Information and Communication Technologies applied to Mental Health

Proceedings of the 1st Workshop on ICT applied to Mental Health

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Preface

Mental health is a vital aspect for the optimal development and quality of life of individuals and society. Mental disorders, including low to severe disorders, affect the day to day life of patients and people involved in their environment, such as family, friends and colleagues. Currently, information technology allows developing Personal Health Systems to help in the prevention and treatment of Mood Disorders, such as anxiety and depression.

This book compiles the contributions presented during the 1st Workshop on ICT applied to Mental Health, where researchers from the Help4Mood and OPTIMI projects were joined to share and discuss their experience and vision about the development, use and business models of Personal Health Systems applied to Mental Health in a multidisciplinary forum.

The aim of Help4Mood (www.help4mood.info) is to develop a system that will help people with major depression to recover in their own home. The Help4Mood system is designed to be used together with other forms of therapy, such as self-help, counselling, or medication. Help4Mood has three main components: 1) a personal monitoring system that keeps track of important aspects of behaviour such as sleep or activity levels, 2) an interactive virtual agent who asks patients about their health and well-being, provides a portal to trusted health information, and feeds back information collected through monitoring and questionnaires and 3) a decision support system that tailors each session with the virtual agent to the individual needs of the person with depression and that supports clinicians in interpreting the data collected through the virtual agent and the personal monitoring system.

OPTIMI (www.optimiproject.eu) is focused on those people under risk of depression because of continued stress. The project has set itself two goals: first, the development of new tools to monitor coping behaviour in individuals exposed to high levels of stress; second, the development of online interventions to improve this behaviour and reduce the incidence of depression.

To achieve its first goal, OPTIMI developed technology-based tools to monitor the physiological state and the cognitive, motor and verbal behaviour of high risk individuals over an extended period of time and to detect changes associated with stress, poor coping and depression. These tools included wearable EEG and ECG sensors to detect subjects' physiological and cognitive state, accelerometers to characterize their physical activity, and voice analysis to detect signs of depression. These automated measurements were complemented with electronic diaries, in which subjects report their own behaviours and the stressful situations to which they were exposed. All participants were regularly assessed by a psychologist, who used standardized instruments to detect stress, poor coping and depression. A few were also asked to wear implanted devices which check levels of cortisol in the blood, an objective physiological correlate of stress. The project used machine learning to identify patterns in the behavioural and physiological data that predict the findings from the psychologist and the cortisol measurements.

To achieve its second goal, OPTIMI adapted two existing systems, already used to provide online CBT treatment for mental disorders. The project tested the treatment systems in targeting individuals at high risk of exposure to chronic or acute stress. Examples include persons with personal responsibility for the long term care of elderly or disabled people, individuals (especially unemployed people) in situations of acute financial stress, workers in emergency services and students preparing for important examinations. Ongoing monitoring with the OPTIMI tools will make it possible to assess the effectiveness of the treatment and to optimize the treatment cycle.

We have structured the book following the four general topics studied by both European projects: 1) Clinical use of ICT in Mental Health, 2) Sensors and Monitoring, 3) Human Computer Interaction and Virtual Agents, and 4) Business models for the ICT applied to mental health.

The first topic about clinical use of ICT in Mental Health starts with the work presented by Rey & Alcañiz, who review the bases and application of Virtual reality for the treatment of psychological disorders. They also discuss the possible contributions of serious games to the psychological treatments. As a conclusion they state that “VR therapies of the future will be based on the combined use of several technologies, including distributed VR, augmented reality, natural interfaces, virtual agents and serious games”.

Serrano et al. analyse, using qualitative methodologies, the physicians and patients’ perceptions about the use of a care system such as the Help4Mood in Spain; and determine by quantitative methods which, among a series of different avatars, was the one that was perceived as the most acceptable. All groups agreed that the avatar should not replace the doctor's visit. Psychiatrists proposed that the avatar would provide more specific information on the evolution, and family physicians requested continuous and very detailed information. Three of the 11 avatars shown in the survey were the highest rated. The characteristics of the avatars were not associated with age, gender or background of depressed patients.

The next part of the book is focused on the data acquisition of the patients’ activity by sensors. Ramos-Castro et al. present an *Unobtrusive Activity Measurement in Patients with Depression* developed in the Personal Monitoring Systems of the Help4Mood Project. They establish the user requirements extracted from the user groups of their project and describe the development and testing of an actigraphy sensor inside a wrist watch or a pocket device, the use or smartphones and the installation of a sleep sensor, all of them based on the acquisition of acceleration data. Besides, Dennis Majoe et al. analyse the technologies developed and the design choices in OPTIMI that lead towards a simple, efficient and energy aware data transfer protocol and RF data communication system for the smart wearable body sensors. The most active topic of research in both projects has been the Human Computer Interaction and Virtual Agents. Wolters and Matheson describe the Help4Mood's overall architecture and integration, and outline the implications that preparing for deployment in the health service has had for design and implementation.

One of the expected breakthroughs in the information society is the way we interact with computers. When users are patients recovering from a mental problem, it is hardly convenient to interact with the patient in an appropriate emotional manner. Martinez-Miranda et al. describe the implementation of the cognitive-emotional module based on the cognitive appraisal theory of emotions to generate the emotions, and appropriate emotional reactions and action tendencies of the Help4Mood Virtual Agent. Moreover, they propose to develop a new cognitive-emotional architecture to generate clinical empathy based on the extension of the current ones limited to natural empathy. Continuing the use of Virtual Agents in patients’ treatment, Ferrini and Albertini explains the Graphical development of the Help4Mood’s Virtual Agent. They provide technical details of both the design and the implementation of the VA. Regarding the design, an iterative approach based on the users (both doctors and patients) was followed. The final result is fully integrated with the rest of the Help4Mood system, such as the cognitive-emotional model and it provides a real-time render. Baños et al. study in their work how ICTs can be useful to deliver treatments through the Internet to allow effective therapeutic services enhancing the possibility to reach anyone who needs it. Mira et al. review the importance of designing tools to identify and assist people at risk. They present *Smiling is fun,* which is a cognitive-behavioural treatment self-applied program via Internet that tries to help people in the prevention of depression and anxiety symptoms, and in the promotion of emotion regulation. Their preliminary evaluation of the software from two participants shows a high level of satisfaction, and acceptance.

Another important aspect of these technologies is to make their use sustainable and their potential to foster European industry. The European project OPTIMI, in its last year of implementation has developed a justified business model for their final solutions. Paniagua et al. analyse the potential market relative to the products developed by the OPTIMI consortium. They started identifying specific markets and scenarios for the commercialization of the OPTIMI outcomes carrying out a cost-benefit analysis, presented in the form of a brief SWOT analysis. Finally, they identified the critical factors likely to determine purchasing decisions. The conclusion of the analysis is that the most interesting scenarios for OPTIMI are monitoring and treating patients who have already suffered a Severe Depressive Episode, sales to Employee Assistance Programs (EAP) providing services to employees at high risk of depression (police, firemen, other emergency workers, call-centre operators etc.), and sales to EAP providing services to elite employees (managers etc.).

Preface

This book tries to summarize the scientific technical view of the research carried out in Europe regarding the use of ICT for Mental Health. Both Help4Mood and OPTIMI Project are pioneers in the use of cognitive appraisal theories and cognitive-behavioural treatments in combination with computational technologies, such as virtual reality, serious games, virtual agents, and cognitive-emotional models.

The results of both European projects draw together the computational treatment for mental health to the clinical practices. Considering the challenges of disseminating evidence-based treatment programs and the thousands of people that need help, this technology is a good opportunity to reach people in need when they need it.

Patricia Paniagua-Paniagua — Juan M Garcia-Gómez

everis, OPTIMI — IBIME-UPV, Help4Mood

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Clinical use of ICT in Mental Health

Virtual Reality and Serious Games: Applications in Mental Health

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Abstract—**Mental health is profiting in recent years from technological advances in fields such as virtual reality. In fact, this technology began to be used in the 90s for the treatment of psychological disorders, specifically, for phobia treatment. Virtual reality is used in these contexts to expose the patient deliberately and in a controlled way to the feared stimuli. It has been shown that the patient anxiety can be attenuated in these settings. Several anxiety disorders have been treated using this technique, including acrophobia, flying phobia, spider phobia, social phobia, and panic disorder and agoraphobia. More recently, adaptive virtual environments for the treatment of more complex disorders such as post-traumatic stress disorder have also been developed. However, even if virtual reality is receiving special attention from the clinical psychology field, there are other technologies that are also being evaluated for psychological treatments. For example, techniques such as serious games are starting to be used. They are games that are used for training or education, and that are designed to work in personal computers or videogame consoles. In the present work, main applications of those technologies in mental health will be reviewed.**

I. Introduction

Virtual Reality (VR) is a technology that allows us to see, hear and feel in a three-dimensional world and interact with it. A virtual environment (VE) can be defined as a world generated with interactive graphics with three-dimensional models, which is combined with an immersive visualization technology and devices for a direct manipulation of the world [1].

The novelty of VR technology is its capability of immersion and interaction. Immersion is obtained by means of specific devices. That way, the user is surrounded by the virtual world and feels that he/she is physically present in the virtual world. The interaction appears because VR is not just a passive visualization of the graphical representation. Instead, the user can interact with the virtual world in real time. There are many kinds of systems that can be considered virtual reality, from videogame consoles that are available for the general public to advanced visualization systems which are only available for big companies and research institutions.

VR has been applied for many years for the treatment of psychological disorders [2]. The first disorders that were treated applying this kind of technology were phobias. All of us feel anxiety or fear in specific moments of our lives. The fear can be defined as a sensation that indicates that something bad is about to happen, and it is usually accompanied by symptoms such as excessive perspiration, tachycardia, trembling, etc. When this fear is not justified by the presence of real danger of threats, or by a rational cause, and when it comes accompanied by a systematic avoidance of the situations that cause it, we are facing a phobia.

In the cognitive-behavioural school, the following techniques are usually applied for phobia treatment:

- "In imagination" or "in vivo" exposure. In the first case, the patient is trained to evoke with mental images the stimuli that provoke the anxiety. In the second one, the patient really experiments those stimuli in prepared situations. The exposure has to be structured, progressive and systematic. The patient has to face step by step the feared situation, so the anxiety will be lower each time, and the self-efficacy personal sensation will grow in each of the situations.
- Cognitive therapy. Patients are taught new abilities to react in a different way to the situations that cause the panic and anxiety attacks. Patients learn to understand how their patterns of thinking contribute to the symptoms. Changing their pattern of thinking can help them to reduce or eliminate their symptoms.

VR can help in the first kind of technique, as long as it can generate the stimuli that provoke anxiety in the patient, showing them in a virtual world in which the patient is able to interact.

In the present paper, we will describe the bases of the virtual reality based exposure therapy and describe some application areas where VR has been used for the treatment of psychological disorders. We will finish with a discussion about the future applications of technologies in psychological treatments, focusing specially on the use of serious games in this kind of applications.

II. Virtual Reality for the Treatment of Psychological Disorders

A. Bases of the virtual reality based exposure therapy

In VR based exposure therapy, VR is used to expose the patient in an intentional and controlled way to the feared stimuli, allowing that the anxiety is attenuated [2]. If the patient avoids the situation or the feared object, the phobia is reinforced. However, each successive exposure to the situation reduces the anxiety by means of habituation processes. Fig. 1 shows an example of VE that could be used for exposure therapy in patients with acrophobia.

Fig. 1 Virtual Environment that can be used for exposure therapy in patients with acrophobia

VR can be seen as an advanced imagination system [2]: it is a medium as effective as reality to generate emotional responses. That is possible because of the sense of presence, that is, the feeling of the user of being there, in the virtual world, despite being physically in another place and knowing that the virtual world is an interactive experience generated by computer. Presence is one of the concepts more studied in the field of VR, with the objective of understanding the complex psychological mechanisms that are associated to virtual experiences [3].

These characteristics make of VR a reinforcing environment, that is, a special and protected place where patients can explore and act without feeling threatened [4]

. None of the patients' fears can happen really in VR. Having that security, patients can experience feelings that would be impossible for them in the real world. Thus, VR can be considered as an intermediate step between the therapist's office and the real world [5].

It is important to point out that it has been demonstrated that VR based therapies are effective for the treatment of anxiety disorders, as has been confirmed by two different meta-analysis [6], [7].

When compared with traditional treatments, VR presents important advantages. When compared with exposure in imagination, these are the main advantages [8], [9]:

- VR is more immersive, several sensorial modalities can be stimulated, which allows more realism.
- Patients can explore freely, life, feel, experiment sensations. VR is an intermediate step between therapist and real world.
- VR is interactive.
- VR allows the therapist to know in each moment what the patients is visualizing.
- VR avoids that the patients have to rely on their imagination capacity.

When compared with in vivo exposure, these are the main advantages [8], [9]:

- VR allows offering exposure therapy to those people who refuse this technique, because it is too difficult or threatening for them. Furthermore, it is possible to exit from the environment in any moment.
- It offers a greater confidentiality.
- The hierarchy of exposure can be designed specifically.
- It can be repeated as many times as needed until anxiety decreases.
- It can be considerably more economical.
- It is not necessary to wait for the feared situations to occur in the real world, because any situation can be modelled in a VE, increasing the possibilities of training.

Other additional advantages of the use of VR for psychology are the following [10]:

- VR systems can register and measure the behaviour of the patients in the environments. That way, data that would be lost with traditional methods can be analysed.
- Flexibility. VE are flexible and programmable. They allow the therapists to present a great variety of controlled stimuli and to measure and monitor the participant responses.
- Current commercial products for vision, tracking and registration of data from the participant can simulate in an adequate way the complex sensorial effects that are necessary for the psychological studies. Sound and haptic systems are also sufficiently advanced.

As any treatment, the use of VR for psychological therapy has some limitations [11]. Firstly, the development of the VE and the necessary hardware are costly. Secondly, any technological problem that may appear during the therapy can interrupt the session. Furthermore, the therapist has to be specially prepared to use a VR system. Thirdly, the concept of VR can distract patients, who may try to use it as an avoidance method if the simulation has not been adequately prepared. Finally, the kind of sensory stimulation that can be generated is always limited by the possibilities of current technology.

B. Application areas

The idea of using VR for the treatment of psychological disorders was conceived in 1992 in the Human-Computer Interaction Group of the Clark Atlanta University [12, 13], and, since them, applications have been developed quickly. The technique has been successfully applied for the treatment of different anxiety disorders [6] [14].

One of the first disorders to be treated with VR was acrophobia [15-17], in the Clark Atlanta University. The scenario consisted of a building with an exterior elevator that could reach different heights from which the patient could go to a balcony and have a look. After 8 sessions, the patient could feel relaxed even in a height equivalent to a floor 15.

VR for the treatment of other phobias such us flying phobia [18-27], small animals' phobia [28] and social phobia [29-31], including also tele-psychology treatments [32], [33], has also been evaluated with successful results.

Other disorders in which VR based treatments have been applied include panic disorder and agoraphobia, post-traumatic stress disorder (PTSD) and eating disorders.

The environments for treating agoraphobia were designed with the objective of exposing the people to the most feared situations in this kind of patients [34-36]. Environments that also simulated physical sensations of patients during panic attacks have also been evaluated, showing that the use of this technique can be useful both in short and long term results [4].

Regarding the use of VR for PTSD treatment, most of the VE designed up to now have been developed specifically for a kind of traumatic event, following a similar approach to the previous studies with phobias, in which the VE were designed specifically for each kind of phobia. For example, VE have been designed for war veterans from Vietnam [37], 11th September victims [38] and Iraq combatants [39], [40], between others.

However, another approach has been evaluated, consisting on the use of a generic environment that admits a personalization depending on the specific trauma of each patient. Technically, that supposes a great advantage, because it is not necessary to develop a new environment for each patient. This approach was started in the European Project named EMMA (Engaging Media for Mental Health Applications). The EMMA World used symbols and personalized objects with the goal of provoking and evoking emotional reactions in the patients which could help them in the emotional processing of the trauma, in the context of a secure and protected environment [41]. Results of the validation of the system showed that the behavioural-cognitive therapy with EMMA was as effective as the standard behavioural-cognitive therapy for treating these disorders. Better results in depression measures, social interference and relaxation intensity were obtained in the case of the EMMA world [42]. Fig. 2 and 3 show both appearances that can adopt EMMA World during the experimental sessions under the therapist control.

Finally, eating disorders are a complex category that includes anorexia, bulimia and binge eating disorder. One of the most serious problems in this kind of disorders is the distorted perception of the own corporal image, which has a great influence on the rehabilitation process. This aspect is difficult to evaluate with traditional techniques. However, several proposes with VR have been presented to help in the evaluation and changing of this perception [43-46], with encouraging results.

Fig. 2 Beach of the EMMA World

Fig. 3 Meadows of the EMMA World

III. The Future of Research on Technologies and Psychological Treatments. The Contribution of Serious Games

VR applications for psychological treatments are expanding with force and own identity in the mental health area. That is because VR helps to add, eliminate or highlight details that can help the therapist to develop the work in a better way. VR can provide the patient with a personalized and secure follow-up, as well as with treatments for problems that would be impossible to treat with traditional means.

However, there are other technologies that are starting to be applied in psychological therapy, including persuasive computing [47], ubiquitous computing [48], mobile devices [49], augmented reality [50] and serious games. The term "serious games" is usually applied to games that are used for training, publicity or education, and that have been designed to work in personal computer or videogame consoles. Following Corti definition [51], these games try to apply the possibilities of computer games to maintain the attention of final users with a specific purpose, for example, for acquiring new knowledge or abilities. Similarly to VE used in psychological therapy, serious games allow learners to life situations that would be impossible in the real world for security, cost or time reasons [52].

There are several application areas of serious games: physical activity (exergaming) [53], health education [54], distraction therapy [55], rehabilitation [56], cognitive abilities [57] and, of course, psychological therapy [58].

As we enter in the XXI century, technological advances continue appearing and everything seems to indicate that technologies will have a fundamental role in all the ambits of our life. Advances of computer human interaction will without any doubt have a great influence in the clinical psychology ambit [59]. Everything seems to indicate that VR therapies of the future will be based on the combined use of several technologies, including distributed VR, augmented reality, natural interfaces, virtual agents and serious games.

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E-Mental Health Care: patients' and professionals views on its acceptability

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Abstract— **The Help4Mood (H4M) project aims to support depressive patients at home. The H4M system will track patient's symptoms and provide general or specific health advice. To achieve its goal, it will develop an avatar to interact with patients, and it can explore psychopathologically and try to engage them to the program.**

No previous experience in Spain with this type of methodology in depressed patients has been used, so it is essential to assess how patients will respond to this initiative, but no less important is to analyze the response of family physicians and psychiatrists to it.

The aims of the research presented in this paper was: 1) to explore, using qualitative methodology, physicians and patients' perceptions about the utilization of a care system such as the Help4Mood in Spain; and, 2) to determine, using quantitative methods, which, among a series of different avatars, was the one that was perceived as the most acceptable.

Methods: We used two complementary methodologies. The first was qualitative methodology (1) and the second a cross-sectional study (quantitative methodology). In (1) 3 focus groups were conducted separately, with psychiatrists, family physicians and patients with a history of depression or relatives of patients. The groups were conducted in 2011. The groups were recorded and written notes were taken. A cross sectional study (2) was developed to complement the information about the acceptability and trustfulness of different avatars. A questionnaire was locally developed assessing acceptability and trustfulness of 11 avatars, sociodemographic data, use of new technologies and features of their family doctor.

Results: All groups agreed that the avatar should not replace the doctor's visit. Psychiatrists proposed that the avatar would provide more specific information on the evolution, and family physicians requested continuous and very detailed information. Three of the 11 avatars shown in the survey were the highest rated. The characteristics of the avatars were not associated with age, gender or background of depressed patients.

Conclusion: Spanish general population/patients and physicians value the avatar if it doesn't replace direct contacts at clinical sites. The design of the avatar can influence adequacy and trustfulness.

I. Introduction

Mental disorders are highly prevalent in our society, and major depression is the most common and one of the most incapacitating [1]. Twelvemonth prevalence in Spain have been estimated at 4% [2]-[4], ranging between 3.6% and 9.1% in western societies. Primary Care (PC) is the first healthcare level where depressed patients are attended, and the lifetime and last year prevalence of Major Depression is around 29.91 % and 9.6% in Spain respectively [5]. Nevertheless the treatment received at PC level is not close to clinical guidelines recommendations [6]. An effort needs to be made to increase patients follow up.

As psychopharmacological treatment, psychological interventions have high evidence for being provided. Nevertheless, the high prevalence of the disorder and other structural conditions (distance between patients and health centres, availability of psychological treatments, price of the therapy) promoted the development of different types of psychotherapies provided by different channels. During the last decade the development of new technologies, as well as the widespread use of computers in homes, have made possible the emergence of online psychotherapy. Some of that are Beating the Blues [7], approved by the National Health

Service in UK in 2006, MoodGym [8], and Colour your life [9] which has been described as cost-effective therapies [10]-[12]. Nevertheless, this type of e-health has a problem with engagement. Only almost 40% of patients who initiate this type of therapies will fulfil all the treatment.

The Help4Mood (H4M) consortium, which consists of partners from Scotland, Spain, Romania, and Italy, aims to develop a system for supporting the treatment of people with major unipolar depression in the community. The H4M system consists of three parts: (1) A Personal Monitoring System that collects activity and sleep data; (2) a Virtual Agent that interacts with the patient in short, structured sessions that involve mood checks, speech tasks, games, and simple activities aimed at challenging negative thoughts; (3) a Decision Support System that controls the interaction between user and Virtual Agent, extracts relevant information from the monitoring data, and produces reports for clinicians.

The H4M research is aimed primarily at improving the monitoring of patients with major depression. An interactive system is being developed, in tandem with physical sensors, which will provide clinicians with detailed information on a range of mental health factors assessed by the interactions with a virtual agent alongside measurements of physical activity and sleep patterns.

It is important that well-designed surveys and qualitative studies are included alongside trials to determine levels and determinants of patient acceptability [13]. When implementing an intervention it is very important to know from the beginning the opinion of the future clients, in order to improve the probability of success. Using cross sectional questionnaires we can reach an important quantity of people allowing investigators to focus in their preferences, while using qualitative methodology we can know their opinion in deep. The H4M consortium develops a study to know the opinion of professionals and possible future clients in all the participating countries. The results of this study can be read elsewhere [14]. The present research wanted to emphasize the opinion of Spanish participants taking into account the Spanish context. The aims of this paper was: 1) to explore, using qualitative methodology, physicians and patients' perceptions about the utilisation of a care system such as the H4M; and, 2) to determine, using quantitative methods, which, among a series of different avatars, was the one that was perceived as the most acceptable. is a template based on a IEEE one. An electronic copy can be downloaded from the conference website. For questions on paper guidelines, please contact the conference secretariat as indicated on the conference website. Information about final paper submission is available from the conference website.

II. METHODS

To answer the objectives presented two different studies were developed in Spain: 1) a descriptive-exploratory qualitative study using focus groups; and 2) a cross sectional study where participants from five different locations were interviewed (general population, Primary Care centres, General Hospital, specific Internal Medicine Units, and Acute Psychiatric Units).

A. *Qualitative study*

A descriptive-exploratory qualitative study using focus groups was undertaken. The study population comprised psychiatrists (A), general practitioners (B) and general population with a past experience related with depressive disorders (C). Three focus groups were performed in March-April 2011. At the beginning of all the groups one of the researchers explained to the participants the H4M project and the debate was opened. The focus groups were audiorecorded and the researchers took written notes all through the focus group. Participants were asked for written consent to participate and to be recorded. Participants received a monetary reward (25€) for participating in the study.

Information about participants' beliefs and attitude about the H4M project was extracted by listening to the audiorecorded interviews and by reading and rereading the researchers' notes.

1. Psychiatrists were asked to participate in their place of work, which is the same as ASB and LB. All of them have experience in treating depressed patients, as inpatients and outpatients (emergency units and community services). The group comprised 6 psychiatrists, 5 were Spanish and always worked in Spain and one was Italian but worked in Spain since 2010. It was conducted in their place of work (Parc Sanitari Sant Joan de Déu, located in Sant Boi de Llobregat, a municipality close to Barcelona), and was guided by ASB and LB. They were voluntarily enrolled to a discussion over 122 minutes.

2. The first centre contacted was one of the 4 GP centres in Sant Boi de Llobregat. GPs were asked to participate using a snowball sampling method. The group was formed by 6 GPs and was conducted in their GP centre, being guided by one pharmacists (MR) and one psychologist (AF) with experience in qualitative methodology. The discussion takes 67 minutes.

3. The patients' group was performed in their GP centre. GPs were asked to approach patients with a past experience with depression and invite them to participate. Also, a snowball sampling was used and patients who had agree to participate provided access to other participants that fulfilled our sampling criteria. The patients/general population focus group comprised 11 participants who had experienced depression in the past or who had lived with a person suffering depression. The focus group was conducted in a meeting room in a primary care health centre in Sant Boi de Llobregat. The group was guided by MR and AF.

B. *Cross-sectional study*

A cross sectional study was developed to complement the information about the acceptability and trustfulness of 11 different avatars. A questionnaire was locally developed assessing sociodemographic data, use of new technologies and features of their family doctor. Participants were assessed face to face by an interviewer using a paper and pencil questionnaire. This questionnaire includes 11 portraits of different avatars which had been taken from websites (table 1).

Avatar images ranged from some like cartoons and others much more realistic, with different landscapes behind. Avatars were presented in 5 different orders trying to avoid any "order of presentation" bias.

Besides every avatar portrait, two sentences were written. First "I would accept that this avatar give me advice and ask me about my health problems". Patients assessed in a 0 to 10 likert scale, where 0 was "totally disagree" and 10 "totally agree". And second: "Value the degree of trustfulness that this image conveys to you". Again, participants valued in a likert scale where 0 was "none" and 10 was "all".

Enrolment of participants: patients included in the cross-sectional survey were from the same health area (Sant Boi de Llobregat). Patients were asked to participate in different health services in order to capture different sensibilities. None participant included in a focus group was later assessed at the cross sectional study. All participants signed an informed consent before participation.

Statistical analysis: mean acceptability and trustfulness of each of the avatars was calculated. Pairwise comparisons of the different avatars were assessed using the Bonferroni method of analysis. Also, we assessed which sociodemographic characteristics of the participant or physician correlated with the choice of the avatars using regression models.

III. RESULTS

A. Qualitative study

Common ideas obtained from the 3 groups included that the avatar has to be complementary to the usual treatment, not replacing visits with the physician; and that it has to be flexible, adapted to patient's severity of symptoms.

In the following paragraphs, specific comments of every group are presented.

1. Psychiatrists' focus group.

The general opinion about the project was that it could help GPs to improve diagnose, and that could be helpful to detect relapses early. They also suggest having technical support (in case something had broken or doesn't run). One negative idea was that it could be too much for people suffering lower depression, because the H4M system could frighten patients as seen them so monitorized.

When asked about which measures would provide the system to the mental health professional, some of them find helpful to know parameters such as substance abuse, physical inactivity, sleep pattern, adherence to treatment, intake, tone, fluency and voice modulation; cognitive functions; suicide ideation; facial expression; heart rate, temperature, blood pressure and social contacts. They also asked about a summary of this information, including alarms in case the patient is worsening.

Main ideas about what the avatar should do include an evaluation of risk suicide, but a debate was generated about which health professional should be informed. They agree with an avatar providing general counselling about sleep hygiene, healthy intake habits, healthy behaviours (exercise…), psychoeducation about depression, about the treatment and secondary effects and how to deal with them.

2. General practitioner's group.

The general opinion about the project was that it would be useful for patients who don't want other therapies or if the resources are scarce. They suggest also the necessity of having a health professional behind the system controlling or filtering the information. Thinking about patients' interaction, they thought the system need to be simple, allowing everybody to interact with it (including people not used to use computers). In order to increase usability they suggest incorporating a voice recognition system, allowing patients to interact without typing. In order to increase engagement, they suggest the system need to be customizable and should send to patients motivating prompts. On the other side, they thought the avatar could be negative because of diminishing social contacts, or because of stigmatization when it is used as a tool for prevent depression. [GP1] "it could be negative because it could remember the patient he/she had a depression in the past". Anyway, they found it could be useful to maintain the avatar running if the patient wants to connect again. Lastly, they suggest that if the H4M system is going to be used as a preventive tool, it has to be financed by the patient, not by the National Health Service.

When discussing about the measures the avatar should take or the way they should be taken they found that it would be useful to have information about the patient's behaviour outside the clinical site: which conversations have with the avatar, how many time they spend at bed, high weigh changes, adherence to treatment, heart rate, hygienic habits, and emotional state. They wanted this information very summarised because of the scarce time available during the daily clinic, and the frequency of delivery has to take into account depression's severity. [GP2] "If the patient is getting worst, I'd like to have the information more often than when is going well". Risk of suicide was also included as a measure, but they prefer this information being delivered to a psychiatrist directly [GP3] "We don't know how to deal with severe suicide ideation, so it could be better to inform the psychiatrist directly".

Lastly, they discuss about what the avatar should do. One idea was that the avatar should provide positive messages in order to encourage treatment adherence by a positive follow-up. Another possibility was to allow a chat among patients with or without an expert or professional guidance. Some GPs thought that a professional would be needed in order to control the chat. At the end of the discussion, one GP suggest the probability to include music-therapy or neuroliguistic programation.

C. Patients' group.

Patients had doubts about the necessity of using this technology/program when you are not living alone. Furthermore, they were worried about who is going to cover the expenses of the service and were not willing to accept that it replaced the physician. They also had doubts about the capability of the system to be empathic or to detect suicide. [Patient 1] "How can an avatar detect suicide if there are physicians who couldn't detect it in a face to face interview? And more, if someone wants to commit suicide, no one could impede it". Patients also thought that could be negative because of creating addiction to the system and diminishing social life. On the other way, they found useful the possibility to detect mood deterioration and then make and advise to the health professional. And also some of them found interesting the program when living with someone, because their family could supervise the exercises or the completion of them.

When talking about which measures they would allow to be taken by the system, they unanimously the need of having the control. Also, the system needs to be inconspicuous, in order to don't produce interferences or increase the stigma. They also express doubts about the time the GP have to supervise everything, and they prefer the system informs mental health professionals, psychiatrists or psychologists.

The last part of the discussion goes through what the avatar should do for them. Participants thought the avatar should provide positive advice and remainders about health ("take your pill", "you have an appointment with your physician"…) and had to straight when communicating, not only saying what the patient expected to hear. Lastly, one of them suggests the television would be a good platform, keeping mobile phones platforms for those with skills in technology. They also wanted to customize the avatar, at least the gender, and one participant wanted an avatar similar to her GP.

B. *Cross-sectional survey*

At the cross-sectional survey, 95 health care consultantees were assessed. From those, 67 (71%) were female, with a mean age of 39.76 years. A 25.53% suffer or had suffered a major depression in the past. Sociodemographic variables and place of recruitment are presented in table 2. Eighty-three participants usually use computers and, from those, 61 (73.49%) use it daily. From the 83 computer users, 75 (94.36%) feel comfortable/confident and 63 (75.90%) never or rarely feel frustrated when using it. Only 37 (38.95%) of 95 assessed participants have a smartphone with internet. From those, 29 (82.86%) use the smartphone every day, 32 (88.89%) feels comfortable/confident and 29 (80.55%) never or rarely feel frustrated when using their smartphone. Cross-sectional participants' use of new technologies is presented in table 3.

TABLE I

AVATARS PRESENTED AT THE CROSS-SECTIONAL SURVEY

Avatar number	Reference	Website
1	Alter Egos	http://www.alteregos.com/
2	Living Actor Cantoche	http://www.cantoche.com/
3	Living Actor Cantoche	http://www.cantoche.com/
4	Living Actor Cantoche	http://www.cantoche.com/
5	Guile 3D Denise	http://guile3d.com/en/
6	Living Actor Cantoche	http://www.cantoche.com/
7	Living Actor Cantoche	http://www.cantoche.com/
8	iClone Reallusion	http://www.reallusion.com/iclone/
9	Crazytalk Reallusion	http://www.reallusion.com/crazytalk
10	Crazytalk Reallusion	http://www.reallusion.com/crazytalk
11	Living Actor Cantoche	http://www.cantoche.com/

TABLE II

PLACE OF RECRUITMENT FOR THE CROSS-SECTIONAL STUDY AND PARTICIPANTS' SOCIODEMOGRAPHIC CHARACTERISTICS

Place of recruitment	N	%	Gender (% female)	Mean age (years) (SD)	Past depression %
Primary Care	26	27.37	76.92	36.77 (2.00)	34.62
Inpatient Psychiatric Unit	11	11.58	81.82	43.18 (3.73)	20.00
General Hospital	15	15.79	53.33	42.80 (5.12)	0
Internal Medicine Unit	15	15.79	73.33	44.80 (4.31)	20.00
General Population	28	29.47	67.86	36.52 (2.16)	27.14
Total	95	100	70.53	39.76 (1.45)	25.53

Participants reported that their GPs are mostly women in a mean age between 40 and 55 years old (table 4). Only 5 participants didn't know their GP.

All avatars had mean scores of trustfulness and acceptability between low and medium (between 2.67 to 6.0/10 and 2.9 to 5.9/10, respectively). Two avatars were rated the lowest in trustfulness and acceptability and other one was not accepted because not enough trustfulness.

TABLE III

CROSS-SECTIONAL PARTICIPANTS' USE OF NEW TECHNOLOGIES

Use of new technologies	N (%)
Do you usually use computers? (yes)	83 (87.37)
How often do you use the computer?	
Daily	61 (73.49)
Once or twice a week	15 (18.07)
Once a month	5 (6.02)
Less than once a month	2 (2.41)
Does using the computer, feel comfortable / confident?	
Never	2 (2.41)
Rarely	6 (7.23)
Sometimes	22 (26.51)

Often	53 (63.86)
Always	0
Do you feel frustrated when using the computer?	
Never	40 (48.19)
Rarely	23 (27.71)
Sometimes	16 (19.28)
Often	4 (4.82)
Always	0
Have you got a smartphone with internet? (yes)	37 (38.95)
Which is the frequency you use your smartphone?	
Every day	29 (82.86)
Once or twice a week	3 (8.57)
Once a month	1 (2.86)
Less than once a month	2 (5.71)
Do you feel comfortable / confident when using your smartphone?	
Never	2 (5.56)
Rarely	1 (2.78)
Sometimes	1 (2.78)
Often	6 (16.67)
Always	26 (72.22)
Do you feel frustrated when using your smartphone?	
Never	22 (61.11)
Rarely	7 (19.44)
Sometimes	7 (19.44)
Often	0
Always	0

TABLE IV

CROSS-SECTIONAL PARTICIPANTS' GP FEATURES

How is your GP?	**N (%)**
Women	56 (85.95)
Age	
25-40	38 (40.43)
40-55	43 (45.75)
>55	8 (5.32)
I do not know my GP	5 (5.26)

The results in acceptability and trustfulness are presented in Table 5. As can be seen, 3 avatars are the most accepted by participants, with a punctuation over 5/10.

TABLE V

MEAN ACCEPTABILITY AND TRUSTFULNESS OF ALL AVATARS EVALUATED AT THE CROSS-SECTIONAL SURVEY (ORDERED FROM THE HIGHEST TO THE LOWEST)

	ACCEPTABILITY		**TRUSTFULNESS**	
avatar	**mean**	**SD**	**mean**	**SD**
7	5.92	2.76	6.03	2.85
3	5.90	2.93	5.95	2.90
11	5.57	2.85	5.70	2.93
2	4.58	2.84	4.73	2.83
6	4.62	3.14	4.56	3.18
4	4.27	2.79	4.28	2.82
1	3.95	2.96	3.90	3.01
5	3.79	2.88	3.66	2.88
8	3.58	2.79	3.34	2.78
10	3.00	2.79	2.77	2.89
9	2.93	2.77	2.67	2.64

When analysing if any characteristic of the participant (sociodemographic characteristics, history of past or present major depression) was related to the preferences, none individual factor was found to have statistical significance.

IV. DISCUSSION

The main idea that resumes Spanish professionals, patients and general population's opinion are two. The first was the avatar has to be a complement in their treatment, non substituting the visits with the physician; and the second means that the system has to be so flexible to adapt the intensity of the follow-up and the messages to their health status.

Patients' preferences include simplicity in use, an empathic avatar, the ability to detect relapses or worsening to inform their GP, keeping the control about the system in their hands (when switch on or off), customization and positive prompts to motivate them with their treatment. Patients also were aware about the possibility of this system to reduce social contacts, or detect suicide ideation.

Patients' suggestions about positive prompts are in line with previous studies as Donkin et al. who pointed out that "to overcome barriers, participants needed external motivators in the forms of reminders of their reasons for engagement and demonstrations of the benefits of completing the program (eg, changing symptom profiles)"[15]. Otherwise, their awareness about social isolation should be taken with caution because there are studies, as Deprexis, proving that online therapies increase social functioning [16].

GP's preferences include the ability to detect suicide ideation (but informing the mental health professional) and/or other symptoms (time spent in bed, weigh changes, hygienic habits, increased heart rate), the ability to detect non-adherence to treatment and a register of patient's emotional state. They suggest that could be interesting to allow chatting but in three different models (only patients, with a "professional patient" managing the group or with a health professional managing the chat). Some previous experiences of open chats offered to patients suffering different illnesses or mental disorders can be found in different websites, and not always can be safely guided by a health professional. In line with this, there is an open forum for depressed patients (http://www.forumclinic.org/depresion/foro) which has, in September 2012, 1,364 open themes and more than 150,000 visits. That is difficulty manageable for a health professional. The implementation of a chat at the H4M system should be designed with some restrictions if it is wanted to be guided by a health professional as some GP proposed.

Psychiatrists' preferences include the monitorization of different physical parameters (activity, intake, sleep pattern, facial expression, voice, heart rate, temperature, blood pressure); monitorization of patient's quality of life, cognitive functions, social activity, and also if there is any drug use or abuse. They suggest also that the information about the health state of the patient need to be short and clear, with the possibility to activate any alarm if the patient is worsening. In their opinion, the system should provide information about secondary effects of medication, about healthy patterns of sleep and/or intake and psychoeducation about depression. This is in line with Christensen et al. who compare cognitive behaviour therapy and psychoeducation delivered via the internet, and demonstrate that both are effective in reducing symptoms of depression [17].

All avatars had low punctuations. Three of them were the best punctured, probably because they are not as similar as others to humans, as the uncanny valley theory suggests. This theory, described by Mori in 1970 in relation to humanoid robots, can help us to understand the punctuations of the avatar assessed. This hypothesis states that "as the appearance of a robot is made more human, a human observer's emotional response to the robot will become increasingly positive and empathic, until a point is reached beyond which the response quickly becomes that of strong revulsion. However, as the robot's appearance continues to become less distinguishable from that of a human being, the emotional response becomes positive once more and approaches human-to-human empathy levels". The images presented are not robots, so we can't be sure this theory is the only that explain their punctuations.

When analysing the relation among patient characteristics and avatar trustfulness and acceptability, we cannot find any. This agrees with Cavanagh et al. who describe that no relationship between CCBT treatment acceptability and age was found [18]. This reinforces the idea of including potential patients in the design of the system from the beginning of its design. It is also interesting to mention that pretreatment expectancies predicted CCBT treatment completion but not outcomes. Then, we should compare not only the treatment completion of H4M system among other online therapies, but also the clinical outcomes.

This study helps investigators to adapt the H4M system to patients' and health professional preferences. Forthcoming clinical studies would help to demonstrate its effectiveness and cost-effectiveness.

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Sensors and Monitoring

Unobtrusive Activity Measurement in Patients with Depression: the H4M Approach

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Abstract—**Actigraphy is a potentially valuable source of additional information about patients with depression. However, the use of actigraphy is not standardized and there is a lack of studies in patients with depression treated in the community, which is the objective of Help4Mood (H4M).**

The aim of the Personal Monitoring System (PMS) in H4M is to obtain objective data about the changes and trends of activity patterns during long periods of time, including day activity, sleep time and, if possible, sleep quality. The PMS use unobtrusive methods with minimum cost related with installation of devices at the patient's home.

We analysed the use of actigraphy devices based on wrist-watches, pocked devices and smartphones for daytime activity. In the case of sleep monitoring we developed a battery-powered wireless under-mattress system based on piezoelectric and piezoresistive sensors. Data from the sensors is transferred automatically to a Personal Computer using Bluetooth in the case of the smartphone or a RF link at 868 MHz (using the SimpliciTI protocol from Texas Instruments) for all the other sensors.

Results studying the influence of measurement sites and signal processing stages in the estimation of the day activity are presented. In the case of sleep monitoring, to evaluate the feasibility of using the system as an indicator of sleep quality, results showing the capability of the designed sensor to detect breathing and heart rate are shown.

I. Introduction

In the last calls of EU projects a lot of activity has been focused on telemedicine, home health monitoring, ambient monitoring, independent living, active and healthy ageing [1] etc., all of them requiring home monitors or wearable or portable monitoring systems

It has been shown in previous studies that Actigraphy is a potentially valuable source of additional information about patients with depression [2]. Most of the studies use simple pedometers and actimeters that can give good estimates about amount of walking activity. However, the use of actigraphy is not standardized and there is a lack of studies in patients with depression treated in the community [2], which is the objective of Help4Mood (H4M).

Ambulatory monitoring during long periods (one day or more) is important, especially for rehabilitation medicine because it measures the actual patient activity. Simultaneous monitoring of heart rate response is clinically relevant [3] but the need of electrodes in contact with your skin makes more difficult the inclusion of this technique for monitoring daily activity in normal live.

Wireless technologies and wearable electronics have opened new opportunities to build effective Personal Health Systems that provides unobtrusive physiological and lifestyle monitoring. For example, Hao and Foster [4] provide a comprehensive review of wireless body network sensors for monitoring physical and physiological data.

The objective of Help4Mood project is to facilitate the clinical management of depressed patients through a remote Personal Monitoring System (PMS) and patient indirect interaction components deployed at the patient's home. The main objective of the PMS is to collect a relevant set of parameters to allow the detection of specific behaviour patterns in the patient. Two types of data will be collected:

- Behavioural data including patterns of sleeping, motor activity and speech;
- Subjective data, including brief validated scales to measure mood, cognition and behaviours.

The identified behaviour patterns will then be used in a first instance by the patient indirect interaction component to prompt the patient to carry out potentially helpful activities.

In this paper, we will focus on the part of the PMS system designed to acquire objective data about the changes and trends of activity patterns. The system must be capable of acquiring, during long periods of time with a network of unobtrusive wireless sensors, those behavioural and objective parameters that are useful for assessing the clinical condition of the patient. In particular, day activity, sleep time and, if possible, sleep quality.

II. Personal Monitoring System Requirements

Based on a research of user and clinical requirements it was concluded that the key measurements in Help4Mood are: Activity, Sleep time and Patterns of use of the Help4Mood system. Also, other measurements were considered of research interest as: speech analysis, reaction times using games, sleep quality and physiological measurements during sleep (like heart rate and breathing).

The most important user requirements, defined in the project, which relate to the sensors devices are:

- Sensors must be unobtrusive and non-stigmatising.
- Sensors must be flexible, adaptable and configurable depending on their relevance for the particular patient's symptoms.
- Patients should be able to easily log and track their mood, feelings, and behaviour by interacting with the system and their actual registers.
- Cost should be minimized and patient privacy should be maintained: we must choose sensors that do not need to be installed and/or calibrated in the home by technicians.

Taking into account the objectives of the project and the application the following technical requirements for the sensors were added:

- Wireless or non-contact sensors.
- Minimum user involvement in normal operation, maintenance or in case of malfunctions.
- Wireless Communication range: dimensions of a house (20 m).
- Transfer of data to the PC: opportunistic protocol (from time to time, delay less than 1 day).
- Speed of data transfer optimized for power consumption.

Considering these requirements, different alternatives to implement the sensor and communication network of the PMS where evaluated. A search of commercially available sensors that fulfil all the requirements was unproductive. Most commercial actimetry sensors are not wireless or require manual downloading of data. The most active market is in fitness and in sports gadgets for monitoring caloric consumption by means of accelerometers and/or cardiac rhythm. The main limitation of most of these devices is that battery life is optimized for short periods of activity (up to 8 hours) and needs cyclic recharge.

In the case of bed sensors for monitoring sleep patterns, the low cost systems give only bed time occupancy. There are a few products that measure movement using under-mattress sensors or radar technologies oriented for example to detection of epilepsy episodes. None of them is wireless.

For these reasons, and to shorten the development cycle, semi-custom sensors for actimetry and under-mattress sleep monitoring have been developed. They are based on a System-on-a-Chip (SoC) from Texas Instruments: the ez430. Moreover, software for smartphones using Android has been developed to enable the use of the smartphone as an actimeter.

A major issue when selecting appropriate sensors is that most of them are very different in terms of communications. On one hand, some use proprietary communication systems with proprietary protocols, data formats and interfaces and on the other hand some employ standard communication systems like Bluetooth, Zigbee or Wi-fi. So, integration is one of the main challenges. Moreover, power consumption should be taken into account.

In assessing proprietary solutions, some of these require the sensor to be connected directly to a PC in order to download data, generally using a USB data cable. Thus, they are not wireless, with all the consequences this implies for ease of use, particularly in the Help4Mood context. Others offer real wireless connectivity and provide a USB dongle that must be connected to a PC. In this case, however, it is necessary to assess the provision of Software Development Kits or aids to the developers (semi-custom device), or whether it is mandatory to use the software they provide (closed product).

TABLE 1

WIRELESS COMMUNICATION SOLUTIONS

	SimpliciTI	Bluetooth	Zigbee	Wi-Fi
Low cost	✔	✔	✔	✔
Low power	✔	✔	✔	✖
Data rate	250kbps	1.5Mbps	20kb	54Mb
Integration	✔	✖	✖	✖
Availability	✔	✔	✖	✔

Table I provides an overview of the characteristics of the main communication solutions. While “simpliciTI” is a proprietary wireless protocol, Bluetooth, Zigbee, and Wifi are standard communication systems which are well-supported, and extensively available, with developments toolkits available for almost every platform. Almost all modern laptops and smart phones provide Bluetooth and/or Wifi connectivity. If this is not the case, a USB dongle could be acquired at very low cost. Following the requirements assessment and a broad review of existing options two devices have been selected to capture the patient’s activity patterns. The first one is the eZ-430 Chronos wrist watch developed by Texas Instruments that uses SimpliciTI. Generally, this would be the desired option, but many people do not feel comfortable wearing a watch so another option is also being considered: a smartphone equipped with Bluetooth and an accelerometer sensor.

III. PERSONAL MONITORING SYSTEM OVERVIEW

The components of the PMS are the Sensor Devices and the Wireless Sensor Network that interconnects them, the developed Sensor Devices are:

- For actimetry
  - Wrist Watch
  - Waist (belt) device
  - Pocket (key chain) device
  - Smartphone
- For Sleep monitoring
  - Under mattress pad (the wrist watch could be used also during sleep time)

Figure 1 show the developed devices and how they connect to the PC. All the devices are connected using the TI simpliciTI protocol, except for the smartphone that uses Bluetooth.

Not all the devices have to be used at the same time for all the patients. The idea is that each patient could select one device for actigraphy (watch, waist, pocket or smartphone) and for sleep monitoring to use either the under-mattress sensor or the watch.

The main characteristics of these sensors are:

- Wrist watch actimeter: RF link at 868 MHz, automatic data downloading, battery life more than one month, memory without downloading to the PC up to 5 days storing one activity index per minute.
- Under-mattress sensor: wireless connection and battery powered (no connection to mains required), battery life more than 2 month, detects presence and patient movements in bed.
- Mobile phone: tri-axial accelerometer, tracking of geographical location, stores incoming and outgoing calls (number and duration), battery life up to 12 hours with screen brightness at minimum.

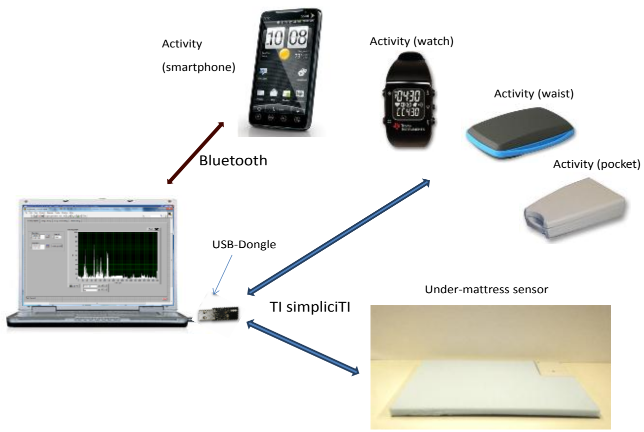

Fig. 1 Temptative components of the Personal Monitoring System. The patient will select the device for actigraphy among four alternatives: smartphone, wrist watch, a belt device or a pocket device that could be used as a key chain

The main specifications of the Personal monitoring System are:

1. Sensors are non-obtrusive and non-stigmatising
2. The actual set of devices must be configurable for each patient. Different sensor devices having the same functionality send the data in the same format
3. Patients are able to easily log and track their recordings
4. Sensors do not need to be installed and/or calibrated in the home by technicians
5. All the devices are Wireless
6. Wireless Communication range. Data transmission between sensors and the patient platform (PC) is possible at short distances in the patient home. The communication range covers a standard flat with a maximum distance of 10 m.
7. Data transfer to the PC is transmitted with a maximum delay of 11 hours if the PC is connected and running the control program without patient intervention
8. The measurement process and the transfer of data between sensors and platforms is fully automatic. This is programed with the task scheduler of windows.
9. Unique identification of the patient. Every sensor has a unique code and is assigned to a patient for a given time.
10. Data structure and format for each monitored parameter. Each monitored parameter has a time stamp, a sensor identifier and the measured value.
11. The platform at the patient site collects data from all the assigned sensors.

IV. Description of Developed Sensors

A. *Actigraphy sensor (Wrist watch or Pocket device)*

We used the Texas Instruments ez430 Chronos watch as the development hardware platform for the actigraphy sensor. We developed programs in C for the microcontroller included in the watch. All technical information on the hardware of the watch can be found in [5]. A version with the watch electronics inside a small plastic box instead of the wrist-watch was produced to be used in the usability test with identical functionality.

The wrist watch was programmed to acquire the three axes with a sampling frequency of 20 Hz. The first step of the signal processing is the high pass filtering of each axis. In this work, we have used a second order Butterworth filter at 1.5 Hz. The next step is to calculate the overall activity computing the time above a threshold (TAT) of 0.04 g for each axis in epochs of 60 seconds. Finally, the three indexes has to be combined to have a unique index of activity. After analysing different approaches [6] we used the most simple, which is to select the maximum TAT over the three axes.

B. *Smartphone*

To assess activity and send data to a PC using a Bluetooth communication we selected an HTC Wildfire Smartphone with Android 2.2. The choice of this phone was justified because it has a lower price (240 € approx.) and has all the required specifications.

- CPU Processing Speed: 528 MHz
- ROM: 512 MB, RAM: 384 MB
- microSD™ memory card (SD 2.0 compatible)
- Sensors:
  - G-Sensor (3 axis)
  - Digital compass
  - Proximity sensor
  - Ambient light sensor
- Battery type: Rechargeable Lithium-ion battery with a capacity of 1300 mAh
- Bluetooth® 2.1 with Enhanced Data Rate

The main issue programming the smartphone has been to minimize power consumption. Therefore, to reduce the transmission time and consequently the power consumption, the raw data of the accelerometer is pre-processed in the smartphone and only the activity index is sent to the PC.

The application turns the Bluetooth radio on and off automatically and keep it on only when it is necessary to transmit. On the remote side (the PC), a daemon program is constantly monitoring the presence of the smartphone to start the data downloading process.

The program on the smartphone starts automatically with system startup and register patient data all day. To ensure scalability each sensor is registered in a different service and in a different class.

An icon in the notification bar shows the program status. The Android operating system uses intelligent memory management. If the application used by the user requires more memory than the available free memory, other background applications will automatically be removed from memory. Since our sensors are registered with some services, they are the last program that will be killed by the system. But since still there is the possibility that it can be killed, in this case a sound and an icon in the notification bar will alert the user to restart the program by just clicking on the program icon in the notification bar itself.

Another problem is the power supply management of the sensor in the smartphone. In fact, in the case where the phone goes to stand-by because the user presses the power button or when the screen turns off due to the system timeout, the accelerometer sensor is turned off. For this reason, an alarm is programmed, with an interval of 10 seconds, which wakes up the phone if the user puts it on stand-by pressing the power button.

In addition, a free widget called `backlight' is placed in the main activity window of the phone to allow switching between two screen brightness levels to save battery.

The patient data are saved on the SD card in .txt files with data separated using tab-stops.

In order to evaluate different algorithms to improve the activity indicator, we save the acceleration raw data (the three accelerometer axes at 20 samples per second) in files. We computed and save also a processed signal using the same algorithm used in the watch (one activity index per minute).

Processing the patient data and saving one measurement of activity per minute the phone works for 14 hours with the screen brightness at minimum and without any user interaction with the menus. The experience with real user is that the battery last between 8 to 12 hours depending on the number of time the phone is used and the time the backlight is increased.

C. Sleep sensor

The system is based on the TI eZ430 watch hardware used for actigraphy that is an EZ430 microprocessor together with a RF communication chip at 868 MHz. The EZ430 has an analog-to-digital converter of 12 bits that can be used to acquire the analogical signals coming from the sensors. We used together two different types of sensors: one to be sensitive to movements and the other to detect the presence of a person on the mattress.

For detecting movements, we used a piezoelectric sensor from Emfit LTD. This Emfit L-sensor consists of a sensing element constructed of elastic electret Emfit film and 3 layers of polyester film with aluminium electrodes. Table II shows the main specifications of this sensor. Changes in the patient's movements on the bed will cause a change in pressure distribution on the mattress and, as a result, on the sensitive area of the sensor. The changes in pressure in the layers of the sensor generate a corresponding electric charge and a voltage will appear on the electrodes.

The electric resistance for piezoelectric materials is very high but not infinite. Therefore when a constant stress is applied a charge is initially generated that will slowly drain off as times passes. In consequence, there is no DC response and they cannot be used for static measurement.

TABLE II

EMFIT-L SENSOR SPECIFICATION

	value	unit	conditions
Sensitivity	25	pC/N	Normal Force
Capacitance	22	pF/cm^2	At 1-150 kHz
Size	290*300	mm	--

Figure 2 shows a typical charge amplifier to be used with the piezoelectric sensor. The input stage of a charge amplifier features a capacitive feedback obtaining a voltage output that is proportional to the generated input charge. Considering the feedback capacitance the circuit has a high-pass response with a charge to voltage gain of $Vo = \Delta Q / Cf$ and corner frequency of $f = {}^{1}/_{2\pi R\, C_f}$. If $R = 1G\Omega$ and C_f is $1nF$ we will have a charge to voltage gain of $1 * 10^9\ [V] * [C]$ and a high-pass cut-off frequency about 0.1 Hz.

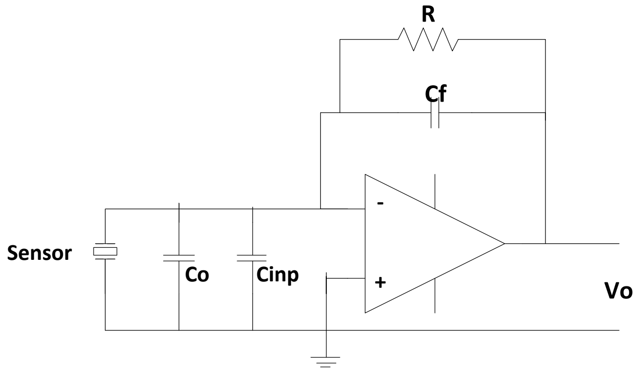

Fig. 2 Typical charge amplifier for the piezoelectric sensor

The sensor for presence detection is based on a piezoresistive sensor (Force Sensitive Resistor 'FSR' from InterLink Electronics). Its resistance will vary depending on how much pressure is being applied to the sensing area, the harder the force, the lower the resistance. When no pressure is being applied to the FSR its resistance will be larger than 1 MΩ.

The resistive sensor is connected directly to the power supply (as a pull-up) and one of the analogical inputs of the eZ430. As the input impedance of the analogical inputs is around 75 kΩ the voltage applied to the Analogical to Digital Converter (ADC) will be the result of a two resistor voltage divider: 0V when no pressure is applied and will increase up to a maximum of 3V when the resistance of the sensor decreases as pressure increases. In Figure 3 the developed board is shown connected to the eZ430 hardware.

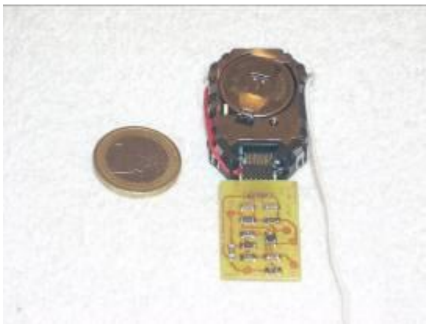

Fig. 3 Charge amplifier connected to the eZ430 used as a data acquisition system

The program acquired data of the piezoelectric film when the presence detector (the piezo resistive sensor) indicates that a person is over the mattress. The movement index is obtained in the same way as in the actimetry devices. After a high pass filter the time percentage over a threshold is calculated every minute, the threshold level has been selected to avoid the detection of breathing movements in an experimental way. The acquisition frequency is 10 Hz. In the side of the electronics box there is a button to allow the synchronization of the device as it is done in the actigraphy devices. The user could also force a data download pressing this button.

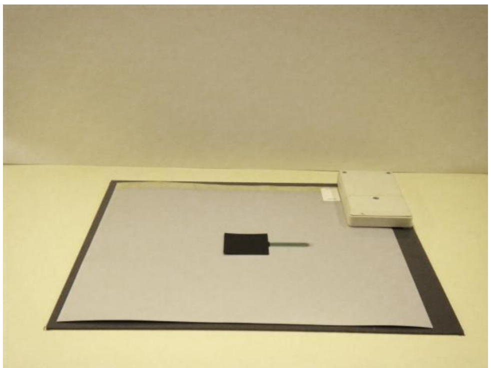

Fig. 4 Under-mattress sensor structure showing the piezoresistive and the piezoelectric sensors together with the electronics inside a plastic box. The sensors are covered with a foam and a fabric (not shown)

V. Test of Developed Devices

A. The influence of sensor location and signal processing

An unobtrusive and not stigmatizing actimetry measurement system must allow the measurement of the signal in a convenient location on the patient's body and, if possible, this location should be chosen by the patient. For this reason the following questions arise:

- For the same signal processing, how do the actimetric indices change with location?
- How should the signals of the three accelerometers of each actigraph be combined in order to minimize the effect of location?
- Which index is least sensitive to changes in location?

To answer these questions we performed some experiments with voluntaries to study the influence of signal processing stages in the estimation of physical activity while measuring simultaneously in three different sites to provide robust indicators of activity in front of changes in site measurement. From these measurements we shown [6] that a proper choice of signal processing steps can improve the agreement among activity indices measured from different sites on the same individual. The results also show that the most suited index is the time above threshold. In this case, the best combination of axes is by applying the quadratic mean, the best filtering of axes is using a cut-off frequency of around 1.5 Hz and a threshold to compute the TAT index of 0.04 g. [6].

B. Sleep sensors

To measure the sensitivity of the occupancy sensor and the minimum weight needed for an acceptable output voltage, the sensor was tested on a real bed under a mattress. The output voltage was measured with a data acquisition board (DAQ6016) with different known weights [7].

To measure the sensitivity distribution over the mattress in which the changes in weight are detectable by the sensor we performed several experiments with real people but also with a simpler model to obtain quantitative results. As a model, we used a cylinder of 32 cm diameter and 80 cm long filled with water and weighing 38 kg to simulate the trunk of a medium size adult. The sensor was put under the mattress, in the centre of the bed (the bed was 90x200 cm) and the water tank was moved to different distances from the centre. We used a viscoelastic mattress with a thickness of 20 cm.

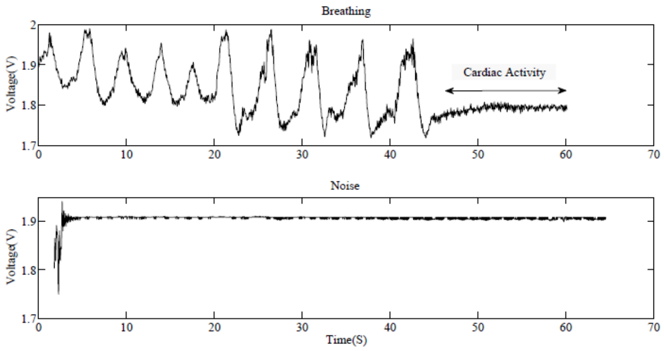

Fig. 5 Signal acquired with the under-mattress device for sleep monitoring, a) person breathing and simulating an apnoea and b) noise lever with nobody in bed

From the results several important points were observed [7]. Changing the number of slats in a flexible bed base will cause a considerable change in the output voltage. Also, the shape of the mattress has to be considered, for instant in a mattress with a non-flat surface the sensitivity will decrease dramatically if the sensor is situated in a depressed area.

From these previous experiments, with this specific mattress, it will be possible to set a constant voltage threshold to distinguish the bed occupancy. However, it is necessary to test other bed bases (slat or rigid) and other mattress types (latex, visco-elastic or spring mattresses). We do not discard the use of an adaptive threshold implemented in the microprocessor to adjust the decision voltage depending on the measured data.

We made some experiments with real people in bed, rolling and going out of the bed. These preliminary experiments have shown evidence of the possibility to detect breathing in addition to movements. Results show that since the standard deviation of the noise signal is much less than the breathing signal (see Figure 5), the system is able to detect breathing if the person stays quiet [7] in supine or prone positions. By comparing the noise level and the signal in the simulated apnoea part, we think that by using some filters the system may be able to detect also the heart rhythm but only during sleep periods without any movement.

VI. Conclusions

For actigraphy we developed four alternative sensor devices to acquire daily activity patterns: a wrist watch, a pocket device (key ring) a waist or belt device and a smartphone. All of them process the acceleration data and stores in the patient personal computer in the same way. We selected the data processing stages to minimize the differences in the activity index due to the location of the sensor on the patient.

As a result of interviews with possible users, the tracking of geographical location and incoming and outgoing calls recording was removed from the smartphone application for acceptability reasons.

For sleep monitoring we developed a wireless system powered by batteries capable of detecting bed occupancy and also and index of movements of the patient similar to the actigraphy devices. The sensor is capable of detecting the breathing when the subject is quiet and in supine or prone positions.

Acknowledgment

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OPTIMI's e-Health Wearable Sensor Radio Data Network

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Abstract— **The implementation of an e-health system which extensively uses body sensors was attempted within the frame of an international collaboration project, OPTIMI, with a view to process and gather physiological data. In such situations there are many practical aspects, that must be taken into account and in particular how data is to be transferred over the body area network. At the time low energy Bluetooth was not available yet a primary aim was to design a low energy wireless system. This paper presents the technologies developed and the design choices that lead towards a simple, efficient and energy aware data transfer protocol and RF data communications system. The results are discussed in relation to the now available low energy Bluetooth Specification and how the experience gained in the project may be translated in future to other such sensor networks.**

V. Introduction

The OPTIMI project incorporates a number of smart wearable sensors, see Figure 1.0. The following summarizes the sensors and their target function:-

- ECG for heart rate and motion
- Activity Sensor (ACT) for ambulatory activity
- EEG to derive affective status (sensitivity)
- Sub Dermal Cortisol
- Sleep Quality using ECG and ACT
- Speech Analysis to estimate depression

In many wearable sensor applications, data from the sensor is streamed to a signal processing computer such as a wearable PDA. This approach can result in a large proportion, perhaps more than 90%, of battery energy being spent in wireless communications rather than data processing. Since small battery cells approximately 15mm x 10mm x 3mm can only maintain a typical radio communications session for 30 minutes before they run out, such small sensors that are worn 24/7 would require frequent recharging seriously inconveniencing the user.

Instead significant energy conservation can be achieved by making the sensor itself do the signal processing using highly optimized signal processing in which the large amounts of real time information are processed and converted to time stamped results comprising only a few hundred bytes per day. When this data is communicated wirelessly not only is their little energy spent on communications but in addition raw data privacy and data security are enhanced.

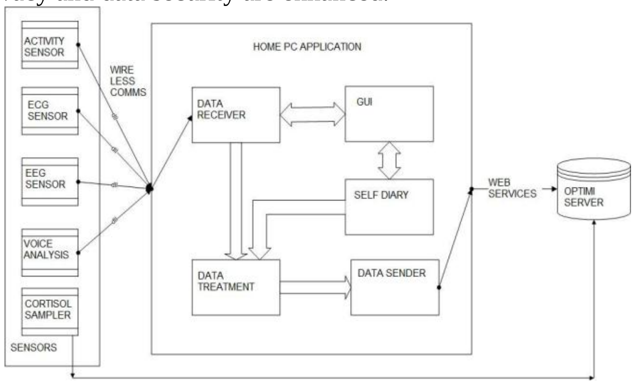

Fig. 4 An overview of the sensors and their interface to an Internet based diagnostics system called the OPTIMI Server

The field of body area networks BANs as applied in pervasive health applications has been studied from several angles. The work reported in [1], [2], [3] reveals that the use of ZigBee and Bluetooth can lead to effective wearable health scenarios.

Even as early as 2009 as researchers such as in [2] had recorded that for a periods of use over 3 to 4 days continuous, the wearable sensor's battery size and weight increases substantially. However since the energy usage depends very much on the modes of operation it was necessary to study the user energy usage patterns to understand how better to trim down processor usage and reduce energy.

The decision to standardise on any RF approach such as Zigbee or Bluetooth is central to the design and energy issue. Choosing a standard can lead to a simplification of the design process since standard protocols generally are supported by off the shelf modules supporting the RF stages. In addition using well established protocols leads to wider inter machine operability and compatibility. Non-standard protocols on the other hand require the developers to design the entire solution often leading to complex designs and low interoperability.

However the benefit of a proprietary solution can be energy savings.

A first design choice in OPTIMI was to go for non-standard protocols and create a proprietary BAN. The aim was to develop a non-standard protocol that was simpler and more energy efficient than industry standard 2.4GHz free licence band solutions such as Zigbee and Bluetooth.

Generally speaking the electronics RF front ends for any 2.4GHz low power system consumes roughly the same power (between 200 and 600 milliWatts) to send or receive a bit of information across almost ALL protocols. What differentiates the final power consumption of a network is how the communications is used to setup sessions and transfer data.

Therefore even the new low energy Bluetooth 4.0 standard was developed as an energy aware improvement on the older Bluetooth standard by concentrating on different software and service implementations.

A second major design choice in OPTIMI it was to conduct as much processing on the sensors so as to reduce the volume of data to be sent over the BAN. This approach goes against the traditional approach of the sensors streaming raw data to a central PDA which then computes the results.

Both design choices are aimed at reducing the impact of energy consumption on the sensor.

The overarching reason is to reduce the size of the battery to be used and extend battery life. Since OPTIMI targets healthy people at risk of illness, there is no motivation to wear bulky sensors to aid in recovery as may be the case in ill patients.

It was our belief that ultimately, healthy users would only wear sensors if they were almost unnoticeable and therefore easily hidden or disguised for example as artefact jewellery.

VI. OPTIMI SENSORS

The OPTIMI sensors are used in slightly different ways to suit different data needs. This usage style is reflected in the way the sensors are designed to communicate.

The following will explain the sensors developed in OPTIMI. Although the design was specific to OPTIMI, it may also have a wider field of application as the same situations found in OPTIMI are very likely to occur more generally in other electronic health sensors such as blood pressure monitoring or other physiological and biological measures. The OPTIMI approach could therefore potentially be used more widely in medical sensor BAN's.

A. ACT and ECG sensors

The ECG sensor is to be worn continuously for several days. The sensor records heart rate and heart rate variability on a frequent basis and stores the results in the sensors FLASH memory. The sensor also records the physical motion of the user as sensed by an accelerometer in the sensor. Due to a limit of memory size, the sensor memory reaches capacity after 27 hours. This is also about the time taken for the battery to reach a level where it should be recharged.

Therefore a routine was defined whereby the user would once a day download data from a sensor that had been recording for the past 24 hours. The routine would be as follows. Remove the ECG sensor, place it near the HomePC, execute the download program on the HomePC, place the sensor on the battery charger, take a second fully charged sensor, execute the HomePC software to activate it to begin recording and place it on the body.

Exactly the same situation holds for the ACT sensor which measures and records a variety of physical motion parameters. Therefore, when the user downloads data and then activates the ECG sensor, the user repeats the same routine with the ACT sensor.

Fig. 5 From left to right, the necklace worn heart rate and heart rate variability sensor, the ankle worn activity sensor and the brain wave sensor

B. EEG Sensor

The EEG sensor is used to measure the user's brain waves during a 3 minute recording session. During this session the user puts the sensor on the forehead and performs certain actions as defined by the HomePC application. The HomePC sends control commands to setup the sensor and to adjust for ambient noise and therefore there is far greater interaction between the HomePC and the sensor than the previous sensors. In addition the amount of data transferred to the HomePC is in the region of 2 megabytes and therefore much greater than the 1 kilobyte for the ACT and ECG.

The EEG can also be used for EEG Neurofeedback training to help relax the user. This requires the sensor to operate in full streaming of the computed results to the HomePC in real time.

C. Home PC

The HomePC must be able to perform a number of tasks in relation to the radio network and communication with the sensors. It must be able to detect which sensors are close to it. Create a session with the sensor. Perform data downloading, sending commands and accepting incoming streamed data.

It is important to note that there may be five or more sensors in the vicinity of the HomePC and a means to distinguish them is important. Finally the HomePC should be able to update the firmware on any sensor should a new version of the sensor code become available.

VII. COMMUNICATIONS

The communications methodology or protocol used in OPTIMI was designed specifically for the project. The main reason was to reduce the high radio energy consumption and to have full control on the privacy of the data being transferred.

A. Energy Awareness

The ECG and ACT sensors are to be worn 24/7 and it was determined, through focus group based human centred design [9], that the size and profile of the sensors must be kept as small as possible.

The smallest Lithium Polymer batteries available are those for example manufactured by Full River [10]. The smallest size, high volume manufactured battery in their range is a 20mAh 3.7V cell measuring 15mm x 10mm x 3mm. the next size up is a 50mAh cell, which is 17mm x 10mm x 5mm.

The ACT is worn around the ankle and requires smallest size and weight and the lowest profile so as not to snag against clothes. Therefore despite the small power budget of the cell, the 20mAh cell was the only possible battery to consider.

The ECG sensor was to be fashioned as an oval medallion and worn as a necklace. Although the profile was necessarily low it was possible to build in the 50mAh cell and maintain user satisfaction on size and weight. The 50mAh cell provides 50mA for about 30 minutes reliably.

Typically the electronics used to drive the radio, which is called the RF front end, consumes around 18mA when receiving and around 13mA when transmitting.

Meanwhile the processor and signal conditioning circuits of the ACT and ECG sensors consume about 4mA and 7mA respectively. Therefore if the processor and radio are switched on all the time then typically the sensor will run out of battery in less than an hour.

In order to extend the life of the sensor to 27 hours, it is necessary to do two things. First the radio must be used as infrequently as possible but still allow the HomePC to start a session. Second the sensor's physiological computation and sensing should be conducted in such a way as to reduce the power consumption. The method used relies primarily on the sensor being switched into a deep sleep power saving mode for short periods of time in between the physiological measures.

Therefore the ECG main code is executed during the capture of 128 Heart Beats after which the Heart Rate and Heart Rate Variability calculations are performed and results stored. Then the CPU switches off and will not perform this action for a period of 18 minutes. So the sensor is fully awake for approximately 2 minutes every 18 minutes.

However since the ECG sensor also contains an accelerometer which needs frequent measurement, the accelerometer circuits are switched on and code is executed once every half second for approximately 10 milliseconds. Data from the accelerometer is gathered and once every 9 minutes the stored data is computed and a final physical activity score stored in FLASH memory.

As a result on average the sensor is fully asleep 90% of the time which results in the intended power savings as a function of the computation and sensing.

B. Sensor and HomePC Hardware

The HomePC is a standard low cost Netbook on which is run the HomePC application. The user will typically switch it on every morning, to update a self-report diary describing their night's sleep and every evening to download data from the ECG and ACT sensors and record their EEG.

RF communications to the HomePC is achieved via a USB plug in device. Nordic Semiconductor [7] has developed a range of ultra-low energy RF chips which support designs in wearable sensors. The nRF24LU1+ is a device which provides a USB interface to a PC and for OPTIMI these were designed into a small plug on device for the HomePC.

The ECG and ACT sensors are based on the Nordic nRF24LE1 micro-controllers which integrate a 2.4GHz RF front end. The CPU is based on an 8051 CPU design with an extended instruction set. The single chip provides all the I/O required for the sensors needs.

The EEG sensor requires a much more powerful CPU to process the brain signals for noise and for Fast Fourier transforms. This is based on a ST microelectronics [8] STM32 Cortex M3 microcontroller. The microcontroller interfaces to a Nordic nRF24L01 chip which incorporates the identical front end to the nRF24LE1 and allows the EEG to interoperate in the same manner.

Using the Nordic solutions the nRF24LE1, and nRF24l01 on the sensors would communicate bi-directionally with the nRF24LU1+ on the HomePC.

C. Connecting to sensors

In order for the HomePC and Sensors to communicate it is necessary to begin a communications session. Such a session would require an exchange of data to first check that this was a valid OPTIMI session, then it would need to check which devices were in play and if they were validly in play, finally a data exchange would be required.

The simplest configuration is for the sensor to always be listening for a radio communications to be broadcast by the HomePC. Since the range of the radio signal is limited to a few metres, only when the user comes near the HomePC would the session possibly begin.

However the reception power drain is very high as discussed earlier. Therefore the sensor receiver front end is switched on for 15 milliseconds every 15 seconds. During this time the sensor awakens, listens for any incoming messages broadcast by the HomePC and if it does not receive any during the 15 milliseconds then it goes back to sleep. This process is interleaved with the normal sensing and computational functions described earlier.

If the sensor does receive a broadcast packet it replies by transmitting an acknowledge packet that contains its address and the sensor type.

The HomePC having received this packet and verifying the sensor type and address, will then allow the user to interact with the sensor via the HomePC application software GUI, and download data or activate the sensor.

Activation and similar commands are described using predefined command strings.

Downloading of data is achieved by the HomePC application requesting the sensor to send selected memory ranges of its data files. In this way the HomePC may download any part or all of the sensor memory space, in discrete chunks of 32 byte packets per transfer. This enables the HomePC to be in full control of any packet corruptions or losses, minimising the work load on the sensor in performing more complex protocols.

D. Flash Over RF

An extremely important aspect of maintaining the code on the sensors was the ability to update the firmware running on the sensor over the RF communications link.

Updating the FLASH Program memory over the RF link avoids any need for electrical connectors or holes on the sensors, over which the firmware update could be sent. It was important that there were no orifices into which debris could build up making the sensor less hygienic. In fact the sensors are now designed with no on/off button and the battery charging is achieved via an induction coil so that the sensor may be hermetically sealed and can be placed in a burst of steam or alcohol for cleaning.

Updating the FLASH over the RF link is also handled by the HomePC. The firmware update functions in this way:

First the session with a sensor is established.

Second the HomePC checks the battery status of the sensor using the battery level command.

Third it instructs the sensor to prepare for a firmware up load. The sensor acts by stopping all activities, switching off all signal conditioning and sensing circuits and awaits packets of data.

In the fourth step the update is executed. This relies on the fact that the nRF24LE1's 8051 core has separate data and code memory and the code memory consists of flash only. However the 8051 core can map the additional 1024 bytes of data memory into the code space which allows one to run code from the data memory.

A further problem to deal with is that the "flash over RF code" does not normally reside in the sensor. Therefore the code that will perform the transfer must itself first be transferred. The procedure is as follows:

- Upload the "flash over RF code" from the PC to the 8051 into the external 1024 bytes of data memory. This is done using a tiny bootstrap flash over RF code with very limited functionality which is included in the sensor's binary image.
- The PC sends a command to the dongle to map this data memory into the code space and starts the "flash over RF code".
- The uploaded "flash over RF code" supports additional commands (of the transfer protocol) to upload the new program code, which comes over in packets of 30 bytes long and writes this directly to the flash.
- After this, the whole application code is uploaded a second time for verification
- Then, the PC sends the reset command, and the sensor reboots.

E. Data Streaming

When used in EEG Neurofeedback training, the Power Spectral Density of the real time measured brain waves is computed by the OPTIMI EEG sensor and the results must be streamed to the HomePC for use in audio based EEG Neuro-feedback to the user.

Therefore approximately 512 floating point values are transferred to the HomePC at a rate of two times per second. The transfer occurs at an average of 44Kbytes per second. To achieve energy savings the RF channel of the sensor is set to work predominantly in transmit mode which consumes less power than receive mode. For approximately 20% of the time the transmit RF front end is switched off to conserve power.

However since there is no reception mode, there can be no checking that the data has been received properly and the HomePC can lose data packets. This was considered acceptable since a temporary loss of data can be handled by the HomePC interpolating brainwave results. However to ensure the HomePC always detects a loss of packets, each packet is sent out with a packet counter.

In this way a low power streaming mode was achieved allowing the sensor to be used for up to 2.5 hours continuously in streaming mode.

F. Data privacy and Sensor Identification

Data privacy has been maintained firstly by keeping the formatting of the data secret within the project and secondly by using a very simple encryption algorithm on the data.

The sensor ID was based on the users given ID number mixed with a base address which included a sensor type and country type. Together this formed the 5 byte address used by the RF front end for source and destination addressing. In this way each sensor could be easily identified and matched to a given HomePC and user. Only authorised sensors could be used by a particular user with a specific HomePC.

VIII. RESULTS

The OPTIMI project has recorded over 100 megabytes of compressed text based data downloaded from over 140 end users.

Approximately 80,000 hours of data were recorded during the trials using some 300 sensors. A set of 60 HomePCs were used, some of them provided to end users as incentives to participate.

During this time each sensor was re-charged approximately 50 times each. 10% of sensors were lost (unserviceable) due to battery failure through repeated charge discharge cycles.

Further breakages occurred due to mechanical damage to induction coils and electrode cables which emphasised the harsh physical conditions end users place on wearable devices.

Through the trials the researchers learnt a great deal about how to deploy wearable e-health sensors which is now summarised as the following main observations.

A. Energy Awareness

The energy dedicated to sensing and processing Physiological data may be split into three parts.

The first is down to the energy consumed by the electrical circuits dedicated to the sensing. In OPTIMI this was made as efficient as possible within our design means, however it still constituted approximately 20% of the energy consumption during normal awake operation. Therefore any optimisation here by going to low power alternatives, e.g. to work at much lower voltages than 3 volts, must be given a great deal of consideration, since other energy savings are hard to find.

The second is the CPU or microcontroller used. For example the non-radio parts of the nRF24LE1 in the ACT and ECG sensors used approximately 60% of the energy budget while the STM32 in the EEG sensor used approximately 40%. The lower percentage of the STM32 is only due to the higher consumption of external sensing devices for the EEG front end.

The third is the RF front end. In our work we found that depending on usage, the communications could use between 20% and 40% of the energy available. The wide range occurs when users behave differently with the sensors.

Under strict ideal conditions it is possible to achieve high energy awareness on the RF side, if the sensor is activated correctly, charged correctly and data download from the sensor is performed correctly.

As soon as end users are able to disturb the ideal situation, then power wastages occur. We found a number of situations where power waste was highest.

When sensors are not adequately charged before activation, or are worn for more than 30 hours the battery voltage level reaches a critical point where the sensor is programmed to stop operating and only listen for HomePC broadcasts. Running the sensor near the critical voltage where the battery may lose charge quickly results in less efficient battery usage. We also found that at low battery voltages RF communications appeared less reliable on the Nordic devices, perhaps due to electrical current outages, and this causes a great deal of extra RF communications when packets are lost and need to be requested several times.

In another case, when users first start a session with a sensor, the sensor becomes activated and switches on the receiver almost all the time in order that responses between the HomePC and the sensor are quick and the user experience is very interactive. However this full receiving mode can only be maintained for brief periods since the sensor is using approximately 20 times more energy than normally. Therefore if the HomePC does not communicate with the sensor, due to the fact the user is not interacting with the HomePC application, then the sensor shuts down and a new connection must be established to continue. Therefore by not behaving as required, the user can cause much higher energy demands on the sensors. Therefore it was apparent that even the way software is written for the HomePC, making the user behave more correctly, can also contribute to energy awareness on the sensors.

Energy awareness was also shown to be subject to the context of use in terms of the physical presentation.

For example to simplify the usage, the sensors were built in two versions, one version with an on off switch and one version without a switch.

The sensors with a switch presented a problem in that users forgot to switch the sensors on. When they did switch them on they forgot to switch them off.

The sensors without a power switch would detect the battery level or the fact the sensor had not been activated for more than 5 minutes since reset and switch to a very low power mode which could only be exited if the sensor was placed on the charger for a few seconds. This was overall a good solution however the deep sleep standby mode would still consume energy and eventually drain the batteries.

We also found that the sensors would behave poorly with shorter battery life when the sensors were treated with regular compression forces (which we determined by the damage to the outer casings) and high temperatures in the heat of the Spanish summers.

Several RF issues also led to poor battery life. We found that the period of RF communication interaction between the HomePC and the sensors could be lengthened due to local RF interference. Since the protocol used will retry several times to ensure a packet of data is not lost due to interference, the data transfer time, during which power is consumption is high, can be extended by up to ten times as long since every packet that is not acknowledged as received is resent several times.

Such a situation occurred when there were several WiFi access points near the HomePC, It is likely that the simple RF protocol of the nRF24LE1 and nRF24L01, which does not automatically frequency hop, requires improvement.

B. Comparison to Low Energy Bluetooth

At the beginning of the OPTIMI project the low energy Bluetooth standard had not been released. When it was released, there was a limited amount of support by chip and software vendors. However it is now available much more widely and could provide an acceptable approach in an OPTIMI style system.

In principle the RF circuits used for low energy Bluetooth and the nRF24L01 and nRF24LE1 consume the same power in transmit and receive modes. So the choice to use a proprietary or low energy Bluetooth approach depends on whether the energy awareness and flexibility of the methods suit the sensor network needs.

The low energy Bluetooth standard neatly provides a specific approach for a sensor to advertise its availability and type. This advertising can be kept very small and infrequent to conserve energy and the differences between it and the OPTIMI protocol are in fact rather small.

The standard allows the master to then send packets of data or receive packets from the sensor using a very simple method that may incorporate acknowledgments or not, so that data transfers are kept light and energy efficient.

Since the total power consumed is a function of the length of time the main reception or transmission circuits are active (and almost independent of the quantity of data transferred) the designer may have more control on energy savings using a proprietary protocol, in which the firmware has always direct control of the RF front end. In low energy Bluetooth, the radio power output setting and interaction timings may be characterised by the user, however the user does not have such direct control.

Low energy Bluetooth does not seem to provide good support for real time data streaming, which is often necessary to test and to record physiological data. The standard does not cater explicitly for updating firmware over RF which is an important aspect in wearable sensors.

However the standard does offer much greater RF robustness by implicitly applying Frequency Hopping. This makes the data transfers far more secure and less affected by WiFi access points. In addition much higher levels of data encryption may be applied improving on data security and privacy.

IX. Conclusions and Future Work

The radio data network designed for OPTIMI was motivated by low energy and to make data transfers simple for the end user. In fact the sensors could have been fitted with USB connectors so that data was transferred over wires and this would have saved a lot of design work and removed the problem of RF communications energy consumption.

However the OPTIMI sensors are very small so that they can be worn without any impression they are in fact on the body of the user. These small devices become very cumbersome when wires are attached to interface to the HomePC and users have less opportunity to damage the sensors if all interactions are preformed wirelessly. Wireless sensors will be more convenient as the time between battery re-charge becomes longer, the HomePC can extract data from the sensor transparently to the user and users can almost forget about the fact there is a sensor on them. This research work has pushed successfully in this direction and achieved high user satisfaction with small energy aware devices.

In OPTIMI we found that this could be only be achieved with a proprietary sensor body area network since more complex standard protocols did not allow fine tuning of the service of each sensor to suit the basic user and sensor requirements. Our achievements were made possible by choosing the simplest, most basic but satisfactory solutions that met both user and system requirements and implement them in a direct manner.

Low energy Bluetooth would appear to have also based its design on this type of simple but satisfactory approach and would most likely be used in future.

However the OPTIMI proprietary solution still covers more important cases such as data streaming and firmware updates and provides a few more flexible means for energy awareness.

The OPTIMI system could be greatly enhanced with Frequency Hopping and better data encryption and a simpler development environment and library.

Acknowledgment

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Human Computer Interaction and Virtual Agents

Designing Help4Mood: Trade-Offs and Choices

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Abstract— **A notable problem in the treatment of depression is that people often hit a plateau during their recovery where they still experience mild to moderate symptoms, and find it difficult to progress beyond that stage.**

The goal of Help4Mood is to help patients and clinicians discover potential reasons for this plateau by monitoring subjective, cognitive, motor, and psychomotor symptoms of depression. In this paper, we describe Help4Mood's overall architecture and integration, and outline the implications that preparing for deployment in the health service has had for design and implementation.

I. Introduction

Depression is a very common condition that affects not just mood, but also activity levels, sleep, and cognition. Recovery is long and difficult; people with depression often take over a year to recover full health and productivity [1, 2]

Most people with depression are seen in the community [1, 3]. This is in line with a recent WHO report which recommends that mental health care should be integrated into primary care [4].

The main aim of Help4Mood is to support community-based treatment in primary care. Appointments with general practitioners are typically short. Therefore, it is important to have an overview of how the patient has been doing at the start of the session, so that clinician and patient can quickly identify sticking points and issues that need particular intention.

Help4Mood helps the patient track a variety of symptoms, from activity to dominant negative thoughts. Patients do not have to devise their own system; instead, Help4Mood automatically ensures that all relevant data is collected. Interactions are designed to be short and engaging, so that tracking does not become a chore. Results are displayed in a one-page summary that is designed to serve as basis for discussion between clinician and patient. Such tracking can be particularly helpful when patients experience a plateau during their long recovery period.

Initially, Help4Mood has been designed to be deployed within health services and by private practices; patients are loaned the equipment for as long as they need it. As a consequence, it was designed to be low cost; additional instrumentation was kept to a minimum. This requires a delicate balance between powerful technology that ensures a good user experience, cost, and functionality. Several papers in this collection [5-8] deal with detailed implementation aspects of Help4Mood, this paper will provide readers with a brief overview of the overall design of the project.

II. The Design of Help4Mood

Help4Mood will be tested in three target countries, the UK, Spain, and Romania. The design was based on an analysis of the care pathways in the three countries, a review of the literature on symptoms of depression, and focus groups with patients and clinicians. The design is continuously updated as new data emerges on the suitability of tests for monitoring recovery in depression.

The symptoms covered can be assessed subjectively and objectively.

- Subjective Assessments:
  - Standardised Questionnaires such as the CES-D-VAS-VA [9] (daily) and the PHQ-9 [10] (fortnightly)
  - Negative Thought Questionnaire
  - Diary (only for the patient, no further analysis)
  - Other self-reports
- Objective Assessments:
  - Activity monitoring [6]
  - Sleep monitoring [6]
  - Psychomotor monitoring, e.g. speech [11]

A. The Basic Scenario

Help4Mood is designed around a short session of 2-10 minutes' duration where patients provide subjective data, and perform objective assessments that require active user input, such as speech tasks. The structure of the session is as follows:

- Welcome, CES-D-VAS (a four-item measure of mood)
- Outline plan for the session, allow for adjustments to length
- One or more of Negative thought exercise, speech, diary, psychomotor tasks, relaxation exercises, or self-reported assessments of nutrition, exercise, and sleep
- Closing

A talking head avatar talks users through the system. The avatar not just reads out what is on the screen, but explains what needs to be done next. Figure 1 shows a screen shot. The text spoken by the avatar is displayed on the left, data entry elements are on the right, and control buttons are at the bottom. Both the avatar and the background are highly customisable.

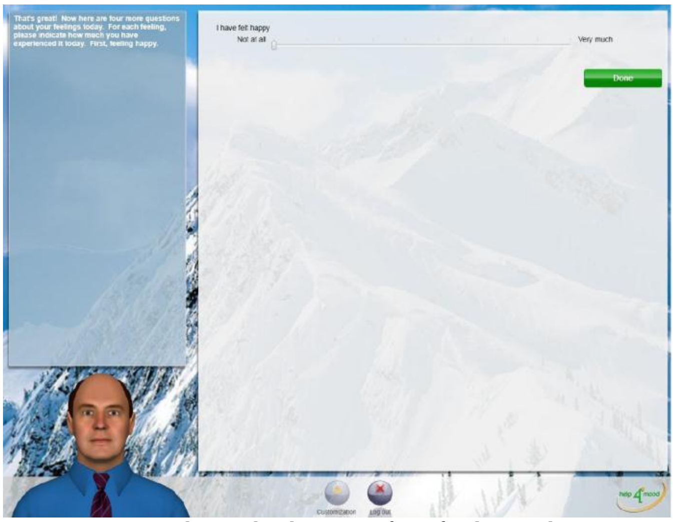

Fig. 1 The Graphical User Interface of Help4Mood

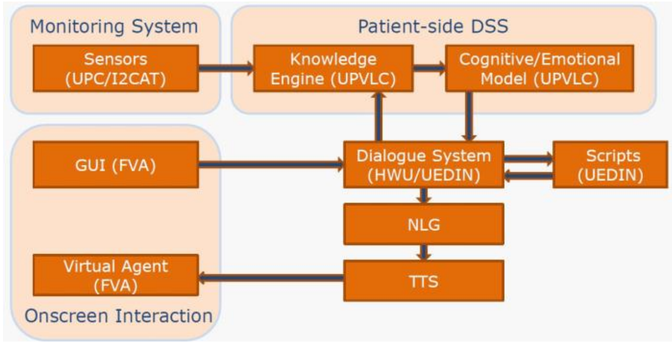

Fig. 2 The Structure of Help4Mood

Four avatars have been generated, each with appropriate eye, mouth, face, and head movements. They can be outfitted with formal or informal clothes.

Sessions are tailored to the patient’s stamina. If a patient is feeling tired, they can opt for a shorter session; if they are up for working with the system for a bit longer, they can opt for a longer session. The patient-side DSS carefully balances tasks so that sessions are not overly repetitive while ensuring that all relevant data is collected sufficiently regularly.

B. *System Design*

Figure 2 shows an overview of the system architecture. The Help4Mood system is controlled by the patient-side decision support system (DSS) which receives data both from the physical monitoring system (PMS) and through on screen interaction with the patient, and processes and summarises this data. No clinician-side decision support system for planning treatment has been implemented since there are extremely few rules for changing or titrating medication for depression.

The Personal Monitoring System consists of the actigraphy solution, which can be implemented as a wrist watch, a key ring pendant, a waist clip, or (provisionally) a smart phone, and the sleep monitor.

The GUI features a virtual agent, which is essentially a talking head. The dialogue system creates the text that is spoken by the virtual agent, first as a string of utterances (Natural Language Generation or NLG), which is then sent to the text-to-speech system (TTS). The output of the TTS is sent to the virtual agent and used to animate the face to fit speech output.

III. FINALISING FUNCTIONALITY

A. *Cost*

Help4Mood was designed to be deployable relatively quickly for reasonable cost. Therefore, we limited additional devices to an actigraph, which can be worn in various different ways, and a flexible, slim sleep monitor that will fit hospital beds and does not require any wiring. While users will presumably derive maximum benefit from using a complete package, Help4Mood will be sufficiently modular to ensure that functionality can be switched on and off depending on the requirements of the site where the system is deployed.

B. *User Experience*

The user experience is optimised iteratively using a cyclical design approach. In an initial pilot, five to ten users who are recovered from depression will test a skeleton version of the system for a week. Detailed interviews and analyses will highlight usability and acceptability issues. Feedback from this trial will be fed back into a larger pilot, again using a case-study design. The final feasibility trial will involve 12-18 users with mild to moderate depression in three countries. A stepped design is envisaged where the control group is waitlisted and receives Help4Mood after the treatment group. Patients are randomised to groups.

Initial work on the acceptability of the usability component of the system has revealed that minimising stigma and supporting the user’s identity are very important. The system has to be easy to use and the programme should be easy to adhere to. Since many people who have with depression find it difficult to get everyday chores done, it is crucial that Help4Mood is not another task that saps energy which is in short supply anyway.

C. *Expert Input*

In addition to user experience tests, the system will also be assessed by clinical experts from the consortium using a set of guidelines derived from the framework developed by Nielsen [12] and informed by the analysis of the first trial.

IV. Development

Clinicians will use prototypes according to specific scenarios and use the guidelines to assess functionality.

Expert evaluation is also used to drive further development. In all IT projects, there is a tension between adding useful functionality and ensuring that the functionality which has been implemented works well. We are currently developing a matrix that weighs clinical desirability against ease of reliable implementation. This matrix will be used to prioritise development. It is particularly important to specify how the functionality should be implemented. For example, the CES-D-VAS-VA questionnaire uses visual analogue scales that are anchored by a negative and a positive pole. Movement of the slider across the scale needs to be seamless; no intermediate points should be displayed.

A test suite for the whole system will be set up that will assess robustness in case of user error. The help system will also be refined iteratively, to ensure that people with depression, who may already have a low tolerance for failure, do not give up on the interface.

V. The Market for Help4Mood

To a large extent, the initial market for Help4Mood will decide further developments. If it is marketed as a research tool, it may not require CE marking, which in turn entails thorough quality assurance and risk management [13]. If it is to be deployed in the health sector, as per the original design, it will first require CE marking, followed by an extensive programme of efficacy and cost-effectiveness trials. The initial trial will be powered using the results of our final randomised controlled feasibility trial.

Help4Mood is unique in several ways:

- it combines straightforward mood monitoring with more sophisticated self-report mechanisms derived from cognitive behaviour therapy
- it is designed to support treatment by a clinician in a telecare context

The clinical orientation sets Help4Mood apart from the plethora of mood loggers that exist both online and on app stores. While these loggers are useful for tracking specific symptoms and feature detailed graphs and summaries, most lack flexibility and have no way to accommodate the detailed theory-driven questionnaires such as the Negative Thought Questionnaire that we have developed for Help4Mood. Help4Mood will offer several choices of interfaces for the treating clinician to facilitate integration with hospital systems

In terms of clinical use, the main competitors for Help4Mood are SMS-based systems such as Buddy [14] which allow users to complete questionnaires using texts. Such systems can be tightly linked with hospital systems to the extent that they can send appointment reminders. SMS is a well-established modality for interacting with patients that does not require any extra investment for patients; anybody with a basic mobile phone can access this technology without a problem. Help4Mood, in comparison, is far more costly; cost-effectiveness will be key for making a case for its deployment.

VI. Conclusion

We have developed the activity and sleep monitoring technology, we have designed a framework for deploying Help4Mood in practice, we have laid a solid foundation for a modular, flexible, configurable system, and are now positioned well to take this system to people with depression and their clinicians and listen to their feedback. In parallel with developing a business model for Help4Mood [15], we will use in-depth mixed methods research to determine the clinical impact Help4Mood can have – on empowering patients, on making treatment more effective and efficient, and on helping people with depression live a full life despite the back dog that hounds them.

Acknowledgment

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The Construction of a Cognitive-Emotional Module for the Help4Mood's Virtual Agent

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Abstract—**Help4Mood is a European research co-funded project aimed to support the remote treatment of people with major depression. One of the main components of the system is the Virtual Agent (VA) which acts as the main interface between the patient and the system. This paper describes the implementation of the cognitive-emotional (CE) module, the mechanism that produces *appropriate* emotional responses in the VA during the interactions with the user. In particular, we present the theoretical foundations of this mechanism which is based in the cognitive appraisal theory of emotions. The initial implementation of the CE module has been developed by adapting the FAtiMA (FearNot Affective Mind Architecture) computational architecture of emotions created to generate *empathic responses* in virtual characters. We also discuss the extension of this architecture to model and generate *therapeutic empathic* responses in the VA directed to enhance and facilitate the interaction of the system with this particular kind of users.**

I. Introduction

The use of the ICT applications such as serious games, virtual reality and non-invasive sensors for the understanding, assessment and treatment of mental health problems has been increased in the last decade. One particular usage of ICT technologies where the mental health field can take advantage is in the remote monitoring and continuous communication with patients under treatment. The automatic analysis of the collected information can be used to provide specific, useful and timely information that support and motive the patient in concrete phases of his/her treatment. This is the main objective of the Help4Mood project: a European Commission co-funded research project aimed to support the remote treatment of people with major depression.

Help4Mood is an ICT platform with three main components: *i) the personal monitoring system; ii) the decision support system;* and *iii) the virtual agent.* This paper presents part of the development of the virtual agent (VA) as the main interface between the patient and the system. In particular, we describe the development of the **cognitive-emotional** module which is the mechanism that produces the VA's emotional behaviour during the interaction with the user. Designed as the main human-computer interface, the behaviour of the VA needs to promote and maintain the motivation and engagement of the patients during the daily sessions in the system. The cognitive-emotional module has been designed for the VA to produce *empathic* responses intended to enhance the interaction with this special type of users. The rationale and the theoretical foundations behinds the CE module is presented in section II and III respectively. Section IV describes the current development and the integration of the module with the rest of the VA's components. Finally, section V discusses the conclusions and the future work.

II. Why a Cognitive Emotional Module?

One of the key objectives of Help4Mood is to promote the adherence and the active involvement of the patient in his/her treatment through the continuous use of the Help4Mood system. As reported in the literature [2], the use of a VA as the interface between the patient and the system – when correctly designed – is an effective strategy for promoting the use of the system by encouraging patients to maintain a continuous interaction and to complete longer sessions.

To guarantee that the VA achieves this objective, the design decisions and the initial requirement analysis were based on data obtained from the 10 focus groups conducted with clinicians and patients in Scotland, Romania and Spain [19]. Some of the key features that the VA should display which have been identified from the focus groups were the following:

- The use of suitable *verbal* and *non-verbal* communication to indicate that patient inputs and self-reports have been *listened to* and *understood*.
- Conveying *appropriate empathy* by displaying only *neutral* or *positive* emotions. Positive emotions should be displayed as responses to the patient's achievements in following the treatment, whereas neutral expressions must be used when patients indicate negative moods, thoughts, or feelings.
- Creating a coherent and *stable personality* which will make the VA more believable. The preferred personalities that can be adapted to the patient's preferences include a *friendly/jovial* VA and a more *neutral/professional* stance.

The identified characteristics obtained from the focus groups have been consistent with the set of relevant features described in the literature when designing synthetic characters used for psychotherapy [1], [7], [11], which include coherent *verbal* and *non-verbal* behaviours, *personality*, *empathy* and *variability* in the behaviour during the interaction, among some others.

To successfully obtain these characteristics in a VA, there should be an internal mechanism that produces a coherent *emotional* behaviour that complements the *cognitive* actions and decisions taken during interaction. A *coherent* and *consistent* emotional behaviour (also referred as *emotional competence* [23]) is a basic ingredient to lead the VA to provide empathic responses. Moreover, the modelling of personality trends contributes with a better consistence in the emotional responses [17] and conveying different styles of verbal and non-verbal communication.

III. Theoretical Roots

The modelling of *emotional competence* in virtual agents is an active research area where theoretical, technical, and ethical considerations need to be addressed. In the last years, several computational models of emotion have emerged trying to cover specific (and sometimes theoretically incompatible) emotional mechanisms. Many of the differences between those computational models are a logical consequence of the different emotion theories where these models have their roots.

In particular, the different psychological theories of emotion differ regarding which components are intrinsic to an emotion, how they are integrated, and how they are related [14]. Intrinsic components of emotions may include cognitive processes, physiological responses, motivational changes, motor expression, and subjective feeling.

The selection of a specific emotion theory as the basis of a computational model depends on the aspects of emotion that the computational model tries to represent. From the current existent theories of emotion, the one that predominates above the others in the efforts dedicated to implement computational models of emotions is the cognitive appraisal theory of emotions [10], [24]. The core concept of appraisal theories refer that the events in a person's environment are constantly identified and evaluated by the individual.

This *cognitive* evaluation (or appraisal) process leads to an emotional response (according to the event's relevance for the person) which in turn generates a specific behaviour to cope with the appraised events. One of the reasons for the success of this theory in computational modelling is that it provides an explanation for the connection between cognition and emotion. This, in turn, helps in the construction of artificial systems that simulate complex human-like behaviours. Moreover, appraisal theories of emotion appear to be the most comprehensive way to represent the complexity of the emotion process, covering the whole path from low-level appraisals of the eliciting event to high-level influence over behaviour [23].

Several computational architectures based on the appraisal theory of emotions have been developed since the early 90's [5], [4], [8], [13] most of them focused on the construction of believable characters within virtual environments. The development of virtual characters based on appraisal theories has allowed the creation of real-time interactive characters that exhibit emotions in order to make them more compelling [16], more realistic [12], more able to understand human motivational state [3], or more able to induce desirable social effects in the users [20].

IV. Development of the Cognitive-Emotional Module

The implementation of the cognitive-emotional module in the Help4Mood VA for the first prototype has been done through the development of a stand-alone Java application which makes use of the FAtiMA (**F**earNot **A**ffec**ti**ve **M**ind **A**rchitecture) software libraries. FAtiMA is one of the existent computational architecture of emotions. It is an open source software which provides an evolving (appraisal theory based) architecture which was developed in the context of three EC projects: the FP-5 VICTEC (http://www.macs.hw.ac.uk/victec/index_geral.html), the FP-6 ECIRCUS (http://www.macs.hw.ac.uk/EcircusWeb/) and the FP-7 LIREC (http://lirec.eu/) projects.

The original objective of FAtiMA was the creation of empathic agents interacting in a virtual environment to tackle and eventually help to reduce bullying problems in schools. The specific approach implemented in FAtiMA for the appraisal and affect derivation processes is the known as the OCC model (the acronym of the authors' names) [18]. This model defines a hierarchical organisation of 22 emotion types such as *joy*, *distress*, *pride*, *satisfaction* to name a few, that are produced as reactions to situations constructed either as being goal relevant *events*, *(self and other) actions* and *attractive* or *unattractive* objects for the agent.

Using FAtiMA, the creation of virtual characters is then possible through the authoring of their *emotional reactions*, *action tendencies*, *goals* and *actions* that will generate the agent's behaviour from the events occurring in the agent's environment. The environment of the VA in Help4Mood is basically composed from all the data received (directly and indirectly) from the user. These data include the objective user's information collected through the *personal monitoring system* (PMS) (such as sleep and physical activity) and the subjective self-reported information through standardised questionnaires. All this information is interpreted and analysed by the *decision support system* (DSS) which derives the specific events used as the input to the cognitive emotional module. The received events will produce the specific VA's emotional behaviour during the interaction with the user according to the specific *goals*, *emotional reactions* and *action tendencies* defined as the internal state of the VA.

D. Defining the Emotions in the Virtual Agent

A key difference in the empathic behaviour of the Help4Mood's VA regarding the original application of FAtiMA and similar initiatives (e.g. [4], [21]) is that the empathic responses (aimed to be displayed through the dialogue content and some facial expressions) needs to be modulated according to the special characteristics of people recovering from depression. From a clinical perspective, it is highly important that the range of emotions displayed should be restricted to neutral or positive emotions (such as *joy* and *happiness*) and that the system should not produce typical empathic behaviours by adopting the same – frequently negative – emotions.

Although the generation of the 22 different emotions defined in the OCC model is possible, the building of a believable virtual character can be achieved by using a reduced set of emotions [17]. Moreover, it is not clear in terms of non-verbal communication how to effectively express the different range of emotional categories on the face of the VA while interacting with the user (e.g. the work developed by Ekman [6] proposed a reduced list of basic emotions that can be communicated efficiently and across cultures through facial expressions, most of which are considered as negative emotions such as *disgust*, *contempt*, *fear*, *anger*, *sadness*; and one positive: *joy*).

So, for the first prototype of the VA's cognitive-emotional module, we have considered the use of three positive emotions plus a *neutral* (i.e. no emotion) stance:

1) *Joy:* activated when an event is appraised as desirable for the VA. Examples of these events include the daily logging of the user into the system (representing the achievement of one of the ultimate goals of the VA: maintain a good level of adherence to the treatment), or the user's acceptance of the activities offered by the VA during the session. This positive aspect will be communicated to the user through some specific words in the interaction dialogue such as "Thanks for logging in today, I am happy to see you again" or "Great! I'm glad that you accept the plan for today's session".

2) *Happy-for:* elicited when an event is appraised as desirable for the user. Examples include good self-reported moods or thoughts and the detection of any improvement in the patient's condition through inferences from the data collected. Again, examples of positive utterances in this context are "That's good, I'm happy to hear that" or "It seems that you are achieving your targets. Good for you" respectively.

3) *Admiration:* activated when an event is appraised as a desirable consequence of a user's action. Examples include the correct completion of the proposed activities during the session or the completion of the whole session and the confirmation (by self-reporting) that the user has followed the recommendations provided by the VA (e.g. to improve physical or sleep activities). An appropriate positive response would be something like "You are doing well!"

4) *Neutral:* when an event is appraised of no particular importance according to the VA's goals, the current active emotion (originated by a past event) is maintained until its complete deactivation. If no emotion is active, the response of the VA will adopt a neutral stance.

In terms of facial expressions, the three positive emotions are represented by a smile (using different intensities) in the VA plus some specific head and eye movements. These are selected depending on the type of the event that activated the emotion and/or its intensity, which is generated by the FAtiMA affect derivation process through the activation thresholds of each emotion and the emotional reactions defined in the character.

The affect derivation process used in FAtiMA is based on the OCC model [18] which makes use of a set of appraisal variables. The `desirability` variable is used to elicit the *wellbeing* emotions: a positive value produces the *joy* emotion and the *distress* emotion is produced otherwise. Additionally, the value in the `praiseworthiness` variable is used to generate the *attribution* emotions. Depending on the `subject` responsible for the event (the self or other agent) and on the positive or negative value of the variable, one of the following emotions can be elicited: *pride* (if `subject`="self agent" and `praiseworthiness` > 0); *shame* (if `subject`="self agent" and `praiseworthiness` < 0); *admiration* (if `subject`="other agent" and `praiseworthiness` > 0); and *reproach* (if `subject`="other agent" and `praiseworthiness` < 0). Finally, the `desirabilityForOther` variable is used to generate the *fortune-of-others emotions*: *happy-for*, *pity*, *gloating* and *resentment*.

E. Emotional Reactions and Action Tendencies

Once the set of emotions has been defined, we also authored the *emotional reactions* and *action tendencies* that the VA can produce as response of the received events. The emotional reactions represent how the VA appraises the events produced in the environment (in Help4Mood, these events are generated by the DSS at the patient site). Conversely, action tendencies represent the VA's reactions to particular emotional states elicited in the VA. Based on the different session's modules that can be produced during the interaction with the user, a set of emotional reactions rules and action tendencies were authored in FAtiMA.

Two examples of the emotional reaction rules containing the appraisal derivation variables that are defined in the first version of the VA are the following:

```
<EventReactions>
  <EmotionalReaction desirability="5" praiseworthiness="3">
    <Event subject="User" action="OPEN_SESSION"/>
  </EmotionalReaction>

  <EmotionalReaction desirability="5" desirabilityForOther="7"
praiseworthiness="4">
    <Event subject="User" action="IMPROVED_MOOD"/>
  </EmotionalReaction>
</EventReactions>
```

In the above example, the first emotional reaction rule defines how much desirable the `OPEN_SESSION` event performed by the user is for the VA. Since the two variables have positive values, both the *joy* and *admiration* emotions are candidates to be triggered. However, due to the defined threshold values in each emotion (where the *joy* threshold value is lower than the *admiration* threshold) only the joy emotion is elicited. In the case where the two values pass the threshold, the VA's emotional state will be defined by the higher intensity value. Similarly, the second rule in the example will produce the *happy-for* emotion (where the *User* acts as the *other agent*) as a consequence of the IMPROVED_MOOD event inferred by the DSS from the data in the users' self-reports.

Immediate reactions from the VA to specific events have also been defined by authoring a set of *action tendencies* (such as the *welcome* message, provide *positive feedback* or say *goodbye* at the end of the session). These actions are triggered when a specific emotion is elicited due to a particular event. The following example is the action tendency used by the VA when the IMPROVED_MOOD event elicits the *Happy-For* emotion:

```
<ActionTendencies>
  <ActionTendency action="BetterMoodFeedback(User)">
    <ElicitingEmotion type="Happy-For" minIntensity="5">
      <CauseEvent subject="User" action="IMPROVED_MOOD"/>
    </ElicitingEmotion>
  </ActionTendency>
</ActionTendencies>
```

The action tendency called BetterMoodFeedback will become active when the *Happy-For* emotion gets a minimum intensity of 5 caused by the IMPROVED_MOOD event. This BetterMoodFeedback represents the *task* that the VA will implement during the next interaction cycle. Both elements, jointly with the current active *Happy-For* emotion, form the <task,emotion> pair message that is sent to the dialogue manager component. The dialogue manager is the module responsible to select the appropriate utterances to *happily* inform the user about his/her latest mood improvement.

For the first prototype of the Virtual Agent, all the configured *emotions*, *emotional reactions* and *action tendencies* have been set to produce an emotional positive behaviour as response to the user self-reported or detected wellbeing. A neutral stance is adopted by the VA when something wrong is reported or detected in the condition (e.g. the mood) of the user. In this way, a *positive* empathic attitude of the VA is always produced while the *negative* emotions are blocked as it was demanded from the requirement analysis obtained in the focus groups.

F. Modelling Personalities

As already mentioned in Section II, one of the results obtained from the focus groups was the preference for two different interaction styles in the VA: a *friendly* and a more *neutral/professional* stance. Two different personalities have been modelled to produce the desired style of behaviour in the VA. The modelling of the two personalities was implemented by creating two roles where different values in the *emotion thresholds*, *emotional reactions* and *action tendencies* were set to produce the distinct behaviours in the VA.

Emotion thresholds and decay rates. The values for a *friendly* VA were set to low values making it easier to elicit the three positive emotions depending on the events appraised. Also, the emotion decay rates were set to low values to keep the relevant emotion active for a longer period. On the other hand, the values of these parameters for the *neutral/professional* VA were set to higher values which elicit an emotion only at particular moments and returns to a neutral stance more rapidly.

Emotional reactions. The values in the desirability, desirabilityForOther and praiseworthiness variables of emotional reactions were also set differently. The differences in these values make that the *friendly* VA appraises the events occurring during the interaction in a more positive way than the *professional* Roger. More positive appraisals produce more frequently positive emotions which are reflected in the behaviour of the *friendly* VA.

Action tendencies. The current defined action tendencies have been authored to provide supportive feedback to the user when certain improvements in his/her state are detected (inferred by the DSS from the results of activities such as voice recording, concentration games and/or progress questionnaires). These action tendencies in the *friendly* VA have been defined even when slight improvement is detected. On the other hand, these same action tendencies in the *neutral/professional* VA have been set only when significant improvement is inferred.

Initial tests using the two different versions of the VA and the simulation and generation of different events have been performed. As expected, the three positive emotions were elicited more frequently and with higher intensity in the *friendly* version of the VA than in the *neutral/professional* version. These differences were displayed in the facial expressions of the VA during the interaction (Fig. 1). Nevertheless, the interesting and useful tests will come from the group of users that will participate in the further first pilot of the project. We expect to discover whether they detect the differences between the two VA's personalities. This will contribute to assessing the levels of acceptance that one or other – or both – of the VAs achieve with the users and what their preferences are.

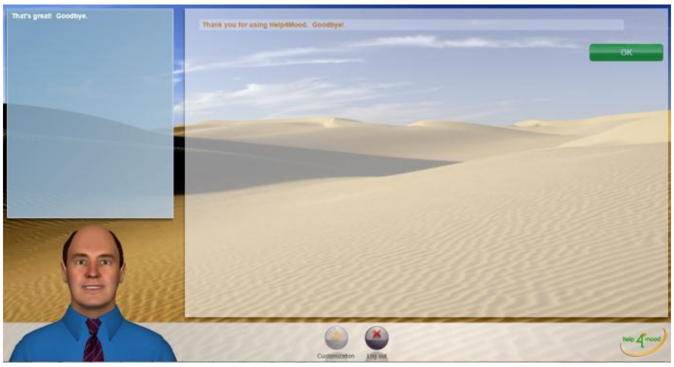

Fig. 1 A *friendly* Virtual Agent in Help4Mood

G. The First Implementation

The first version of the cognitive-emotional module has been developed and integrated with the rest of the modules that form the core architecture of the Virtual Agent (see Fig. 2). This integrated version already leads the behaviour of the VA to manage the content of the daily sessions to be offered to the user. The actual session contains an initial *welcome* dialogue to start the interaction each time the user starts the system. After that, the VA asks five questions that form the *daily mood check* questionnaire based on the validated CES-VAS-VA questionnaire [15]. Depending on the user's responses, the cognitive-emotional module produces the corresponding positive emotional reactions in the VA displayed through the facial expressions. After collect and save the patient's responses, the VA verifies if there is new data coming from the Personal Monitoring System (PMS). If no new data is detected, the VA produces a ***reminder to use*** dialogue used by to remember the patient about the importance and explain how to use the monitoring devices. Finally a ***farewell*** dialogue is produced to close the session. The first evaluation of the VA will be performed through the provision of this daily session to a group of initial users in the further stages of the project.

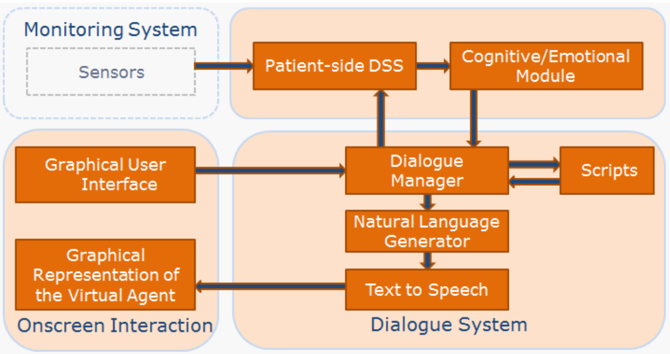

Fig. 2 The Virtual Agent components

V. Discussion and Future Work

Although the use of the FAtiMA architecture has been a reasonable solution for the first prototype of the cognitive emotional module, it is important to note that this architecture was originally developed to build agents able to show *natural empathy*. As presented in [25], it is important to distinguish the difference between natural empathy (experienced by every people in every-day situations) and *therapeutic empathy* in order to provide to the patients with a useful feedback for their particular treatment and promoting an effective therapeutic alliance.

The term therapeutic empathy is defined as when the therapist is sensing the feelings and personal meanings which the client is experiencing in each moment, when he can perceive these from "inside", as they seem to the client, and when he can successfully communicate something of that understanding to his client [22]. This particular type of empathic behaviour is the one that it is clinically relevant and should include the mechanism to modulate those useless or inadequate emotions. Thus, we are now focused in the evolution of the VA's cognitive emotional module towards this specific objective.

Based on the same theoretical roots, i.e. the appraisal theory of emotions, we are studying how the conceptualisation of therapeutic empathy (such as the presented in [25]) would be added to implement a computational therapeutic empathy system. A central aspect is the integration of a double appraisal mechanism that allows an *emotion regulation* process [9] aimed to cope with the user's negative self-reported or detected events. This process would enhance the *emotional* model of the VA which currently *simply* blocks any negative emotion produced by this kind of events. Once this mechanism has been implemented, the outcome behaviour produced in the VA can be then clinically evaluated in the further stages of Help4Mood and assess its suitability for the VA – patient interactions.

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Graphical development of the Help4Mood's Virtual Agent

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Abstract— **The graphical user interface of the Help4mood system plays a crucial role in the user's acceptance and adoption of the system. The GUI process includes also the appearance and the animation of the virtual agent. To meet the user's expectations, the clinical team has been involved from the early stages of the GUI design [1]. The design process adopts an iterative approach, submitting improved versions of the GUI to the users and the clinicians in order to collect feedback and suggestions to be integrated in the further versions.**

The target users of the Help4Mood system are people with major depression in its mild to moderate form [1]. Their level of motivation is usually low and the interface should involve them, providing a very easy-to-use system, displaying little information at a time, requesting minimal actions and allowing customization and flexibility of the interface.

Regarding the development of the agent, two levels of challenges have been driven the design team: the technical issues, including the real-time render and the integration with the rest of the help4mood components and the visual appearance of the virtual character, including speech, behaviour, movements and realism.

I. THE HELP4MOOD INTERFACE

The Help4Mood interface supports visually the interaction between the whole Help4Mood application and the patient, presenting questionnaires, collecting mood and psychomotor data, offering exercises and psycho-education, and providing access to an on-demand crisis plan if the user is feeling particularly low [3].

Two main components have been developed for the Help4Mood interface [4] (Fig. 1)

- **The window application** that allows the user to interact with the Help4Mood system.
- **The Virtual Agent**, which is the embodied 3D talking head (avatar) that interacts with the user during the sessions. The VA is embedded in the window application.

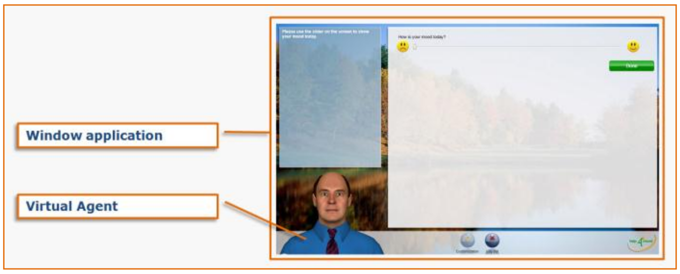

Fig 1. The two elements composing the GUI

The GUI (the Window application and the VA) is controlled by the Help4Mood DM (Dialog Manager) that activates the actions to be performed by the interface and is responsible to collect data coming from the user's interaction [4]. The Window application and the VA are synchronized by a parser that enables content actions and avatar action (expression, movement and speech). For example, the window application can show a questionnaire while the VA is talking, according to DM requirement. Or the avatar can rotate the head and look at the content area when content starts to be displayed.

II. WINDOW APPLICATION

The development of the Window application has been implemented using the .NET framework and the WPF (Windows Presentation Foundation) environment [5]. During the design phase, the user and clinicians requirements defined the following criteria for the GUI design, based on data obtained from the 10 focus groups conducted with clinicians and patients in Scotland, Romania and Spain [6]:

- Easy to use
- Relaxing visual layout (backgrounds, colours)
- Use more agent interaction and less user navigation
- Design well defined areas for navigation and contents
- Interface elements compatible with touch screen device
- Integration with the other H4M components
- Flexibility of system customization and upgrades in the future

Based on the DM request, the application presents to the patient different types of elements in order to support data collection and active interactions, like questionnaires, diary, speech recording, cognitive games, exercises and psycho-education suggestions.

A customization area gives the patient the possibility to change the background of the application *(fig 2)* or select a different VA out of four talking head avatars, two male and two female. Each avatar will be available in two clothing styles, formal or informal, to match the desired interaction style *(fig 3)*. A no-avatar option is also available [4].

Fig 2. Background customization area

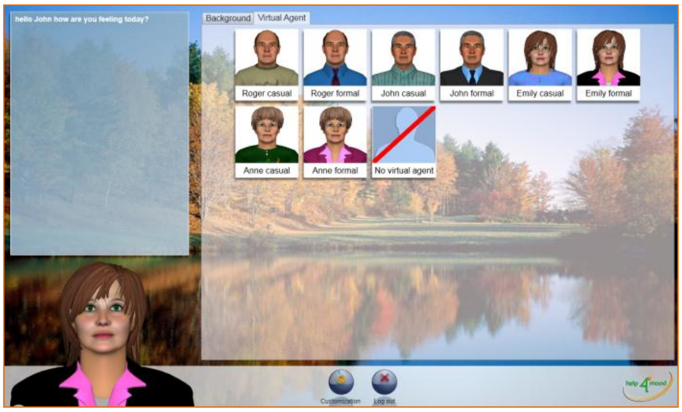

Fig 3. Agent customization area

III. The Virtual Agent

To design and animate the VA the state of the art technologies in the market have been analysed, taking into account the following criteria, derived from the user group requirements:

- Acceptance of the visual appearance by the users (based on user requirements)
- Integration with all the Help4Mood components
- Technical requirements (use of standard hardware)
- Flexibility for future evolution of the project
- Independence from software houses and/or character's design companies
- Cost effectiveness

A. Character design

Based on the project requirements [2] three software's have been selected to fulfil the design process (fig 4):

Facegen [7] used to design the different faces of the VAs combining and mixing all relevant parameters such as race, gender, age, etc.

3DS Max [8] used for the models fine tuning, for materials and clothes design, for lights and cameras and for pose, morphing and bones animations.

OGRE Exporter plug-in for 3DS Max [9] used to export the final OGRE objects.

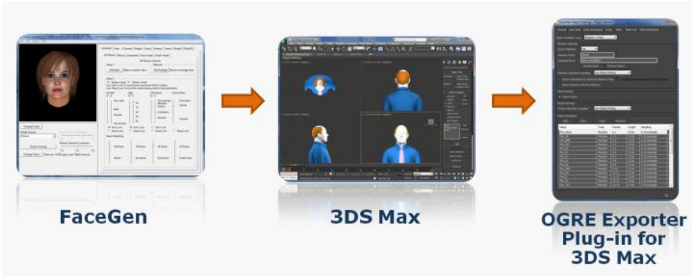

Fig 4. Process to generate the 3D models and animations

B. Character rendering

There are three main solutions to animate 3D characters:

- pre-rendered
- real-time rendering
- mixed solutions

The Help4Mood project involves different components to control the movements, expressions and speech of the VA. These requirements drove the selection of the **real-time rendering** solution to have a total flexibility on the VA control and for future development.

After a deep analysis of the solutions offered by the market, OGRE [9] has been selected has the real-time open source rendering engine to ensure a robust, stable and reliable 3D rendering environment for the agent.

Main pros:

- No cost
- A powerful set of tools available
- Very good performance even on standard laptops (C++ programming language assures high speed of real time rendering and low hardware requirement)
- Good documentation and SDK
- Perfect integration with .NET environment

After the design phase, the exported VAs has been integrated inside OGRE and a dedicated **VA rendering module** have been implemented *(Fig 5).*

Fig 5. VA dedicated rendering module

IV. The process of the VA design

First phase: In the first phase of the design process different type of characters has been submitted to the target user; real human characters, 3D virtual human characters, 3D cartoons characters, cartoons animated objects, 2D cartoon characters *(fig 6)*

Fig 6. Type of characters submitted to the target users

The target group expressed their preferences on a 3D virtual human character with a light cartoonish look.

Second phase: In the second phase seven 3D characters have been modelled and dressed up with casual and formal clothes, neutral and smile expression, with and without glasses. The users expressed their preferences for characters with no glasses, no too elegant and fancy, no too young, dressed up without doctor's coat. The four characters have been selected out of seven *(fig 7)*

Fig 7. Selection of the 4 characters out of 7 submitted to the focus group

V. The process of the VA design

During the animation phase 4 main elements have been implemented:

- Phonemes and lips animations
- Head gestures
  - Head up
  - Head down
  - Head left
  - Head right
- Automatic behaviours
  - Eyes blinking
  - Breathing
- Emotions and facial expressions
  - Neutral
  - Smile

All this animations are a mix of pose, morph and bones animations and can be combined together using percentages to have the maximum flexibility (i.e. Agent moving head up 30% and head left 70% with a strong or slight smile, while saying something).

Phoneme and lips animations are controlled by parameters that define the intensity, duration and timing of each single phoneme. Movement between phonemes are interpolated linearly. When there is no action requested from DM for a certain time, the VA enters in "idle state", and play idle animations randomly, like smiling, rotating the head etc. To make the VA more realistic automatic behaviours such as eye blinking and breathing are randomly performed *(Fig 8).*

Any animation is controlled by the DM by XML data exchange.

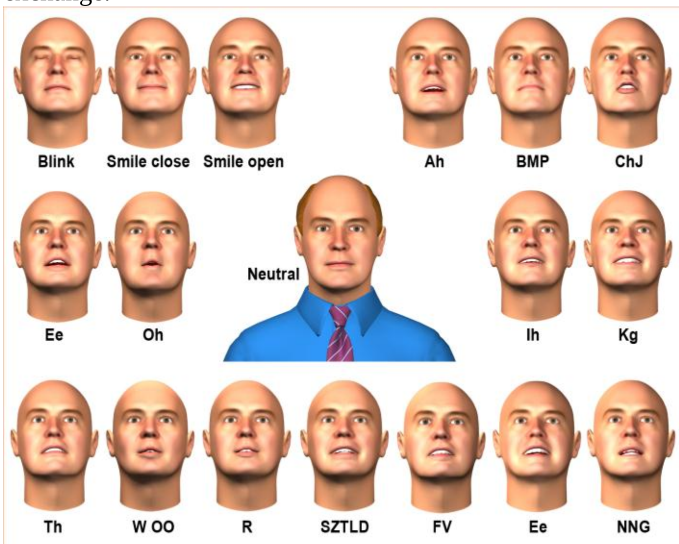

Fig 8. Phonemes and expressions of the first character

VI. Integration (plug-in architecture)

After the implementation of the Windows application and the VA the two components have been integrated in a final GUI.

The GUI is designed as a **plug-in architecture**, multi-thread and thread safe. At action source ends, GUI is able to accept actions request from the DM and also from other sources such as the GUI itself (Idle animation sensor is an example).

At action execution ends, action request will be broken into actions and dispatched to different action executors. In Help4Mood we have 3 executors:

- **VA executor**
- **GUI executor** (questionnaires, diary, speech recording, cognitive games, exercises and psycho-education suggestions)
- **System executor** (shutdown action).

This architecture gives a high flexibility for future developments. It will be possible, for example, to add, executors to play music, play games, execute system monitor and clean up. Plug-in mode gives the possibility to extend actions and sync and execute them in parallel [10] *(fig 9)*.

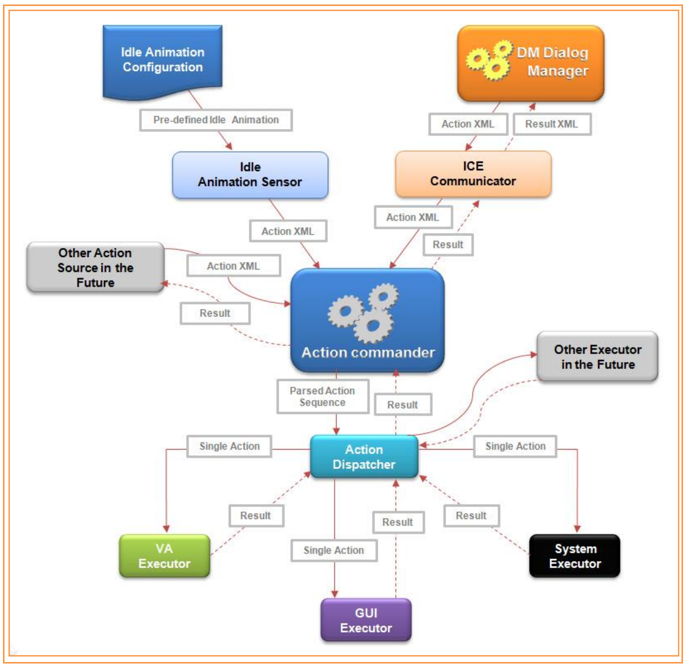

Fig 9. The plug-in architecture

VII. CONCLUSIONS

Help4Mood has been designed following specific requirements suggested by experts in the field of clinical depression. This approach drove the technical choices towards the adoption of an open architecture, flexible, easily customizable to fulfil the clinicians' needs and ready to be adapted for future use in other domains of health, like Ambient Assisted Living targeting elderly or disables. In the future, integrating more complex daily sessions, the application will allow clinicians to monitor and collect valuable information of patients' daily life and progresses, to complement, support and improve the therapeutic intervention.

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Delivering Psychological Treatments in the XXI century

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Abstract—**Effective psychological treatments for mental disorders are available. However, less than 50% of people suffering these disorders receive correct treatment; reasons include the cost and time required and the lack of well trained professionals. Therefore it is necessary to further elaborate the axis of the efficiency, including such important issues as the range of applicability of a treatment, the degree to which patients accept it, expertise and availability of qualified professionals or cost-effectiveness. Information and Communication Technologies (ICTs) can be useful to deliver and improve the application of therapeutic services, allowing deeper into effectiveness and enhancing the possibility to reach all who need it. Here we analyse some of the advantages and limitations of the Internet-delivered treatments.**

I. Introduction

Mental disorders include a wide range of problems, which can significantly disrupt the life of an individual, regardless of age, ethnicity, religion, culture or socioeconomic status. Data are really alarming. Mental health diseases will soon reach pandemic proportions in Europe. According to the WHO [1], one out of four people suffers from some type of mental disorder in the course of their life. Mental disorders mean a 40% of the chronic illnesses, the leading cause of years lived with disability, apart from being the cause of the 45-55% of absenteeism. The economic cost of these problems is enormous; the *International Labour Organization* conservatively estimates it to be 3% to 4% of gross national product of the member states of the European Union [2] and 20% of the costs of the European Union's health systems are due to the treatment of mental disorders. The impact that mental disorders have on the quality of life is higher to those chronic or heart and respiratory diseases do. In 2020 it is expected depression to be the number one cause of disease in the developed world. Clearly, effective and efficient treatments for mental disorders that can be widely disseminated are needed to address this important public health problem [3] [4].

Effective psychological treatments for several mental disorders currently exist, especially for Emotional Disorders, and a number of evidence-based cognitive-behavioural treatments (CBT) targeting anxiety and mood disorders have been developed in the last 20 years [5] [6] [7]. Research has showed that evidence-based CBT treatments are as effective as pharmacological treatments for many mental disorders, without the adverse side effects or the expense of many medical treatments [8] [9] [10].

Along with these effective treatments, various diagnosis-specific treatment manuals have been developed; much of this research and treatment emphasis on disorder-related specificity was stimulated by the widespread adoption of the DSM (the last version DSM-IV-TR), which emphasizes the differentiation of psychiatric disturbances [11]. This effort certainly represents a big progress; however, it also implies placing an important additional burden on clinicians who wish to apply empirically supported treatments to their patients, and hampers the dissemination of evidence-based psychological treatments [12].

Despite the fact that effective CBT treatments for mental disorders are available, less than 50% of patients receive correct treatment; reasons include the cost and time required and the lack of well trained professionals. Thus, many patients decide not to seek help [13] [14]. Secondly, those who receive treatment usually do so only after multiple adverse effects have occurred, which ultimately costs more than if the patients had received timely, successful treatments [15]. Finally, evidence-based treatments entail significant dissemination challenges [16] [17].

There is a clear desire to find effective ways to disseminate effective treatments and to design strategies that guarantee that patients receive treatment in an appropriate manner [18] [19].Voices have recently been raised regarding the need to radically change the way psychological treatments are delivered, as it is highlighted in the seminal paper by Kazdin and Blase [20]. They propose "rebooting" psychotherapy research and practice to reduce the burden of mental illnesses. According to Kazdin and Blase, a radical new approach is needed, something going beyond individual and one-to-one psychotherapy. They refer to the individual, one-to-one therapy with a client (child or adult), family, or group (e.g., 8–10 clients). To do so, these authors propose designing a portfolio of models of treatment delivery. These authors highlight, within this portfolio, the outstanding role of the technologies and multidisciplinary approaches to the problem. Interventions that incorporate technology will reach far greater numbers of people than traditional psychotherapy and will grant access to segments of the population that have been relatively inaccessible and neglected.

II. Internet-delivered treatments

In recent years, promising efforts have been made using ICTs in the psychological treatments field; the results have changed the delivery of mental health care, and have provided solutions, which have proven to be an useful tool to solve several mental health problems and disseminate psychological treatments [21], [22].These ICT based strategies are not new; in fact, in the late 1970's the first computer programs to increase people's consciousness of their eating habits appeared [23], [24]; in the 1980's and the 1990's programs addressing other issues appeared [25]. An important work by Isaac Marks defends the utility of these strategies [26], [27] [28]. All these efforts support the usefulness of these procedures in the movement Improving Access to Psychological Therapies Programme (IAPT) [29]. They have been added as an alternative to evidence-based treatments in the clinic guidelines of the National Institute of Clinical Excellence (NICE Guidelines). The NICE Guidelines in England support programs such as "Beating the Blues" for treating depression and anxiety [30]-[32] and "FearFighter" for treating phobias and panic disorder [33], [34]. Craske et al. [3] are leading efforts to develop flexible global protocols, from a trans-diagnostic treatment perspective. This approach has been tested in the U.S. in the biggest controlled trial in this field to date [4], [35].

Moreover, it has recently been shown that psychological treatments can be delivered through the Internet [36]. This alternative is called evidence-based computer CBT treatments or CCBT, and has been proposed as a more affordable and effective intervention for several mental disorders [37], [38]. The existing protocols are relatively more or less interactive, and are typically built on evidence-based, cognitive–behavioural approaches [39]. With internet-based interventions, clients can be supported in a variety of different ways, from guided self-help to sophisticated expert-system based treatments. The level of therapist involvement can vary from no assistance or minimal therapist contact by email or telephone, to a higher involvement.

In 2004, the *International Society for Research on Internet Interventions* (ISRII) was formed to encourage eHealth researchers to collaborate in their efforts to further the science behind developing, testing, and disseminating Web-based treatment programs [40]. Recently, the National Institutes of Health in the United States and other government agencies and various industries around the world have already allocated efforts in this direction. For example, the Australian strategy [41] scheduled for the next 10 years indicates that is expected to coexist two mental health plans, a traditional service model along with e-services that complement and improve the shortcomings of current services mental health. At this moment Australia is at the forefront in the development and delivery of e-Interventions and already offers an array of self-help and prevention and treatment programs by means of virtual clinics that are open to the public or accessible via research trials. Other countries as England, Holland, Sweden, are also working in this line.

III. Advantages and limitations

What are the advantages of internet interventions over other forms of mental health care delivery? First, the potential to provide far greater access to treatment than would otherwise be obtainable, thereby enabling greater numbers of people to receive mental health services. By delivering treatment via the internet, greater access can be provided to those who are disadvantaged due to geographical isolation, physical impairment or other mobility, time or financial restrictions; moreover, patients who otherwise would not come for treatment can receive it online. Furthermore, delivery of interventions through the Internet provides anonymity and easy accessibility, therefore making it a suitable option for patients to avoid the stigma incurred by seeing a therapist, and to obtain treatment at any time or place, work at their own pace, and review the material as often as desired. So, it may be possible to reach people through the Internet who might not otherwise receive treatment for their conditions.

Another important advantage is that internet interventions are cost effective; with costs reduced to between one third and one sixth of other psychological treatments (e.g., [41]). In this sense, one advantage of Internet-delivered treatments is that they can reduce contact time between patient and therapist. Thus, these approaches can help to disseminate evidence-based treatments [42], [43].

Recent systematic reviews of CCBT treatments delivered via Internet show that these approaches are effective for the treatment of mental disorders [30], [44]-[51]. Meta-analysis studies show the efficacy of Internet-based treatment and effect sizes comparable to those for face-to-face treatments [47]. As suggested by Ritterband et al. [40], it is not essential that internet-based treatments are more effective than face-to-face therapy, but that they provide comparable benefits and outcomes. Furthermore, it must be also highlighted that one of the clear advantages of CCBT treatments delivered via Internet has been the relative lack of any adverse events.

Despite these advantages however, high participant dropout rates are not uncommon in Internet-delivered self-applied treatments, which have shown a higher attrition rate (ranged from 2% to 61%) compared to traditional face-to-face treatments [47].The attrition problem has various causes, but a study of the interaction between the user and the system would likely improve these rates, and also it is important the development of theoretical models of adherence [52]. Andersson et al. [36] reviewed evidence on these interventions and made several suggestions about "what makes Internet therapy work". In their opinion, an important aspect is the kind of support provided by the therapist. It is needed to identify predictors of suitability, compliance and completion of Internet treatments. As [53] point out, this analysis will allow to identify which type of therapeutic delivery is likely to be most efficacious for each individual (e.g., internet-based or face to face), thereby maximizing treatment outcome and cost effectiveness.

IV. CONCLUSIONS

We are only seeing the beginning of a new era for psychological treatments. Internet based interventions are an emerging and very promising area in mental health care. Recent reviews show that CCBT for mental disorders (especially Emotional Disorders) via Internet has the capacity to provide effective health care for those who might otherwise remain untreated. Clarke et al. [54] stated that these kinds of strategies highly disseminable, and low-cost interventions can help solving important public health problems. Klein [55] claims that healthcare systems and their related practices are by nature "conservative, steeped in tradition and slow to change", however this author argues that the field of e-Interventions has developed a critical mass that can no longer be easily ignored.

In a recent interview, Alan Kazdin argued that although the treatments for mental health problems have made great strides in recent decades, the major problem is that the evidence-based treatments are not reaching people who need them. Kazdin claimed this was because the mental health field continues to rely heavily on individual psychotherapy, and is not prepared to help the vast majority of patients. Kazdin said "... For me, it's like an emperor's new clothes situation. All these people — including me — do very expensive controlled trials of therapy and yet we see that most people aren't getting treatment at all. Something is wildly, drastically wrong. Considering the challenges of disseminating evidence-based treatment programs and the thousands of people that need help, it is imperative to conduct further research in this area. Internet-based treatment has arrived and it is beginning to truly serve us. The prediction seems to be that Internet technologies are here to stay, to grow, and to improve even further in the coming years.

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Coping with Stress: A Program for the Prevention of Depression

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Abstract—**Emotional disorders are one of the most common health problems worldwide, and their economic costs are very high. It is known that 25% of all human beings will suffer from depression at any moment over their lives and, according to the World Health Organization depression will become the second most important cause of disability in 2020. These data underscore the importance of designing tools to identify people at risk, who are exposed to high levels of stress or are in a difficult situation. Information and Communication Technologies (ICT) can help us in this task. Recent systematic reviews of literature on evidence-based Cognitive Behavioural Therapies (CBT) delivered via the Internet show that these approaches are effective. Taking all this into consideration, within the framework of the OPTIMI project *(Online Predictive Tools for Intervention in Mental Illness)*, financed by the 7th Framework Programme of the European Union, we have designed tools based on ICT for early detection and prevention of depression. *Smiling is fun* is a CBT self-applied program via the Internet that tries to help people in the prevention of depression and anxiety symptoms, and in the promotion of emotion regulation. The aim of the present work is to describe this program, the design followed in the study, present preliminary data from two participants regarding: their opinion, level of satisfaction, acceptance of the program, and the pre and post-treatment scores of the main primary and secondary measures.**

I. Introduction

Emotional disorders (mood and anxiety disorders) cause important costs to economy through the loss of productivity. These illnesses damage the family and friends networks and therefore it markedly impacts at the societal level. For example, in England the cost of mental health problems has increased to £105.2 billion in 2009/10 [1] and in the United States of America, direct treatment costs of mental disorders were estimated to be around 2.5% of the gross national product. Indirect treatment costs are two to six times higher [2]. Furthermore, depression is the leading cause of disability and the 4th leading contributor to the global burden of disease in 2000. By the year 2020, depression is projected to reach the 2nd place of the ranking of DALYs (Disability Adjusted Life Years) calculated for all ages and both sexes [2], [3]. Today, depression is already the 2nd cause of DALYs in the age category 15-44 years for both sexes combined [2]. These data confirm that we need to develop new strategies to help those affected, and more importantly, given the near exponential increment in the number of sufferers (young, adolescent, adult, aged, and repeat episodes), we need to develop better tools for identification of subjects at risk and to design effective prevention programs. Depression and anxiety are treatable illnesses with Cognitive Behavioural Therapies (CBT) as the treatment of choice [4], [5], [6]. However, the provision of mental health care is generally less than adequate in terms of accessibility and quality, less than 50% of people with emotional disorders receive appropriate treatment either because of its the cost, the time required in its application and / or lack of well trained professionals. Therefore, many patients are reluctant or have difficulty getting help [7]. Information and Communication Technologies (ICTs: virtual reality techniques, computer-assisted therapy, using the Internet as a support for the implementation of treatment ...) may be useful to improve ways to apply these psychological treatments. Recent systematic reviews of literature on evidence-based CBT treatments delivered via the Internet show that these approaches are effective [8], [9]. These computerised treatments are actively being tested and every time more used for wide application to meet the growing need for treatment, and provide a good alternative for traditional CBT that is restricted due to a combination of the number of available therapists, with adequate quality training, as well as economics and physical accessibility [10].

Taking all this into consideration, within the framework of the OPTIMI project (*Online Predictive Tools for Intervention in Mental Illness*) financed by the 7th Framework Programme of the European Union, we have designed tools based on the ICTs for early detection and prevention of depression.

OPTIMI tries to improve the current Computerised Cognitive Behavioural Therapies (CCBT) state of the art approaches. The central hypothesis is that there is a significant relationship between depression, stress, and the person's coping ability [11]. That is to say that the central issue in the onset of depression and stress related disorders is the individual's ability to cope with stress on a psychological and a physiological level. Some cognitive, behavioural, and physiological monitoring tools have been developed using different sensors. Furthermore, we have developed an assessment and treatment protocol ICT based: *Coping with Stress and Emotion Regulation Program* (Smiling is Fun), an internet-delivered, multimedia, interactive, self-help program for emotional disorders. The program tries to combine the most effective existing psychological procedures for stress management with strategies to promote emotion regulation, coping capacity and resilience. It follows a trans diagnostic perspective and is based on classical CBT techniques, as behavioural activation. However, it also includes other psychological strategies to improve positive mood. We hypothesized that this program will allow the individual to learn and practice adaptive ways to cope with depression and daily problems.

The aim of the present work is to describe the design following the OPTIMI study, describe the Smiling is fun program, and present preliminary data about the acceptability, and pre and post treatment main scores from two participants who used it.

II. METHODOLOGY

A. Participants

Participant one (P1) is a 44-year old Caucasian man, married, and with a university degree. As for education he has a higher educational level. With respect to his marital status he is married. At the moment he started the treatment program he was unemployed, referred to have dependents, had debts, and one member of his family suffered from a chronic disease (Alzheimer).

Participant two (P2) is a 25-years old Caucasian man, single and with basic information. At the moment he started the treatment program he was unemployed (and other family members were also unemployed), he had a mortgage, legal problems, and suffered from chronic back disease.

The inclusion criteria were being male, aged 18–65 and unemployed. They also had to be willing to participate in the study and able to use a computer, apart from having an Internet connection at home. Exclusion criteria were proneness to skin allergies that might be exacerbated by wearing stick-on sensors, personal history of depression/psychosis (acute BDI II $\geq$ 19), history of depression/psychosis in any first-degree relative, heart conditions, epilepsy, daily intake of recreational drugs, sleep medication, and regular intake of any medication for heart conditions or that might interfere with cardiovascular function.

B. Measures

The measures used in the present study are:

Beck Depression Inventory II [12]. This is one of the most widely questionnaires used to evaluate severity of depression in pharmacological and psychotherapy trials. The instrument has good internal consistency (Cronbach's alpha of 0.76 to 0.95) and test-retest reliability of around 0.8 [12]. The Spanish version of this instrument has also shown a high internal consistency (Cronbach's alpha of 0.87) for both the general [13] and the clinical population (Cronbach's alpha of 0.89).

Mini-International Neuropsychiatric Interview (MINI) [14]. This is a short structured diagnostic psychiatric interview that yields key DSM-IV and ICD-10 diagnoses.

Overall Anxiety Severity and Impairment Scale [15]. OASIS consists of 5 items that measure the frequency and severity of anxiety, as well as the level of avoidance, work/ school/home interference, and social interference associated to anxiety. A psychometric analysis of the OASIS scale found good internal consistency (Cronbach's alpha = 0.80), test-retest reliability (k = 5.82) and convergent validity [15] for this scale.

Overall Depression Severity and Impairment Scale [15]. ODSIS is a self-report measure which consists of 5 items, evaluating experiences related to depression. ODSIS measures the frequency and severity of depression, as well as the level of avoidance, work/school/home interference, and social interference associated to depression. So far, no other studies examining the psychometric properties of this scale have been published. It is recommended to use and to interpret it in the same way that OASIS [15].

Positive and Negative Affect Scale [16], [17]. PANAS consists of 20 items that evaluate two independent dimensions: positive affect (PA) and negative affect (NA). The range for each scale (10 items on each) is 10 to 50. The Spanish version has demonstrated high internal consistency (0.89 to 0.91 for PA and NA in women and 0.87 for AP and 0.89 for AN in men) in college students [17]. This is consistent with the findings in the literature [16].

Brief COPE [18]. It is a self-report questionnaire used to assess a number of different coping behaviours and thoughts a person may have in response to a specific situation. The questionnaire has shown good internal consistency with Cronbach's alpha between 0.60 and 0.90 [19].

Multicultural Quality of Life Index [20]. It is a self-administered questionnaire that uses 10 items to assess global perception of quality of life in addition to physical and emotional well-being, self-care, occupational, and interpersonal functioning, community and services support, and personal and spiritual fulfilment. The homogeneity of the questionnaire proved to be good, yielding a Cronbach’s alpha coefficient of 0.79 [21] and has applicability, reliability, and validity.

Perceived Stress Scale [22]. The PSS is a 14-item self-report questionnaire that assesses the degree to which recent life situations are appraised as stressful. Spanish validation of this scale has an internal consistency of 0.86 [23].

Opinion of Treatment Scale [24]. This questionnaire assessed aspects that address these two scales relate to: 1) the logic of treatment, 2) the satisfaction experienced, 3) level of recommendation 4) the perceived usefulness treating other psychological disorders, 5) perceived usefulness in the same case 6) intervention aversiveness.

C. Design

The work follows a between-group design with three experimental conditions (see Fig. 1): i) Intervention program plus sensors. Participants in this condition have access to the CCBT Intervention Program and use the sensors (IP+S: CCBT, N=19), ii) Intervention program. Participants in this condition have just access to the CCBT Intervention Program (IP: CCBT, N=22), and iii) Waiting list control condition. Participants in this condition do not have access to the sensors neither to the CCBT Intervention Program (C, N=20). There are five assessment moments: Pre treatment, Post treatment, three, six, and twelve month follow ups. At this moment the work is in progress, that is why in the present study we present preliminary data from two participants: one of the IP+S: CCBT condition, and another one of the IP: CCBT.

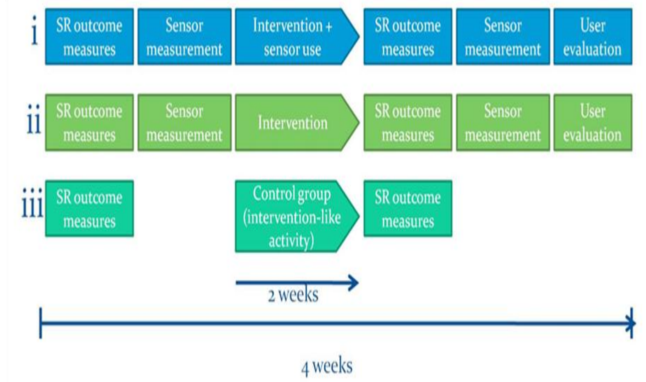

Fig. 1 The three experimental conditions

D. Treatment

The participant received a totally self-administered via the Internet CBT program (*Smiling is fun*). The treatment protocol consisted of 8 treatment interactive modules with the following main therapeutic components: motivational, educational, cognitive, behavioural activation, and positive psychology. A detailed description of the treatment program will be described in Section III: *Smiling is Fun* program.

Participants that belong to the IP+S group, besides accessing the CCBT Intervention Program, have used the physiological sensors: EEG and ECG sensors to detect subjects' physiological and cognitive state, and accelerometers to characterize their physical activity. These sensors are technology-based tools to monitor the physiological state and motor behaviour of individuals and to detect changes associated to stress, poor coping, and depression. The participants receive feedback in graphical form data from the sensors.

E. Procedure

First, the participants were recruited via announcements to the University community, advertisements in the media, Internet, and direct contact with local Job Centres. All volunteers who contacted us had to answer an online questionnaire which assessed whether they met the minimum requirements to join the study (unemployed men). Next, we called 205 men (pre-screening by phone) to filter the most important exclusion criteria. The participants who went through the pre-screening by phone were asked to attend an initial interview. In this interview the Diagnosis of major depression was carried out with MINI International Neuropsychiatric Interview and scoring of depression using the Beck Depression Inventory II. Furthermore, the participants completed the self-report questionnaires and a screening questionnaire to determine eligibility that is based on the exclusion criteria listed above. Finally, the participants who met the inclusion criteria (N=61) were randomized to the control group, the intervention group, or the intervention plus sensors group.

Participants from both intervention groups received a weekly phone support call (2 minutes) where they were reminded of the importance of carrying out the tasks that are proposed in the different modules of the treatment program, and about the convenience of doing one module per week.

III. SMILING IS FUN PROGRAM

Smiling is Fun is an internet-delivered, multimedia, interactive, self-help program for emotional disorders, which will allow the individual to learn and practice adaptive ways to cope with depression and daily problems. Each module includes exercises to practice such techniques. The program includes a *Home module*, which contains a number of elements to explain very simply what *Smiling is Fun* is, its goal, who can benefit from this, use conditions acceptance, and who we are (see Fig. 2); a *Welcome module* which provides the user with information about the content of the modules included in the program and recommendations for the user to benefit the most from it; and eight treatment modules: (1) *Motivation for change*, whose aim is to analyse the advantages and disadvantages of changing, emphasizing on the importance of being motivated, (2) *Understanding emotional problems*, that provides information to recognize and understand the emotional problems, (3) *Learning to move on*, that focuses on behaviour activation by teaching the importance of "moving on" to acquire a proper level of activity and involvement in life, (4) *Learning to be flexible*, which aims to teach a more flexible way of thinking and to interpret situations and learning to think about different alternatives, (5) *Learning to enjoy*, which focuses on the importance of generating positive emotions, promoting the involvement in pleasant and significant activities, and contacting with other people, (6) *Learning to live*, that focuses on understanding the importance of identifying the individual's own psychological strengths and selecting and carrying out meaningful activities linked to values and goals in life, (7) *Living and learning*, which focuses on developing an action plan to boost the individual psychological strengths, (8) *From now on, what else…?*, which aim is to go on and strengthen what has been learnt during the program.

Furthermore the program uses three transversal tools: 1) Activity report for self-monitoring, whose aim is to provide feedback to the user and help him see that his mood is related to the activities performed, and also the benefits of being active are greater to the extent that activities are meaningful to him. 3) The calendar (see Fig. 3) allows the users to know where they are throughout the program and provides them with information regarding homework and tasks already achieved, remembering also those still outstanding. 3) "How am I?" offers a set of graphs and feedbacks to chart the user's progress.

Fig. 2 Home module

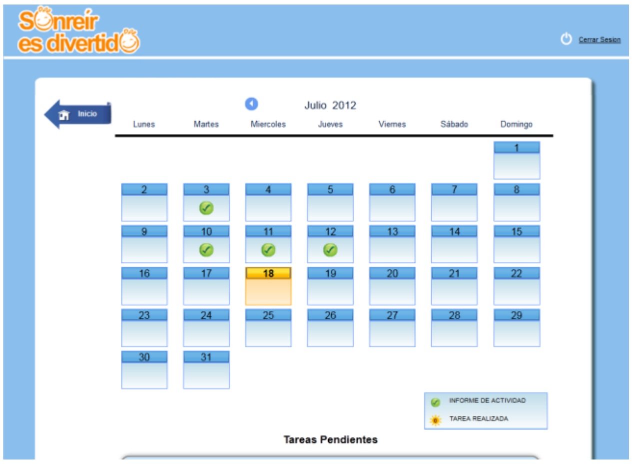

Fig. 3 The calendar.

IV. RESULTS

Results of P1 and P2 before treatment and post treatment are shown in Table I.

TABLE I
RESULTS OBTAINED FROM P1 AND P2

	P1		P2	
	Pre	**Post**	**Pre**	**Post**
BDI-II	6	2	10	7
OASIS	5	2	0	0
ODSIS	0	0	0	0
PANAS +	34	36	35	37
PANAS -	15	10	18	17
QLI	8'1	8'1	7'3	7'9
PSS	4	3	2	1
Brief COPE				
Active coping	4	6	7	8
Acceptance	5	6	8	8

Regarding the results obtained from the pre and post treatment, they showed in both cases improvement in mood as measured by the BDI-II. Furthermore, P1 presented less anxiety in the post-treatment measured by the OASIS. ODSIS scores are stable in both participants. Concerning positive and negative affect, the positive affect slightly increased and the negative affect decreased in both participants. Despite being in the same stressful situation their perception of quality of life is relatively stable and decreases their perceived stress. Finally there is a slight improvement in the active coping and acceptance, two important subscales of the Brief COPE. In addition (see Table II), they considered that the program is logical, they are satisfied with it, and they would recommend it to a friend. Moreover, they think that the treatment could be useful in treating other psychological problems and have found the program has helped them. Finally, they do not consider the program was aversive.

TABLE II
RESULTS OBTAINED FROM THE OPINION OF TREATMENT SCALE

Item	**P1**	**P2**
How logical do you think this treatment is?	8	10
How satisfied are you of the treatment you received?	9	8
How would you recommend this treatment to a friend who had the same problem?	10	10
How do you think this treatment could be useful in treating other psychological problems?	9	8
To what extent do you think the treatment was helpful for you?	8	8
To what extent was this treatment aversive to you?	1	1

Finally, the answers concerning the opinion from P2 about the sensors at post-treatment showed that he has a good opinion about them (see Table III).

TABLE III
THE OPINION FROM P2 ABOUT THE SENSORS

Questions	**Answer**
Were the sensors easy to put on and remove?	Yes
Did the sensors interfere in your daily life?	No
Was it easy to understand graphs showing data from the sensors?	Yes
Was it helpful to see data from your sensors?	Yes

V. CONCLUSIONS

The results obtained in this study show that *Smiling is Fun* can be a useful tool for the prevention of depression. The participant's opinion after the treatment was in general very positive. Data show that the system has been well received and accepted. Results are encouraging because, although the participants were going through a very difficult situation, they did not show any depression symptoms, and even some variables improved, such as positive affect, perceived stress, and active coping.

Although the results obtained in the present study are promising, they must be taken carefully since this is only a two-case study. Therefore, data from all participants is needed in order to withdraw firmer conclusions.

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Business models for the ICT applied to mental health

Potential market for the OPTIMI products

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Abstract—**This document analyses the potential market for services based on OPTIMI technology. We identify specific markets and scenarios for the commercialization of the OPTIMI outcomes presenting a cost-benefit analysis for each scenario. We conclude that the most interesting scenarios for OPTIMI are monitoring and treatment of patients who have already suffered a Severe Depressive Episode, sales to Employee Assistance Programs (EAP) providing services to employees at high risk of depression (police, firemen, other emergency workers, call-centre operators etc.), and sales to EAP providing services to elite employees (managers etc.).**

I. INTRODUCTION

Mental disease is one of the greatest personal, societal and economic problems of the modern world. While millions suffer, health services struggle to keep up. Mental health care represents over a third of the cost of health care to all EU Nations; the costs in terms of lost productivity are probably higher. The most common of all mental disorders is Depression. This disease causes immense individual and family suffering, in many cases leading to suicide. The goal of OPTIMI is to contribute to the prevention of Depression.

Currently the main treatments for depression are drugs and evidence-based Cognitive Behavioural Therapy (CBT). Clinicians have few options for prevention; the only available diagnostic tools for early diagnosis or for measuring the effectiveness of interventions are standardized inventories. OPTIMI aims to improve this situation. Depression is often associated with poor coping behaviour in the face of stress. Some individuals are extremely resilient but others find it difficult to cope.

Based on these premises, OPTIMI has set itself two goals:

- The development of new tools to monitor coping behaviour in individuals exposed to high levels of stress;
- The development of online interventions to improve this behaviour and reduce the incidence of depression.

At the time of writing, OPTIMI already developed and tested wearable and domestic appliances based on EEG, ECG, Cortisol levels, Voice analysis, Physical activity analysis and a self-reporting electronic diary. In addition, OPTIMI obtained significant preliminary results related to the effectiveness of predicting the risk of depression from the combined study of physiological and psychological variables through artificial intelligence techniques. Currently, we are finishing testing two applications adapted from two existing systems, already used to provide online CBT treatment for mental disorders.

This document will present preliminary work regarding the exploitation of the OPTIMI outcomes, specifically, we analyse possible markets for OPTIMI products and services. Currently, we do not have still the data required to estimate the cost-effectiveness of OPTIMI technology and methods. On the cost side, there are still opportunities to optimize and simply the sensor design reducing costs for manufacturing and support. On the benefits side, we need to test the effectiveness of the system in different scenarios. This requires properly powered randomized controlled trials (RCT). In this document, therefore, we will not present a fully-fledged costs-benefit analysis. What we will try to do is to assemble enough evidence to identify potential markets for OPTIMI-based services.

On this basis, we analyse the cost and benefits associated with the use of OPTIMI in three distinct market segments: services for insurance companies and national health services, services for Employer Assistance Programs, and services for individuals, outside a clinical context.

II. MARKET ANALYSIS

In this section, we present a preliminary analysis of the potential market for OPTIMI. We begin by quantifying the enormous economic cost of depression for the countries of the main OPTIMI partners (China, Spain, Switzerland, and the UK). In the next step, we identify different scenarios for the deployment of OPTIMI in clinical and non-clinical contexts and examine the costs and benefits of OPTIMI in each scenario. In several, we find that OPTIMI is unlikely to be cost-effective. However there are at least three scenarios, which present important commercial opportunities. However, we point out that it will first be necessary to organize properly powered RCT.

A. *Prevalence and cost of depression*

1) *UK:* The *ECNP/EBC Report 2011: Cost of Disorders of the Brain in Europe* [1] provides the following estimates of the prevalence and cost of mood disorders in the United Kingdom (see Table 1).

TABLE I

COST OF MOOD DISORDERS IN UK

Number of patients (million)	3,9
Prevalence (%)	6,28
Cost per patient (medical and non-medical costs) (Eur)	4,887
Total cost of depression to the UK economy (medical and non-medical costs) (Eur million)	19,238

2) *Switzerland:* [1] provides the following estimates of the prevalence and cost of mood disorders in Switzerland (see Table 2).

TABLE II

COST OF MOOD DISORDERS IN SWITZERLAND

Number of patients (million)	0,5
Prevalence (%)	6,42
Cost per patient (medical and non-medical costs) (Eur)	4,224
Total cost of depression to the UK economy (medical and non-medical costs) (Eur million)	2,144

3) *Spain:* [1] provides the following estimates of the prevalence and cost of mood disorders in Spain (see Table 3).

TABLE III

COST OF MOOD DISORDERS IN SPAIN

Number of patients (million)	3,0
Prevalence (%)	6,49
Cost per patient (medical and non-medical costs) (Eur)	3,232
Total cost of depression to the UK economy (medical and non-medical costs) (Eur million)	9,705

4) *China:* A recent paper [2] estimated a 12-month prevalence rate of 2,5% in Beijing and 1,7% in Shanghai. The same paper estimated the total cost of depression in China at 51.370 million Renminbi (RMB) (or US 6.264 million) at 2002 prices. The paper estimated the direct cost at 8,90 million RMB (or US 986 million), about 16% of the total cost. 84% of the total cost 43.280 million RMB (US$ 5.278 million), was due to indirect costs for lost productivity etc.

B. Opportunities for OPTIMI

We have identified three potential markets for OPTIMI products and services, namely health providers (national insurance companies and insurance companies), employee assistance programs, and individuals. On this basis, we have developed the following scenarios:

- Health Providers
  - i. Use of OPTIMI for the monitoring ("watchful waiting" or "active monitoring") of patients at high risk of depression or with sub-threshold symptoms.
  - ii. Use of OPTIMI for treatment and monitoring of patients with sub-threshold symptoms of depression.
  - iii. Use of OPTIMI for treatment and monitoring of patients at risk of relapse after recovery from a depressive episode.
- Employee Assistance Programs
  - i. Use of OPTIMI CCBT and monitoring services in stress management programs for employees in the private and public sector, especially programs targeting employees expose to high levels of stress in their jobs.
- Individuals
  - i. OPTIMI-based stress management and monitoring.

C. Cost benefit analysis

In what follows, we analyse the costs and benefits of OPTIMI for the five scenarios described earlier. We begin by describing the costs of the service, most of whose elements are common to all scenarios. We then go on to analyse the benefits. For each scenario, we begin by providing a detailed description of the scenario. We go on to analyse the benefits OPTIMI can offer, presenting our argument in the form of a brief SWOT analysis. Finally, we identify the critical factors likely to determine purchasing decisions.

1) Costs of OPTIMI products and services

From the point of view of the owner of OPTIMI technology (e.g. the OPTIMI Consortium, a subgroup of OPTIMI partners, a future licensee of OPTIMI technology), the costs of designing, implementing and deploying OPTIMI products and technology consists of the following elements:

- Fixed costs (costs that do not depend on volume of sales)
  - i. Costs of developing OPTIMI technology.
  - ii. Costs of validating OPTIMI technology for specific uses (clinical trials).
  - iii. Costs of initial OPTIMI infrastructure (hardware, user support).
  - iv. Initial marketing costs.
- Variable costs (costs that depend on the volume of sales)
  - i. Costs of manufacturing sensors (lower for larger numbers of users).
  - ii. Ongoing marketing costs.
  - iii. Costs of operating OPTIMI infrastructure.
  - iv. Costs of providing user support.

From the point of view of the customer, it will be necessary to pay a mark-up to the owner of the OPTIMI technology, who will need to make a profit. In some scenarios, there may also be additional costs of implementation (e.g. costs for providing clinical support to patients). Health provider evaluations of OPTIMI will be based on the total cost of implementation. Some of these costs will be the same in all scenarios. Some will differ. In what follows, we analyse them one at a time.

4.1) Fixed Costs

i. Costs of developing OPTIMI technology

We estimate that developing the current OPTIMI prototypes into a commercial product would require the work of a team of 1 manager, 3 software developers and 3 hardware developers for a period of approximately 18 months. At an estimated cost of Eur 100.000 per person per year this gives a total capital expenditure of Eur 1.050.000.

ii. Costs of validating OPTIMI technology for specific uses (clinical trials)

For the three clinical applications of OPTIMI (scenarios 1.1-1.3) it will be necessary to validate the technology with at least one RCT per scenario. Based on the experience of one of the OPTIMI adapted software "Beating the Blues", an effective RCT for the use of OPTIMI for treatment or as an adjunct to treatment would require the recruitment of 200-300 patients each of whom will have at least three interviews with a clinician. On this basis we estimate the total cost of RCTs as Eur 1.380.000.

TABLE IV

ESTIMATED COST OF RCT ALLOWING DEPLOYMENT OF OPTIMI IN THE CLINIC

Item	**Value**	**Unit**	**Calculation**
A) Number of patients	300	People	
B) Interviews per patient	3	Interviews	
C) Cost per interview	100	Euro	
D) Total cost of interviews	90.000	Euro	A*B*C
E) Equipment cost per patient	100	Euro	
F) Cost of equipment	30.000	Euro	A*E
G) Total patient-related costs	120.000	Euro	D+F
H) Management staff	2		
I) Annual cost of management staff	100.000	Euro	
J) Technical support staff	2		
K) Annual cost of technical support staff	70.000	Euro	
L) Duration of trial	1	Year	
M) Total staff costs	340.000	Euro	L*(H*I+J*K)
N) Total cost of trials	460.000	Euro	G+M
O) Number of Trials	3	Trials	
P) Total cost of trials	1.380.000	Euro	

iii. Costs of initial OPTIMI infrastructure (hardware, user support)

It is not possible to launch an OPTIMI service for any scenario, without an initial hardware infrastructure, and without an organizational structure to provide management and technical and marketing support. An OPTIMI service provider will carry the associated costs regardless of the number of users initially attracted to the service.

TABLE V

ESTIMATED COSTS OF INITIAL INFRASTRUCTURE AND STAFF

Item	**Number**	**Unit cost**	**Total cost**
Manager	1	100.000	100.000
Marketing staff	2	70.000	140.000
Technical staff	2	70.000	140.000
Technical infrastructure	1	50.000	50.000
Total			430.000

iv. Initial Marketing

It is essential to the viability of OPTIMI that it attracts a large user population. It will therefore be necessary to invest a significant sum in initial marketing of the system. We assume, rather arbitrarily that the OPTIMI advertising budget equivalent will amount to 20% of total fixed costs (including advertising). This gives a total initial advertising budget of Eur 830.000.

v. Fixed Costs per user

Spreading the fixed costs of launching an operational version of OPTIMI across a target population of 20.000 users and assuming an amortization period of three years, we obtain a fixed cost per user of Eur 62. Obviously, this figure is highly sensitive to the initial assumptions. With a larger or a smaller user population the cost would be proportionately lower or higher.

TABLE VI

CONTRIBUTION OF FIXED COSTS TO THE END-USER COST OF OPTIMI SERVICES

Item	**Value**	**Unit**	**Calculation**
A) Technology development	1.050.000	Euro	
B) RCT	1.380.000	Euro	
C) Initial infrastructure	430.000	Euro	
D) Advertising	830.000	Euro	
E) Total cost	3.960.000	Euro	A+B+C+D
F) Amortization	3	Years	
G) Cost per year	1.230.000		E/F
H) N. Users per year	20.000		
I) Cost per user	62	Euro	G/H

4.2) Variable Costs

i. Costs of manufacturing sensors (lower for larger numbers of users)

For production volumes in excess of 1.000 units, we conservatively estimate the following unit costs for sensors

- ACT: Euro 43,00/sensor.
- ECG: Euro 52,00/sensor.
- EEG: Euro 65,00/sensor.

Using this numbers the total cost for the complete set of sensors and the technical assistance service would be 170.00 euros. Different scenarios would use sensors in different ways. In *scenario 3 (Direct sale of OPTIMI products and services to individuals, for purposes of self-help)*, the end-user would pay the full cost of the sensor. In all other scenarios, sensors would be given to users only for the duration of monitoring or treatment, which we assume would be brief (2-3 weeks). In this case, it would probably be possible to use each set of sensors for at least 3 users and the average cost would fall to approximately Eur 56/user. It is also possible that results from the current OPTMI trials will make it possible to eliminate one or more of the sensors. In this case the cost would be lower. In D7.7, we will present a preliminary analysis, testing the feasibility of this approach.

ii. Costs of operating the OPTIMI infrastructure

If OPTIMI is to serve a target population of 20.000, each using the system for a period of 3-6 weeks, technical infrastructures should be dimensioned to handle 2.000-

3.000 users in any one period. The current design of the OPTIMI service means that many of these users would come online at the same time in the evening and morning when they connect the sensors to the HomePC application and upload their data. This means that traffic patterns could be very uneven placing heavy demands on server and network infrastructure.

For a target population of 20.000 we estimate the costs shown in the table below:

TABLE VII

COSTS OF OPERATING OPTIMI INFRASTRUCTURE

Item	**Cost 1 year (euros)**	**Observations**
Technical infrastructure	100.000	
Network	100.000	
Staff	250.000	1 manager + 3 technicians
Total	450.000	
Cost per user	23	

iii. Costs for user support

In our scenarios, technical and customer support takes the form of support via a call center, which receives a fee of Eur 1 per minute support provided. The British IAPT program currently estimates that each patient using CCBT requires an average of 60 minutes support. Given the added complexity of OPTIMI the amount of support required would presumably be higher. From experience in the calibration trials, we estimate that each user will require an average of 90 minutes support. We therefore estimate the cost of technical support as Eur 90 per participant. If the OPTIMI trials lead to a reduction in the number of sensors per user and reduced complexity, users would probably require less technical support and costs could be lower.

iv. End user prices

On the basis of the estimates above, we estimate the price of OPTIMI for individual users, who bear the full cost of the OPTIMI sensors, and for users in a clinical setting who share sensors with other users, bearing only a part of the cost. The calculations assume a target population of 20.000 (a relatively small figure). It is further assumed that the OPTIMI provider applies a 40% mark-up, and spends 20% of revenues on marketing. On these assumptions the end-user price for a course of monitoring/treatment with OPTIMI would be of the order of Euro 580 for individual consumers and Eur 390 for users in a clinical setting. These estimates are sensitive to the size of the target population, to the cost of the sensors and to costs for user support. With a larger user population, and with cheaper, less complex sensors, end-user prices could be significantly lower.

TABLE VIII

END-USER PRICE OF OPTIMI

Item	**Consumer market (individual sensors)**	**Clinical market (shared sensors)**
Share of fixed costs	62	62
Sensors	170	56
Infrastructure	23	23
User support	90	90
Direct cost	344	230
Markup 40%	138	92
Price before marketing	482	322
Marketing 20%	96	64
Price per user	578	386

v. Additional Costs of implementation

Individual users of OPTIMI have no cost of implementation except for the purchase of the sensors and the service. However, when OPTIMI is used in a clinical setting, health providers will assume additional costs. These will include, as a minimum, the cost of a nurse or a technician to brief the patient the first time he/she uses the sensors. We estimate this cost at approximately Eur 50 per patient. Adding this cost to the costs considered in the previous paragraphs, we calculate that for health providers, the total cost would be of the order of Eur 440 per patient. This is the figure to be considered in analysing the cost-utility of the service.

D. Use of OPTIMI in different scenarios

Evidently, the benefits of OPTMI in particular scenarios depend on its effectiveness. To date, the OPTIMI Consortium has limited, preliminary data on the ability of the system to detect poor coping behaviour and no data at all on its ability to improve this behaviour. Similarly, the Consortium has no data on OPTIMI's ability to prevent or treat depression. Obtaining such data requires appropriately powered RCT. However, it is implausible that OPTIMI will be more effective than current best practice. Its main advantage is that it is scalable: with OPTIMI, it becomes possible to offer preventative services to far larger populations than could ever be served by human psychotherapists. This means that, if the price is right. OPTIMI can still be cost-effective, even if it is less effective than face-to-face psychotherapy. In what follows, we will examine this proposition for the scenarios presented earlier.

1) Scenario 1.1: Use of OPTIMI for medium-term monitoring ("watchful waiting") of patients at high risk of depression or with sub-threshold symptoms

In this scenario, the OPTIMI sensors and prediction engine are used to detect warning signs of stress, poor coping and depression in patients believed to be at high risk or with sub-threshold symptoms. The system is used without CCBT.

NICE guidelines currently suggest that patients reporting sub-threshold symptoms of depression should be placed in a regime of "watchful waiting" or "active monitoring". In practice this usually means that the patient was asked to periodically fill in a PHQ questionnaire, administered by a nurse in the surgery or available online, at no charge to the National Health Service. Anecdotal evidence suggests that at least in the UK, this practice is now less popular, and that many primary care physicians immediately prescribe CCBT or "bibliotherapy". However, in other countries (e.g. Switzerland), this practice is less widespread and seems unlikely to win general acceptance. In these conditions OPTIMI could provide a tool that is less expensive than repeated clinical interviews, but more effective than an online questionnaire. Obviously, this effectiveness would need to be demonstrated in an RCT.

1.1) SWOT analysis

Strengths: (1) Results from the OPTIMI calibration trials provide proof of principle that OPTIMI could provide an effective monitoring tool; (2) in countries where providers are not willing to limit monitoring to online questionnaires, OPTIMI could be the only cost effective way of reaching patients; (3) in countries in which physicians do not accept the use of CCBT or bibliotherapy OPTIMI-based monitoring could be used as a method for selecting patients to receive face to face psychotherapy or pharmacological treatment.	***Weaknesses:*** (1) The sensitivity and selectivity of the OPTIMI prediction tool is still too low to justify its adoption in a clinical setting; (2) even for a more effective tool, winning approval will require an expensive RCT; (3) studies suggest that to prevent one case of depression it is necessary to treat 17 patients with sub-threshold symptoms [3]. This makes any form of preventative monitoring an expensive option (4) For the same reason, a properly powered RCT would have to be relatively long (at least 18 months) and would require a relatively large number of participants. Such a trial would inevitably be expensive.
Opportunities: In most countries, health providers do not have the resources to offer regular face-to-face interviews with high risk patients; where interviews are offered the interval between appointments is often too long to detect warning signs before a fully blown depressive episode. OPTIMI thus provides a service that would not otherwise be available.	**Threats: (**1) In some countries, particularly the UK, many practitioners consider watchful waiting to be less cost-effective than immediate low-cost treatment with CCBT or bibliotherapy**;** (2) OPTIMI would need to demonstrate its cost effectiveness with respect to online questionnaires; (3) given the low cost of CCBT and its proven effectiveness it may be more cost-effective to combine monitoring with CCBT treatment (see scenario 1.2).

1.2) Critical factors influencing the purchasing decision

A recent study [3] suggests that to prevent one case of depression it is necessary to treat 17 high risk patients. OPTIMI achieves roughly the same level of effectiveness and the cost of providing the service is Eur 436/patient the cost of preventing a single case using the OPTIMI technology would be of the order of Eur 7.650 (see calculation in Table 10). Assuming that each case causes the loss of 0,17 QALY the cost per QALY would of the order of 45.000. This is slightly above the threshold at which health providers are likely to pay for the service and significantly higher than the incremental cost of a CCBT program such as Beating the Blues, which has been estimated at Eur 2.293/QALY. If OPTIMI is to win approval it is essential that:

- The cost/patient is lower than the cost used in this analysis.
- The system is shown to be significantly more effective than CCBT and bibliotherapy.

TABLE IX

COST PER QALY OF TREATMENT AND MONITORING WITH OPTIMI

Item	**Value**	**Calculation**
A) Cost per patient	436	
B) Number to treat	17	
C) Cost per case prevented	7419	A*B
D) Utility of case prevented	0.17	
E) Cost per QALY	43640	C/D

The decision to use OPTIMI would depend on its relative effectiveness compared to other treatment options. It is plausible that monitoring with OPTIMI sensors followed by pharmacological therapy for patients showing symptoms of depression, could be more effective than CCBT, with or without the use of OPTIMI sensors (see following scenario). However, demonstrating this hypothesis would require a properly powered RCT.

2) Scenario 1.2: Use of OPTIMI for monitoring and treatment of patients with sub-threshold symptoms of depression

This scenario extends *scenario 1.1* by adding treatment with CCBT.

2.1) SWOT analysis

Strengths: (1) CCBT is already accepted as a viable treatment for sub-threshold depression; (2) given provider unwillingness to invest in face to face therapy, this may be the only technique capable of reaching patients.	**Weaknesses:** (1) There is currently no evidence that OPTIMI is superior to CCBT on its own. Gathering such evidence will require an RCT; (2) given the relatively low rate of incidence of depression, even in high risk subjects, a properly powered RCT would require a relatively large number of participants and would thus be expensive.
Opportunities: In most countries, health providers do not have the resources to provide monitoring or traditional psychotherapy to patients at risk of depression.	**Threats:** In this scenario, the main competing intervention is CCBT without sensors. This would be significantly less expensive than an intervention with sensors. It is essential therefore that OPTIMI should demonstrate the added value provided by the sensors.

2.2) Critical factors influencing the purchasing decision

The critical factors in this scenario are very similar to those considered in the previous one. However, the addition of CCBT is likely to improve effectiveness without adding significantly to the cost of the service. The choice between this and the previous scenario will therefore depend on the acceptability of CCBT as a preventative treatment for depression. This varies significantly between countries.

3) Scenario 1.3: Use of OPTIMI for monitoring and treatment of patients at risk of relapse after recovery from a depressive episode

In this scenario, OPTIMI is combined with conventional CCBT to treat patients who have recovered from a severe depressive episode.

Patients who have suffered a Severe Depressive Episode are reported to have an 80% lifetime risk of recurrence ([4]). Other studies suggest that with treatment as usual, rates of relapse within the first 12-18 months of an episode are in the range 37% [5] – 66% ([4] – patients who have already suffered 2 or more previous episodes). In brief, the risk of relapse is extremely high.

Studies suggest that the best method for preventing relapse is to provide active therapy, using either pharmacological or non-pharmacological interventions. Both methods are reported to significantly reduce rates of relapse [6] though some studies suggest that non-pharmacological interventions have a significant effect only in patients who had already suffered multiple episodes [4] or in older patients [7]. In current practice, many patients receive no active treatment (often because they do not tolerate anti-depressive medication) and monitoring takes place in primary care with long intervals between appointments. Against this background, OPTIMI monitoring combined with CCBT could provide an optimal technique for treating and monitoring patients.

3.1) SWOT analysis

Strengths: (1) Previous work demonstrates the feasibility of reducing relapse through adequate preventative interventions; (2) given provider unwillingness to invest in traditional psychotherapy, OPTIMI may be the only technique capable of reaching patients who do not accept pharmacological treatment; (3) given high natural rates of relapse, the number of patients to treat is likely to be much lower low than in scenarios involving patients with less risk; (4) given the low numbers to treat OPTIMI is likely to be a cost-effective intervention; (5) in view of the high natural relapse rate in depression, an OPTIMI RCT could be relatively short and would require a relatively low number of participants. Trials reported in the literature have lasted between 12 and 18 months and have included from 150 to 250 patients	**Weaknesses:** While it is plausible that OPTIMI would be effective in this scenario, there is as yet no evidence to show that this is so. Collecting such evidence would require an RCT.
Opportunities: In most countries, health providers do not have the resources to provide high-frequency monitoring and face to face care for patients who have suffered from severe depressive episodes.	**Threats:** In this scenario, the main competing intervention is CCBT without sensors. This would be significantly less expensive than an intervention with sensors. It is essential therefore that OPTIMI should demonstrate the added value from the sensors.

3.2) Critical factors influencing the purchasing decision

The Segal study [6] reports that “mindfulness therapy” reduced relapse rates from 46% to 38%. The Teasdale study [4] reports a reduction from 66% to 37% but only in patients who had already suffered more than 2 depressive episodes. These results suggest that successful treatment can achieve a reduction of between 8 and a 29% in the absolute number of relapses i.e. the number of patients who need to be treated to avoid a single case of relapse lies in the range between 3,4 and 12,5. Given the costs calculated earlier this implies that if OPTIMI is as effective as can be reasonably expected, the cost of preventing a single case of relapse lies in the range Eur 1.050 – Eur 3.750. Both figures are well below the threshold value of Eur 6.628 representing the maximum price health providers would be willing to pay. However, health providers will also compare the cost of treatment with OPTIMI against the cost of alternatives, in particular CCBT without the use of sensors. Acceptance of the OPTIMI solution thus depends critically on (1) the demonstration of its effectiveness in RCT; (2) the demonstration of significant added value with respect to CCBT without sensors.

4) Scenario 2: Sale of OPTIMI products and services to Employee Assistance Programs, offering self-help services for employees

A number of large European companies are investing in Employee Assistance Program, whose services include support for employees suffering from workplace stress and related (see http://www.eapa.org.uk/page--providers.html; http://www.icasworld.com/). Low cost stress-management programs based on OPTIMI technology could be extremely attractive to these companies, and would not require the level of clinical validation required for the deployment of OPTIMI in a medical setting. However, the majority of current programs are in the UK and Ireland. It is not certain therefore that this model can be applied to other countries.

4.1) SWOT analysis

Strengths: EAP programs can adopt wellness-related technologies without requiring RCT. OPTIMI addresses the need to reduce workplace stress, and associated absenteeism and presenteeism. This is a need, which employers feel strongly. OPTIMI could be especially important for employees exposed to high levels of stress in their work (e.g. emergency workers, police, call-center operators). EAPs for these workers are likely to be significantly less price sensitive than programs for workers exposed to lower levels of stress.	**Weaknesses:** Outside the USA and the UK (e.g. in Spain and China), EAP programs are infrequent or non-existent. In countries where such programs do exist, they can be very sensitive to price. According to anecdotal evidence services have rejected services that cost as little as Eur 50/user. Even if EAP do not require RCT, evidence of effectiveness is obviously a powerful factor influencing sales.
Opportunities: (1) Programs for employees exposed to high levels of stress in their work are likely to less sensitive to price than other programs; (2) EAP programs for elite employees (managers etc.) often provide expensive benefits (e.g. gym membership) to members. Such programs are likely to be relatively insensitive to the price of OPTIMI technology.	**Threats:**

4.2) Critical factors influencing the purchasing decision

For the general market, the critical factor is likely to be price. It is likely that OPTIMI would be too expensive for this market, even with lower costs than those considered in this analysis. However, there are significant opportunities for services targeting employees exposed to high levels of stress and for sales to EAP programs for elite employees.

5) Scenario 3: Direct sale of OPTIMI products and services to individuals, for purposes of self-help

An OPTIMI provider sells OPTIMI CCBT and monitoring services directly to consumers, who use them in self-help mode without any form of clinical assistance (except some kind of emergency line for patients feeling suicidal). Such a system could be significantly simpler, easier to use and cheaper than the system tested in the OPTIMI trials.

5.1) SWOT analysis

Strengths: The wellness market is weakly regulated and consumers are insensitive to data on clinical effectiveness. Sales of OPTIMI on this market would not require an RCT and could thus begin as soon an industrial-quality product is ready for market.	**Weaknesses:** (1) Other wellness devices available on the consumer market (electronic scales, heart rate monitors, devices for measuring blood pressure and blood sugar etc., pedometers etc.) have prices ranging from 20 to 200 euros. Compared to these devices, whose benefits are easily understood, OPTIMI seems expensive and harder to understand; (2) nearly all successful devices are sold by major manufacturers with an established brand. OPTIMI does not have such a brand; (3) the current OPTIMI sensor system is relatively complicated to use and requires a significant investment of effort by the user.
Opportunities: (1) The wellness market is large and is growing rapidly (especially in China). This market could potentially provide very high volumes of sales. With very high volumes end-user prices could be significantly lower than the prices we are using in this analysis.	**Threats:** (1) Commercialization of OPTIMI as an unregulated "wellness" product could contaminate the OPTIMI brand making it hard to sell OPTIMI for clinical applications; (2) OPTIMI does not have a monopoly of sensor technologies for health applications.

5.2) Critical factors influencing the purchasing decision

To buy OPTIMI wellness products in significant volumes, customers would require "cool design", ease of use, low prices (compared to other health-related devices), heavy marketing and strong branding. The best way for the OPTIMI partners to satisfy these needs would probably be to license OPTIMI technology to a major player already present in the wellness market. Such a strategy could conceivably yield generate revenue for the OPTIMI partners.

VI. Conclusions

The three most attractive scenarios for OPTIMI are:

- Monitoring and treatment of patients who have already suffered a Severe Depressive Episode.
- Sales to EAP providing services to employees at high risk of depression (police, firemen, other emergency workers, call-centre operators etc.).
- Sales to EAP providing services to elite employees (managers etc.).

In the first case, it is essential that OPTIMI should demonstrate its effectiveness in a properly powered RCT.

However, the cost of such an RCT would be relatively low, and the probability of success relatively high.

In the second and third cases, there is no legal requirement for an RCT. However, results from such a trial would provide useful support for marketing. The main markets for this kind of service would be in countries where EAP are widespread.

OPTIMI could also prove to be cost effective in the monitoring and treatment of high-risk patients who have not suffered a previous depressive episode. Winning approval would require RCT, which would be more expensive than in the case of patients at risk of relapse. In countries that accept CCBT and bibliotherapy as acceptable therapies, it would also be necessary to demonstrate that OPTIMI is more cost-effective than these treatments. Given the relatively high cost of OPTIMI this might be difficult. However, countries in which cheaper forms of therapy are less widely accepted could constitute a significant market.

The results of our analysis suggest that OPTIMI is probably too expensive for the individual market. If OPTIMI were to seek to enter this market the best strategy would probably be to license the technology to a well-known producer of products for the wellness market.

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