CLONE: a Promising System for the Remote Monitoring of Alzheimer's Patients

An Experimentation with a Wearable Device in a Village for Alzheimer's Care

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ABSTRACT

Alzheimer's disease is a form of dementia that affects a large segment of the older population and, due to aging, its prevalence will substantially increase in the next decades. This paper describes an experiment of application of remote monitoring technologies for the collection of data to detect the onset of crises in patients affected by Alzheimer's in an Italian village dedicated to the treatment of the Alzheimer's disease. Furthermore, the paper details the design concept of Eclipse, a smart wearable that compensates for the current lack of Alzheimer's specific wearables on the market.

CCS CONCEPTS

• **Applied computing** → *Health care information systems*; • **Human-centered computing** → *User studies*; *Participatory design*;

KEYWORDS

Alzheimer's, Assistive technologies, Wearables, Data analysis

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1 INTRODUCTION

Alzheimer's Disease (AD) is the most frequent form of dementia [2] and can be defined as a severe progressive neurologic pathology in which the main cognitive function of an individual are compromised. The World Alzheimer's Report [3] estimated that 46.8 million people worldwide were living with dementia in 2015, number that will almost double every 20 years, to 74.7 million in 2030 and 131.5 million in 2050. Besides affecting significantly the patients'quality of life, this disease imposes enormous costs on national healthcare systems [3]. Additionally, Alzheimer's also causes a substantial burden especially to caregivers, who provide physical and emotional support to patients on a daily basis [10]. Symptoms of Alzheimer's include the sudden onset of crises - such as aggressive behaviours - and this requires patients to be continuously controlled, which generates stress and anxiety in those providing help.

This paper aims to explore the application of remote monitoring technologies able to detect the onset of crises in patients affected by Alzheimer's, that may alleviate the psychological burden suffered by caregivers. In particular, an experimentation phase has been carried out at the Residenza San Pietro in Monza, Italy - an Alzheimer's nursing home of La Meridiana[1]: a group of patients wore a commercial wristband that monitors physiological signals in real-time; data have been collected for ten weeks and usability, usefulness and feasibility of the approach have been evaluated. This paper presents an overview of the whole project - named CLONE -, the results of the experimentation achieved in the first months and

[1]http://www.cooplameridiana.it/il-paese-ritrovato/ (in Italian) - La Meridiana is a co-operative managing the Alzheimer village dedicated to the treatment of the Alzheimer Disease (in Italian) operating since June 2018

the proposal of an innovative wearable device named Eclipse, specifically designed for Alzheimer's patients. The paper is organized as follows: in Section 2 we report related work; Section 3 defines the collection of users'requirements, while Section 5 describes the experimentation phase. Interviews with the caregivers and doctors, reported in Section 6, provided interested insights for the design of a new wearable device, presented in Section 7. Finally, in Section 8 we draw conclusions and discuss future work.

2 RELATED WORK

Assistive Technologies (AT) are considered one of the most promising available solutions for reshaping dementia care [2]. Indeed, they can help in reducing the burden on public finances through the delay or obviation of institutional care for PWD (People With Dementia) while empowering older adults in daily life activities thus improving their quality of life. In addition to this, AT has the potential to decrease the psychological burden on formal and informal caregivers and to compensate for the progressive scarcity of human caregivers while enhancing quality of care [1] and increasing staff members'satisfaction in their work [6]. The number of publications in literature regarding AT for dementia has been considerably increasing in the past few years, as the disease is one of the elderly's problem most studied in the field of assisted technology care [9].

Wearable devices represent one of the most popular typologies of AT [8]. Indeed, medical wearables already cover a significant share of the overall market and are expected to grow exponentially, reaching more than 17.8 billion US dollars in 2021, with a CAGR of 135 percent for 2015-2021 [14]. Among the medical devices, some aim at gathering information on specific diseases, such as “Valedo” and “Lumo Lift” for skeletal system diseases, PIP for detection of stress level and “Embrace” from Empatica for epilepsy. However, none of them currently addresses specifically Alzheimer's or other types of dementia.

Numerous AT projects can be found in literature, indicating the great potential of technology-assisted care in the field of dementia [11, 15]. However, only few projects are similar, in some ways, to the study implemented and described in this paper. In particular, in order to be considered analogous to ours, a project must (i) deploy continuous monitoring technologies (ii) by means of wearable devices (iii) to detect, or predict, abnormalities in the behaviour (iv) of patients with dementia or, more specifically, the Alzheimer's disease. Moreover, (v) at least an initial data collection on targeted users should have been performed with the proposed technology. No project has been found in literature that simultaneously meet all the five criteria. For instance, Chen et al. [5] describe the interesting implementation of Care Media, a system based on continuous audio-visual recording of ADLs in shared facilities (so it does not meet criteria (ii)) with the objective to automatically recognize, qualify and classify human behaviour and detect abnormal patterns of activity. About 5000 hours of recording were classified manually into different categories of behaviour and then used to train an algorithm. Despite false positive were present, the system was able to detect aggressive behaviour with an accuracy of 80 percent. It has also been tested in a pilot with 15 patients with AD in a nursing home. Nonetheless, the limitations of this approach are evident: besides the huge manual work required, there are also challenges related to human motion and position, camera angles and lightning.

Wearable devices are instead used by Avvenuti et al. [4], who propose a proactive monitoring system capable of capturing body movements and the brain activity through EEG/REM sensors. The system would then search for correlation among these parameters to predict situations in which a subject with AD was prone to fall. All the signals are captured unobtrusively by means of miniature sensors into a small device worn by the patient, and warnings are generated to allow preventive measures. However, the authors only described the system and related architecture but still had to collect data from AD patients, extract meaningful association rules and validate the algorithm.

A further study using monitoring technologies is detailed in Pedro et al. [13], with the specific focus on people with AD. The authors propose a system of wearable sensors (two accelerometers, one EDA and one ECG sensor) and use data obtained from 20 healthy and young people to train and compare different algorithms. In their work, they just focus on accelerometers data to try to detect psychomotor agitation, and show that a Support Vector Machine can achieve the highest accuracy in this task. They expect in future work both to collect data from real patients and to study also ECG and EDA signals.

In conclusion, given the absence in literature of analogous projects, we are confident that the present work covers an empty but strongly promising area of research and will provide additional knowledge and insights to the extent literature, while posing strong foundations for future studies.

3 USERS REQUIREMENTS COLLECTION

Four main stakeholders have been identified in this project: (i) the elderly-oriented institution La Meridiana, (ii) AD patients, (iii) caregivers and (iv) doctors.

La Meridiana, official partner of the project, is committed to implement cutting-edge technologies inside clinics and nursing homes in order to reduce the cost of dementia care and ensure patients higher standards of living, while guaranteeing seamless monitoring and safety. One of the requirements coming from this first stakeholder that required particular attention has been the compliance with the very recent EU - GDPR (2016/679) regulations, which address the private, anonymous and secure management of patients'data. Those specifications had to be carefully met throughout the data collection and management phase.

Many requirements came out from the attentive analysis of the target users, their vulnerabilities and needs. Therefore, we identified with our partners the characteristics of the wearable device to use for the collection of physiological data for the detection of crisis and identified the process for data collection.

There are many BPSD (Behavioural and Psychological Symptoms of Dementia) associated to AD, but the most burdensome for patients'and caregivers'quality of life are psychomotor agitation and psychological alterations [13]. The former can be detected by means of an accelerometer, while the latter are significantly connected to electrodermal activity (EDA) measures and heart rate (HR) variations [12]. Therefore, in order to identify possible crises,

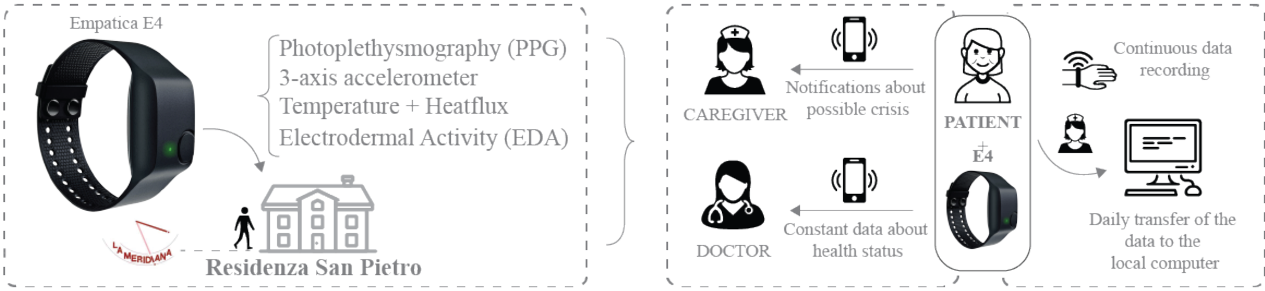

Figure 1: The general framework of the experiment.

the wearable should allow to measure accurately at least the movement of the body in 3 axis, EDA, HR and HR variability. Additional physiological signals can also prove to be useful for the detection of crises.

Elderly people should wear a wearable device that is as comfortable as possible, and that minimizes the impact of a long experimentation. It has to be secure, hypoallergenic and must present a minimal level of water resistance, such that there is no risk in performing activities such as washing hands.

The caregivers, instead, are involved in an experimental study that should have a very low impact on their daily tasks. As a consequence, the device must be easy to use, intuitive and should require barely no maintenance. In addition, the software interface to interact with must be easy and simple, and the operations required to run the study have to be minimized.

From the technological perspective, instead, the device must be reliable, both in terms of availability, precision in the measurements and in minimization of errors due to human factors. The battery therefore must guarantee a sufficient duration, the device must be already validated in previous studies and must measure several parameters.

4 THE WEARABLE DEVICE: EMPATICA E4

Among the commercial wearable devices, Empatica E4 bracelet[2] has been chosen since it was the device with the highest compliance level to the requirements. It is a smart bracelet equipped with the sensors necessary to monitor the following parameters:

- Blood volume pressure (BVP)
- Interbeat interval (IBI)
- Heart Rate (HR)
- Electrodermal activity (EDA)
- 3-axis acceleration
- Skin temperature

On top of that, a little button on its surface gives the possibility of registering Flag events, i.e. to mark specific instants, for example, to notify an ongoing crisis. Figure 1 shows an image of the selected product.

Even if provided with Bluetooth connection for a live streaming of the values measured, the recording mode has been employed, which allows to register data up to 48 consecutive hours to be then downloaded connecting the device to a PC.

[2] https://www.empatica.com/research/e4/

5 EXPERIMENTATION OVERVIEW

The objective of the experimentation is to collect physiological and behavioural data from elderly people affected by Alzheimer's during their everyday life, and to explore opportunities to find relationships among the physiological trends and the onset of crises. In particular, potential findings in that direction would allow to develop a system able to anticipate or notify the happening of crises by means of remote monitoring technologies. Figure 1 shows the main stakeholders involved in the project and the relations among them. Inside La Meridiana's Residenza San Pietro residence, five selected patients were invited to wear an Empatica E4 wristband during their everyday life. A univocal code had been assigned to each patient selected. For each code, the team sewed a custom and coloured fabric strip on the devices in order to make the bracelets distinguishable. In particular, devices were worn in the morning, after the hygiene session, and removed at night, before going to bed. Thus, the recordings started between 6 and 10 am (right after hygiene time) and finished around 7 or 8 pm. This schedule brought a two-fold advantage: the devices could recharge during the night and be available for being used the day after and, on top of that, the risk that the patients wet the devices was drastically reduced since they could not forget to remove them before the early-morning and late-evening hygiene sessions.

Their caregivers were asked to manage the wearables, assisting the patient in wearing and removing the devices, to recharge them at night, and to report episodes of crisis. Crises could be labeled by making pressure on the flag button situated on the device and by reporting the episode on a paper journal, designed in collaboration with the caregivers. On the one hand, the flag button allowed to have a precise moment in which the crisis had been identified, thus enabling a precise synchronization of labels and data streams. On the other hand, the journal was necessary (i) to distinguish actual crises from accidental pressures of the button, (ii) to give caregivers the possibility to report crisis even if unable to physically push the button (e.g. when the patient is aggressive) and (iii) to collect more detailed information about the dynamics of the events. Indeed, under explicit request of the caregivers, the form provided the possibility to write additional information for each crisis to have a complete overview of what happened during the session, facilitating the interpretation of the recordings.

During a dedicated training session, caregivers and doctors were informed in detail about the functioning of all the devices and the experimentation procedure. Caregivers had the possibility to try

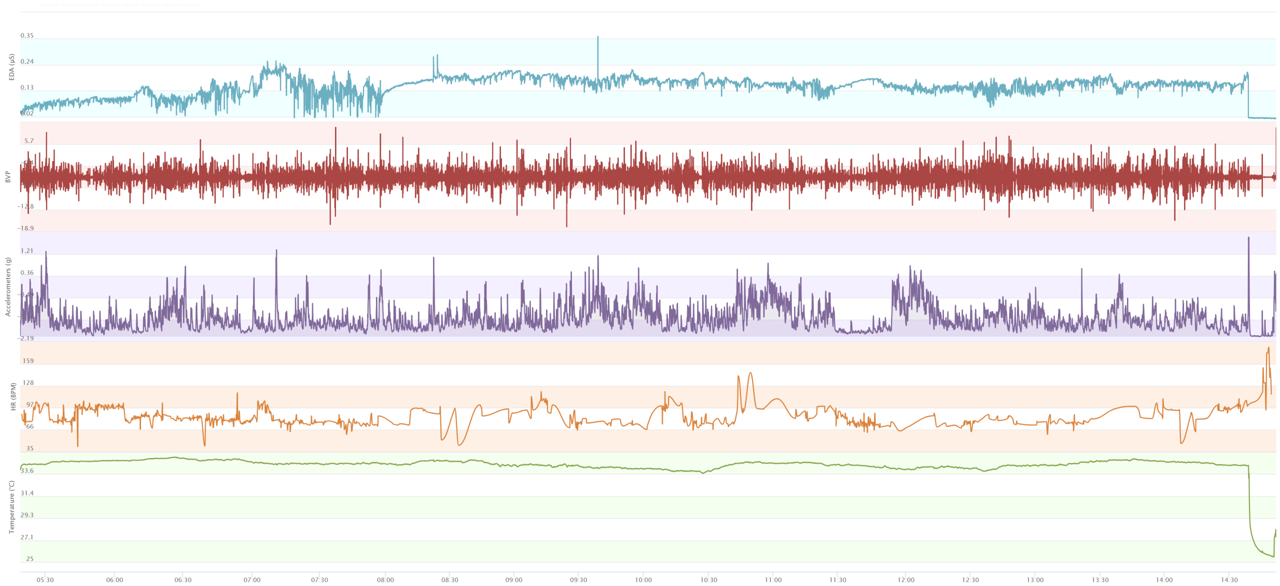

Figure 2: A recording session.

the bracelets and the software, and to ask questions about their doubts. To further minimize the possibility of problems in absence of the team, a remote control software had been installed on the PC used in the experimentation. Moreover, the team provided a simplified E4's user manual containing easy to understand instructions to adequately operate the device and to perform autonomous troubleshooting.

The physiological data gathered through the E4 are transmitted to the team's cloud platform by connecting the devices to a PC installed inside the care facility and using a secure application programming interface (API) designed and developed by the team. The obtained dataset consists in several sessions, each one corresponding to a recording on a device. Every session contains a separate CSV file for each measurement. During the experimentation period, around 250 sessions were correctly recorded; each session lasts on average 9-10 hours. Figure 2 shows an example of a recording session.

The data from various sensors of the wristband were subjected to cleansing and conditioning by a data preprocessing pipeline developed by the team. Following the examples of [7], 13 additional features have been extracted out of the original signals through a sliding-window technique: Mean, Standard Deviation, Variance, Median, Range Max, Range Min, Root Main Square Metric, Power of the Signal, Energy, Skewness, Kurtosis, Interquartile Range and Mean Absolute Deviation of Signal.

5.1 System Architecture

As shown in Figure 3, the internal architecture of the system has been abstracted in a stack composed of 4 elements:

(1) **Sensory**: The first layer was responsible of the collection of data from sensors. As described in section 4 Empatica's E4 was the device used for sensing data. This layer of the stack included also the peripherals and supportive tools to make the sensing device work properly.
(2) **Connectivity**: The second layer of the stack included the components necessary to reliably transmit the data from the Sensory level to the Storage one, and the physical machines associated with the project. In particular, the layer were composed by two main data transmission channels:
   - The data transmission between the smart devices at the care facility, that is supported by Empatica's software and devices;
   - The data transmission among machines outside the care facility, supported by custom designed RESTful API running over POLICLOUD web server, provided by Politecnico di Milano.
(3) **Storage**: This layer was responsible of preserving the data collected, in compliance with the applicable privacy and security regulations. The database solution is based on MongoDB system, a document model database.
(4) **Cognition**: The top layer of the stack was related to the intelligence of system. It primarily concerned data preprocessing and analysis tools to extract meaningful information out of the gathered data, to highlight patterns that might lead to the identification of episodes of crisis.

6 INTERVIEWS WITH CAREGIVERS AND DOCTORS

Doctors and caregivers from Residenza San Pietro have been interviewed multiple times throughout the experimentation and represented a reliable source of knowledge and experience in the Alzheimer's field. Some of the most insightful parts of those interviews are reported below.

Doctor - About Follow-Up Activities:

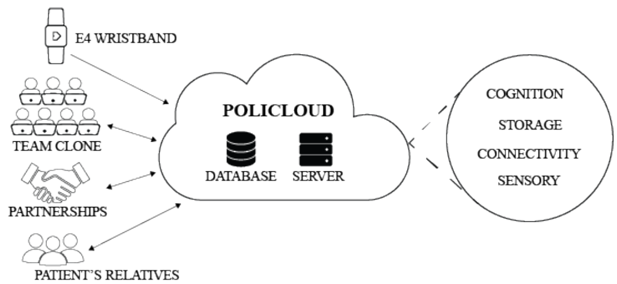

Figure 3: High level overview of the system architecture.

- *Group member of CLONE- Imagine you have an algorithm which is able to detect the occurrence of crises in advance. As no algorithm can ever be perfect, would you prefer it to generate false positive or false negative results?*
  Doctor- Supposing that an algorithm like this actually existed, I would prefer to get false positives. At least we can try to calm them down in advance and reduce the number of those abnormal behaviours.
- *Group member of CLONE- As you know, the project aims at analysing the patterns followed by the measured parameters in highly critical contexts. Would you suggest any specific situation or circumstance for which this analysis may be particularly relevant?*
  Doctor- Well, maybe it would be interesting to see what happens to patients'parameters in the most emotionally-intense moments of the day, such as the visits of their relatives. Sometimes relatives make patients calmer, sometimes more agitated. In any case, their visits have an effect on them and it would be worthwhile to see this effect in terms of parameters. Also, I'd observe parameters'patterns during brain-stimulation activities. In theory they are designed to stimulate the cognitive activity of the patients, so I'd expect to see an increase of the EDA. I mean, an actual increase in the EDA would be a concrete demonstration that those activities do have an effect on the patient.

The doctor provided interesting suggestions about targeted-analysis on specific events that could be performed as follow-up activities of this project. Thanks to the system architecture implemented these analyses can be be carried out in future work, providing a significant contribution in the quite unexplored field of AT for Alzheimer's.

Caregiver - About the Interaction with the E4:

- *Group member of CLONE- Did you have problems with the E4 software installed in the PC?*
  Caregiver- Well, actually we did. The software crashes many times and this is a problem as we cannot spend our time in front of the computer. Patients need to be monitored continuously, we cannot leave them alone. It would have been much better if we could connect the devices to the computer and then don't worry anymore about it.
- *Group member of CLONE- How do patients feel about wearing the E4 band?*
  Caregiver- Well, it depends on each patient. One patient sometimes refuses to put the E4 because it bothers her. I think it is because the band is very thick and requires to be pressed and firmly tightened to the wrist, which actually may be annoying. A number of patients complain about its discomfort and continuously try to enlarge the band. Sometimes I found the device around the clinic, or on their nightstand, as they took it off during the night. But if I tell them that wearing the device is a request from the doctor, they stop complaining as they trust her a lot. Honestly, I think that they may get used to the E4.
- *Group member of CLONE- Do patients touch the on/off button? Do you think it should it be hidden?*
  Caregiver- I think that in the E4 is already hidden. The first time we used it, my colleagues and me could not find it. Also, people affected by Alzheimer's do not have an incredible sight. But in general, yes, I would take care to put it in a hidden position. Patients tend to play with whatever they have in their hands, so, if the button is too exposed, they may press it accidentally.

Multiple aspects regarding the interaction of both caregivers and patients with the E4 wristband emerged as critical, suggesting that the device was not appropriate for the context of use. From the interview it emerges that the product should be non-intrusive, comfortable and intuitive for the caregiver. Its functioning should be compatible with the daily activities and should permit the seamless and real-time monitoring of patient's parameters. These precious insights inspired the design of a new product called Eclipse, specifically targeted to Alzheimer's patients and their caregivers and centred on their needs.

7 ECLIPSE: A WEARABLE TARGETED AT ALZHEIMER'S PATIENTS

Eclipse is a smart wristband that has been specifically designed for Alzheimer's patients (see Figure 4). It is embedded with a wide set of sensors which allow the real-time monitoring of environmental and physiological parameters including localization, wrist movement, heart rate, skin temperature, Electrodermal Activity (EDA) and IBI. The feature that makes the product unique is the attachable battery. The battery charger is plugged into the main body of the device, working as a power bank. It allows to charge the device without taking it out from the wrist, thus without interrupting the monitoring of the patient. This feature was explicitly requested by La Meridiana's caregivers as the removal of the wristband for its charging was a troublesome task both for them and also for the patients. Another peculiar feature is Eclipse's closing system. The latter makes the wearable hard to open by the patients to avoid any unconscious autonomous removal of the device, while remaining handy for the caregiver. Finally, the surface of the device presents a texture and one edge. Those strategies increase the tactile properties of the product and enhance the interaction between the product and the user, creating an emotional connection between the two.

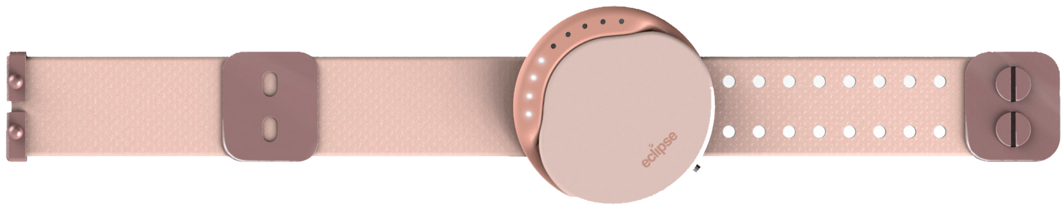

Figure 4: Eclipse concept.

8 CONCLUSIONS AND FUTURE WORK

This project provides two notable and novel contributions to assistive technologies for dementia care, with a specific focus on Alzheimer's patients.

The first contribution consists in the generation of a dataset of physiological parameters measured on elderlies affected by Alzheimer in a controlled environment. The data analysis subsequently performed allowed to extract, from the data collected, a selected set of features that allow to recognize states of crisis; we are still collecting data, to obtain a larger dataset to be used as input for training multiple types of machine learning models. No analogous studies are present in literature even though research in this field is considered increasingly essential. Furthermore, the experimentation showed how the technology is sufficiently mature to be adopted in nursing homes environments and not only in simulations performed in laboratory, in terms of economical cost, reliability and ergonomics, both for the device itself and for the computer interfaces.

On the other hand, the experimentation conducted in the nursing home entailed the interaction of doctors, caregivers and patients with a technologically advanced device. The level of technology acceptance of these actors was surprisingly positive. However, several aspects regarding their interaction with the E4 wristband emerged as critical, suggesting the necessity of a dedicated wearable device, specifically designed to address needs of caregivers and the vulnerabilities of patients. Eclipse, the second contribution of this project, compensates for the current lack of Alzheimer's specific wearables on the market, providing the first tangible support to this widespread disease. It embeds an extremely wide set of sensors while maintaining a non-intrusive design, overcoming the trade-off between features and intrusiveness. Several design elements contribute to make the product unique, including the attachable battery, that allows charging the device without interrupting the monitoring of the patient. Differently from the majority of AT for dementia [8], Eclipse is a successful user-centred concept specifically developed inside a context that made evident the needs of the users and their verification.

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