. The system will include some precautions to support compliance such as an automatic sound device, ringing with a daily frequency, or the reception of SMS/e-mail of alert. These notifications to support compliance will be considered also for physicians. Finally, a ‘warning button’ should be included in the device. Patient/caregiver should use it only in case of a warning contact request with clinicians. The reply should come within 24 hours. Caregivers should be trained to correctly choose between an emergency service call and a warning contact request. The possibility to correct and to come back to the previous items should be allowed by the system. It should be possible to change the response to items during the day and not to change responses given day before. Another requirement is completeness: all the responses are needed each day.

The patient targeted tests that will be incorporated into the ALADDIN platform will include tests like the MBPC (Memory and Behavior Problem Checklist), tests for Aggressiveness evaluation, tests for Mood evaluation, CDR (Clinical Dementia Rating scale), as well as questionnaires evaluating other measures of cognition or everyday life incidents (e.g. questions on falls, sleep difficulties, insomnia incidents, drug side effects). Questionnaires will be evaluated in the Likert Scale.
Regarding the caregiver, the platform will include an implementation of the Zarit Burden interview, evaluated also in the Likert scale.

4. Functional Specifications

Before proceeding to the core of Functional Specifications we should at first define the three distinct kinds of end users for the ALADDIN platform, as well as the kind of their interaction with the system.

First we have the patients, who are on the first stages of dementia and their condition is mild enough not to require institutionalization yet. However, they do need a caregiver to help them cope with everyday life. The patients’ interaction with the system is indirect, since it will be facilitated with the aid and supervision of the caregivers.

Second group of users are the clinicians. Medical personnel, is assigned with the task of monitoring and treating the patients. Clinicians have full access to almost all (if not all) functionalities of the system. They schedule tests, process answers, receive alarms, prescribe changes in drug use, check the patients calendars and files, etc.

The third group of end-users are the carers. A carer is an authorised person, that supervises the patient’s daily activities, spends with them a lot of time and assists in the monitoring process. The carer helps in the administration of Mental and Cognitive Evaluation tests, inputs in the system (when applicable) the patient’s measured values, and sends to the doctor relevant alarm signals in case something goes severely wrong.

Functional Specifications allow for an easier sketch of the system’s design, by providing an idea to the designer and developer of what the major inputs and outputs of the system will be.

The specification of the system functionalities starts with the identification of the User Requirements. There is a relation between user requirements and functional specifications which is n-to-n since one user requirement can indicate the need for many functionalities while at the same time one functionality may be useful in satisfying many user requirements (as part of a workflow or as standalone functionality). The following figure illustrates the resulted one way mapping that yielded from analysing user requirements (user requirements are listed on the left side):

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**Figure 2 : Mapping of User Requirements to Functional Specifications**

In our analysis for the definition of the functional specifications we considered the following parameters:

- **Stakeholders** are the references to actors consuming a particular functionality (the functionality’s end-users).

- **Short Description** is a description explaining in rough terms what the functionality does as well as the role of the stakeholder.

- **UI Implementation** is an idea of how this functionality can be depicted in the system’s UI. Not all functionalities must have such a UI implementation.

- **Input** is the information used by the functionality as input when invoked. It is not applicable for all functionalities.

- **Output** is the informational output of the functionality. It is not applicable for all functionalities.

- **Actions** are the actions that take place when the functionality is in use and that affect other system functionalities or stakeholders. Not applicable for all functionalities.

By following this breakdown for each functional specification identified to satisfy the user requirements we can enable system designers and developers better understand the interactions as well as the associated non-functional requirements.
By this analysis, the functional specifications are decomposed and it is possible to provide the first summarised view of the system in terms of generic input/output specifications as well as of the UI structure. It is presented below as a hierarchy of system views:

![System Views Hierarchy](image)

Figure 3: System Views Hierarchy

The Log in View which is the root of all views is a straightforward functionality, especially when data privacy issues are involved. The Log in functionality is related to Authorization, Authentication and Accounting.

Figure 3 depicts the fact that the main functionality of the platform revolves around a schedule of tasks set up by its users whose profiles are registered with the system, of course containing different granularity of detail depending the on the user type. These tasks are assignments of any of the following types:

- Set/View Mental Evaluation Tests
- Set/View Monitored Values
- Set/View Generic Tasks (as free text)

Through a shared calendar, the system users can assign these types of tasks to other users (including themselves). Results of the first two types of assignments may generate new objects such as graphs and indications on identified patterns. This rationale demonstrates the need for the system to create solid dependencies between users in order to protect privacy but also to be more effective. In other words, the system must avoid allowing any clinician to set assignments to any carer or patient unless of course the clinician is the responsible one.

Extra to this core functionality, ALADDIN has ports for supporting external social networking activities especially for the patients and carers which is however linked to its central authorisation, authentication and accounting mechanism so as to maintain and dynamically handle the abovementioned dependencies.

Among the Inputs and Outputs of the system there are some entities that are crucial in the analysis. These are data sets or structures that their content may change dynamically and can be found in the following table:

<table>
<thead>
<tr>
<th>Entities</th>
<th>Updating Frequency</th>
<th>Lifetime</th>
<th>Consists of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-demographic and Clinical Features</td>
<td>Rarely</td>
<td>Until deleted</td>
<td>Personal details (name, DoB, PoB, etc) medication record</td>
</tr>
<tr>
<td>Physical Measurements</td>
<td>Daily, Weekly, Monthly (depends on monitoring parameter)</td>
<td>9-month</td>
<td>Blood pressure, Weight and Actigraphic Evaluations</td>
</tr>
<tr>
<td>Notification Options</td>
<td>Rarely</td>
<td>Until deleted</td>
<td>Phone calls, SMS, email</td>
</tr>
<tr>
<td>Patient or Carer Tests (Score)</td>
<td>Daily, Weekly, Monthly</td>
<td>9-month</td>
<td>Memory and Behaviour Problem Checklist (MBPC), Aggressiveness</td>
</tr>
</tbody>
</table>

### Table 1: ALADDIN native data concepts

5. **SYSTEM SERVICES**

After having analysed user requirements and functional specifications, a first outline of the specific services the ALADDIN platform will offer is now complete and concise. More analytically the envisaged services the ALADDIN platform will provide are described as follows.

#### 5.1 Evaluation of the Quality of Sleep and Physical Activity of the Patient

With this evaluation it is possible to assess the quality of sleep and improve any existing sleep disorder using pharmacological or non pharmacological means. We can also obtain information about the type of physical activity involved: if the patient is restless, has abnormal motor behaviour, etc [2], [9]. As for the registry of falls, as well as evaluating consequences and carrying out the pertinent response and treatment, we can put into place prevention measures for them and thus avoid new falls and their results.

#### 5.2 Evaluation of General Health Aspects and the Nutritional State of the Patient

Through the use of the system, body weight, blood pressure, and cardiac frequency can be monitored. Weight and blood pressure are entered manually into the system, while actigraphic data will be automatically retrieved from the actigraphic sensors. These data can be monitored weekly or as often as necessary. They are received and evaluated at the clinical site and allow us to monitor the general status of health of the patient, their nutritional state, and can also give us information on the adverse effects of medication, such as acetylcholinesterase inhibitors used in the treatment of Alzheimer’s disease and which can provoke the lowering of cardiac frequency or syncope, amongst other adverse effects. Neuroleptic medication used in the treatment of psychiatric or behavioural symptoms in patients with dementia can cause arterial hypotension or falls.

#### 5.3 Monitoring of the Patients Cognitive Functions and Cognitive Stimulation Techniques

The fundamental objective is to delay the cognitive decline of the patient as much as possible. The system will be used as a tool for the cognitive assessment of patients through specific questions. Furthermore, cognitive stimulation techniques will be carried out. Work will be done in the domains of patient temporal and spatial orientation.

With the help of the carer, the patient will work at home using the monitor in a Web environment that will allow him or her to access the cognitive exercises, the specialist personnel at the clinical site being able to monitor the effects. When necessary, the specialist personnel will be able to contact the carer/patient using the phone.

#### 5.4 Detection and Control of Psychiatric and Behavioural Symptoms (PBS) of the Patient

The carer will reply to some basic specific questions based on The Memory and Behaviour Problem Checklist (MBPC) [3]; the carer will access the questionnaire through the home monitor; the
connection with the clinical site will allow the detection of psychiatric problems and behavioural problems. Upon detecting a problem, the specialised personnel will contact the carer, when necessary, by phone

5.5 Monitoring of Daily Activities, Physical and Social Activity and Mental Health of the Patient

The carer will reply to some basic specific questions based on The Memory and Behaviour Problem Checklist (MBPC), accessing the questionnaire through the home monitor, the same as for the PBS. The connection to the clinical site will allow the detection of difficulties and problems that arise.[9]

5.6 Control of Side Effects and Adherence to Pharmacological Treatment of the Patient

The carer will reply to some basic specific questions based on The Memory and Behaviour Problem Checklist (MBPC), accessing the questionnaire through the home monitor, the same as for the PBS. The connection to the clinical site will allow the detection of side effects related to pharmacological treatment. The specialist personnel will contact the patient’s home as necessary.

5.7 Register of the Use of Resources by the Patient

One of the objectives of ALADDIN project is to avoid visits to emergency services, non-programmed medical visits, hospital admission or internment in Residential Centres or in Long Term Care Units. For this reason, the Web environment will be used during the entirety of the pilot operation and will be evaluated against the above set objectives.

5.8 Control and Monitoring of the Carer Workload

The family member who serves as carer of a patient with dementia has to make a constant effort in caring for their relative. For this reason, it is necessary to provide the carers with the necessary support in order to help them in this task and reduce their workload. Additionally to giving support to the carer through the home-based clinical monitoring of the patient and helping to solve problems that occur, the level of work overload of the carer will be monitored using the Zarit [4] scale (a questionnaire measuring the work overload of the carer). The carer will access and respond to the questionnaire periodically by means of the home monitor.

5.9 Monitoring of the Quality of Life of the Carer

One of the main objectives of the ALADDIN project is the improvement of the quality of life of the carer. For this reason, it is vital to have access to an instrument that allows the measurement of said quality of life. Therefore, the carer will periodically respond to the Quality of Life Scale (QOLS) [5] questionnaire by means of the Web environment.

5.10 Monitoring of the Mental Health of the carer

Another main objective of the project is to monitor the mental health of the carer, given that caring for a demented patient can often lead to disorders of a psychiatric nature, such as depression and anxiety, amongst others [6]. This can have repercussions on their quality of life and may lead to the institutionalization of the patient. So, the carer will periodically respond to a questionnaire that they can access by means of the Web environment, in order for the specialised personnel to be able to detect and treat emotional disorders of the carer.

5.11 Expected Results

The continuous use of this information, as well as the progressive adaptation of personnel, welfare, patients and carers to this type of system, should allow in the near future:

- Identification of the data sets needed to assess risks of deterioration of the patient’s condition as well as of the carer’s condition.
- Validation of the tools for self-management of the disease.
- Validation of the effect of social networking utilities on both the patients and their carers.

The validation and assessment of these methodologies and tools will provide input regarding feasible approaches to cope with:

- Delayed institutionalization of demented patients, keeping them safe in their home environment and assisting them in their daily activities.
- Promotion of the patient’s cognitive and physical activity in order to delay mental and physical decline with web-based activities.
- Relieving the stress of the carers.
- Early detection of behavioural disturbances and their evaluation from the clinical point of view in order to start and monitor an appropriate drug therapy.
- Remote evaluation of adverse effects of medication.

6. Conclusion

The ALADDIN service will bring forward several significant benefits for patients, carers and clinicians alike.

The main benefit for patients, expected from the use of the ALADDIN service will be the prevention of emergencies due to worsening in symptomatology, cognitive decline, behavioural aspects, overall severity and medication side effects.

Primary and secondary outcomes to be evaluated in the pilot study will be:

- For patients:
  - primary outcome: emergency contacts (urgent outpatient services, telephone call, emergency room visits, visits to GP, or nurse practitioners or neurologist or gerontologist…);
  - secondary outcomes: clinical variables, cost evaluations, quality of life.
- For caregivers:
  - primary outcome: carer burden;
  - secondary outcome: quality of life.
- For clinicians:
  - primary outcome: individualised time point for the clinical management of the patients
  - secondary outcome: reduction of workload, efficiency improvement.

An additional secondary outcome will be cost evaluations since an important aim of home-care is to reduce costs. Therefore we will monitor both direct (such as costs for in and outpatients activities and treatments) and indirect costs (changes of productivity of family members, changes in time spent travelling for doctor's appointments, cost of travelling and cost of reduced contact with health professionals).

The early detection of these clinical warnings leads to the avoidance of “critical” situations, a lesser burden for the caregiver.
and tangible improvement in quality of life and a better long term outcome for both the caregiver and the patient.

7. ACKNOWLEDGEMENTS
ALADDIN consortium consists of 8 partners, namely the Institute of Communication & Computer Systems (GR), Fraunhofer FOKUS (DE), the University of Bologna (IT), the Psychiatric Hospital of Attica (GR), the National Hospital for Neurology and Neurosurgery (UK), Badalona Serveis Assistencials (ES), ATOS Origin (ES) and AETHIA S.r.l (IT). ALADDIN is funded under the first call of AAL Joint Programme, AAL-2008-1.

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