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Wearable Monitoring Systems for Psychological and Physiological State Assessment in a Naturalistic Environment.

R. Paradiso, T. Faetti and S. Werner

Abstract— **Wearable monitoring systems based on Smart Fibers and Interactive Textile (SFIT) platforms combine imperceptible sensing and computing functions with an interactive communication network. The integration into clothes of bio-potential sensors for health monitoring provides daily physiological parameters through a continuous, personalized, self-made detection of vital signs and the tracking of behavioral indicators of the subject. SFIT platforms can be used unobtrusively into the routinely daily activity to perform remote monitoring of persons in different circumstances and situations: during controlled exercises and diagnostic procedures as a biofeedback tool, during the usual daily life, during sleep or even to monitor behavioral indexes and mood disorders. Treatment of stress may include also training in cognitive-behavioral skills. Moreover, physiological signs and behavioral monitoring based on a multivariable approach leads to an enhanced sensitivity and specificity of these systems for the prediction of critical events. This paper presents two applications: a platform used in the frame of PSYCHE project, based on textile platforms and portable sensing devices for the long term and short term acquisition of data from patients affected by mood disorders and a platform addressing healthy subjects, based on biofeedback methodology, designed for the training of professional drivers named Mental Bio.**

I. Introduction

PSYCHE project [1] aims at the development of a personal, cost-effective, multi-parametric monitoring system based on textile platforms and portable sensing devices for the long term and short term acquisition of data from selected class of patients affected by mood disorders. The goal is to develop novel portable devices for the monitoring of biochemical markers, voice analysis and a behavioral index correlated to patient state. The acquired data are processed and analyzed in the established platform that takes into consideration a personalized data referee system, as well as medical analysis in order to verify the diagnosis and help in prognosis of the disease. A reference database with annotated physiological and behavioral signals from patients with bipolar disorder, cyclothymic subjects and healthy individuals is under construction, the database is the main part of the integrated platform offering a basis for content-based searches, tools for feature extraction and signal processing, as well as tools for integration with Electronic Health Record information. The physiological data that are collected with non-invasive wearable devices include heart rate variability, respiratory rate, activity and movement. These devices (WWS systems produced by Smartex srl) are currently available [2] and have been distributed among healthy volunteers and patients for the acquisition of data that will serve as reference for the database. Data acquisition is also considering other parameters based on biochemical measurements, voice analysis for emotional assessment [3] and the detection of attitudinal indicators (social interaction, daily activity, productivity, emotional perception) that can be used to extrapolate predictive indexes. Moreover the building of the reference data base foresees the study of sleep pattern alteration, peripheral measures in cardiovascular and respiratory functioning, electro-dermal response, as well as the secretion of stress-related hormones, including change in the diurnal variations of all these measurements (circadian rhythms)[4].

Biofeedback is a method of treatment to feed back to patients, physiological information of which they are normally unaware. By watching the monitor, patients can learn how to adjust their thinking and other mental processes in order to control "involuntary" bodily processes. Processes that can be controlled include brainwaves, muscle tone, skin conductance, heart rate, respiratory rate and pain perception [5]. Biofeedback may be used to improve health or performance, and the physiological changes often occur in conjunction with changes to thoughts, emotions, and behavior. Clinical biofeedback techniques are widely used to treat several conditions. These include: migraine headaches, tension headaches, and many other types of pain, disorders of the digestive system, high blood pressure and low blood pressure, epilepsy, paralysis, tremor and other movement disorders [6]. In this paper we present a platform based on the concept of mental economy where biofeedback is used to train professional Formula 1 drivers.

II. PSYCHE Platform

The main objective of PSYCHE project is to implement and validate, from technical, functional, clinical and usability points of view, the concept of remote monitoring of bipolar patients through a personal, multi-parametric monitoring system. The project foresees 3 phases; the results from the first one will be summarized in this paper;

Acquisition Phase: during this phase, the signal protocol acquisition has been defined, in both controlled and naturalistic environment, the parameters to be monitored has been selected and used to set up the raw signals database, to

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R. Paradiso is with SMARTEX s.r.l, Prato, Italy (phone +39050754350, fax +39050754351; email: rita@smartex.it).

T. Faetti is with SMARTEX s.r.l, Prato, Italy

S. Werner is with FORENAP, Rouffach, France

exchange data among the different organizations involved in the project, aiming at the implementation of the software platform of the final system.

Development Phase: this phase aims at the implementation of the whole PSYCHE platform based on the sensing cloths and the portable devices, the software with data mining and data management, and both user and professional interfaces.

Validation Phase: finally the system has to be validated with bipolar patients according functional, clinical and usability criteria, the final validation protocol is under study.

A. Physiological measurements

The aim of the acquisition study performed on selected groups of healthy volunteers and patients is to identify the parameters that are relevant for the implementation of the data base and the building of the final software platform, as well as to evaluate the acceptability of the concept for the final users. The following physiological parameters have been identified as relevant for the acquisition phase:

- ECG signal, in particular RR intervals, due to the changes observed in autonomic nervous system tone correlated to depression, i.e. HRV diminished/increased in depressive states and increased after successful anti-depressive treatment

-Body activity, this parameter decreases during daytime in depressive states and increases in euthymic phase prior to relapse and in manic phase, for this reason is a possible predictor of treatment response

-Respiratory Rate, no data has been found from literature related to this parameter as a "mood state" marker but useful for sleep evaluation together with HR and activity

-Sleep: sleep disturbances is considered as one of the early signs of a mood shift episode, sleep architecture in term of REM latency, REM density, total sleep time, sleep onset latency, move in correlation with mood. Sleep quality and wake periodicity can be deduced from the combination of activity, ECG, respiration and ambient condition signals.

-Voice: in literature are reported correlation observed between mood and some physical variables extracted from speech (fundamental frequency and its variations over time, variation of signal intensity over time, speech activity, spectral distribution of energy, speech rate, speech pauses duration). The acquisition of this signal should overcome privacy and ethical issues. The efficiency of a smartphone platform in term of signals quality is under evaluation.

B. Other signals that would need further sensors development:

-Electrodermal Response: fluctuations of the electrical conductance of the skin (SCR), this signal can be correlated to changes in activation and in the psychological state of the subject, as there is a relationship between sympathetic activity and emotional arousal. SCR is highly sensitive to emotions; it is a good marker if the acquisition is done in a supervised environment or in controlled conditions.

- Lithium dosage: the American Psychiatric Association recommends lithium as first line therapy for bipolar disorders. Lithium's therapeutic dose is uncomfortably close to its toxic dose. Toxically high blood lithium levels can cause respiratory depression, seizures, coma and even death. So far, no devices are available for the standard practice to remotely check the concentration of the drug. For this reason a portable biometric measuring device has been developed, preliminary tests on samples of saliva collected on patients are currently carried out.

- Glucose monitoring: glucose is one of the important parameters to detect the onset of Metabolic syndrome- slow down of metabolism reflected by weight gain and eventually become diabetic. Non-invasive method of glucose detection still has to be developed, glucose concentration monitoring can give very good indication of how physiologically, the patient is responding to the treatment.

C. Users interface: attention and emotional assessment

Cognitive dysfunctions: during the depressive state, patients can deficit in verbal learning, memory, attention and executive functioning; while during manic state, deficits are generally widespread and more pronounced. Tests that could be administrate remotely, should be sensitive and discriminating in bipolar illness ("state" markers), easy to perform and no time consuming. Moreover they must be easily integrated in the user interface platforms.

-Attention: Continuous Performance Test (CPT) is a sensitive and discriminating tool, as manic patients make more false alarms and perseverations, while depressive patients make more omissions and are markedly slower. Easy to be implemented in a portable device, tests can be self-administered, and take 7-10 min for each patient assessment.

-Emotional state: Emotional Visual Analog Scale (e-VAS), self-rated test, very easy and short test (sad smiley / happy smiley) is sensitive to mood changes (sleep deprivation or circadian mood variations).

-Mood Diary: adapted to be implemented on a smart phone platform can be used to follow daily mood variations, it can be combined with others personalised functions to promote psyco-education and biofeedback as well as motivation for the patient.

D. Rating scales

Scales are helpful for standardized evaluation of clinical symptoms and to provide a complete evaluation of the clinical status, they are sensitive to changes.

-Clinician-rated scales, generally are too long and time consuming, may be not well-accepted, for this reason they don't seem adequate for the continuous monitoring of bipolar patients

-Self-rated scales: for depression it has been selected the self rated version of the QIDS: as it is easy to administer and sensitive to changes in depressive severity. For mania: Altman self-rating Mania Scale (ASRM), that correlates significantly with YMRS, very good psychometric features.

For both, depressive and maniac states: the Internal State

Scale of Bauer (ISS Bauer): 16 items-based visual analog scale of depressive and manic symptoms in bipolar patients, with very good psychometric features.

III. RESULT AND DISCUSSION

In Table I are summarized the 3 different studies, on healthy volunteers and on patients recruited by two different organizations. The first one on healthy subjects is based on Tryptophan depletion model to induce depressive like sleep abnormality; this study was performed on 11 women from 18 and 45 years. The other two studies are still open.

	1. Healthy subjects (Forenap)	2. Bipolar Patients (Forenap/INSERM)	3. Bipolar Patients (UNIPI)
Aim	- To detect physiological changes during a TD procedure (model of sleep depression-like disturbances) - To collect raw data for signal processing, feature extraction, and algorithm development - To compare WWS system with standard sensors - To evaluate acceptability / usability	- To detect clinical state variations - To determine voice parameters modified by clinical state variations - To collect raw data for signal processing, feature extraction, and algorithm development - To evaluate the acceptability / usability	- To evaluate the feasibility of remote monitoring of psychophysiological parameters in patients - To identify reliable markers for clinical diagnosis, prediction of clinical state, response to treatment and relapse - To collect raw data
Physiological parameters with WWS **Comparison with std sensors**	- heart rate - respiratory rate -motor activity Yes (day & night)	- heart rate - respiratory rate -motor activity -Yes (during the day)	- heart rate - respiratory rate -motor activity -Yes (day: ECG & respiration)
Other parameters recorded	- Sleep classification with PSG (to compare with classification by PSYCHE system)	- Voice recordings	- Voice recordings - Plethysmography -Skin conductance and resistance (SCR)
Biochemical parameters	- Trp concentration dosage		-Cytokines and BDNF dosage
Neuropsy. tests (memory, emotion, mood)	PAWT, eVAS, PANAS, ISS Bauer	eVAS, Bond and Lader VAS, RAVLT, CPT, Verbal fluency tasks, SAM & ISS Bauer	eVAS, Bond and Lader VAS, POMS, TEMP-S questionnaire & ISS Bauer
Clinical scales	QISD and MINI (at screening only)	QIDS and YMRS	SCID structured Interview, QIDS and YMRS
Acceptability usability	Evaluated by healthy volunteers and operators	Evaluated by patients only	Evaluated on a semi-structured interview

Table 1 Summary of studies performed during the acquisition phase.

The signals acquired during the studies have been analyzed to extrapolate the relevant parameters for mood assessment with the aim to relate physiological and behavioral signals to bipolar state and derive a quantitative and measurable indicator/predictor of state changes. The raw signals recorded during the studies are pre-processed in real time and off line in order to obtain an improved SNR as well as to estimate basic physiological parameters (e.g. HR, BR, HRV, etc) and thus to minimize the storing requirements.

The algorithms related to the sleep module and for the quantification of the sympatho-vagal balance have been implemented; the analysis software can completely perform the following functions: sleep staging, with classification of REM, nonREM and Wake; sleep efficiency (TotalSlepTime/ TimeInBed), sleep parameters (REM %, REM latency, etc.), sleep fragmentation, HRV analysis for (LF, HF, LF/HF, etc.)

The quality of the signals acquired in controlled condition during day and during night acquisition was good, t-test performed on HRV values done on the signals acquired during bipolar patients study, gave $p < 0.5$.

The extraction of reliable features and parameters on the data acquired remotely through wearable platforms has shown to be feasible.

IV. MENTALBIO PLATFORM

A. *Mental Economy Concept*

In the last 20 years Formula Medicine[7], a specialized driver training center, has carried out many researches on Formula1 drivers that shows how the mental performances of the athlete are predominant in the conditioning of the race results. Typically, during the race the driver isn't able to hold the same performance as in qualifying and the lap times are at least three tenths above his potential, but when the race requires the driver to speed up and reach the limits (as just before the pit stops), the lap times decrease while his heart rate increase of a mean of 15 beats/min reflecting a large increase of mental effort. Furthermore fMRI investigations have shown that professional racing pilots recruited a significantly lesser extent of task-relevant brain areas as compared to naive drivers during simple visio-motor tasks, despite equal levels of performance [8],[9]. As expected, these neural differences between the two groups were present during tasks that do not require any exceptional skill, as shown by the absence of any difference in task performance. These findings suggest that neural efficiency may be a matter of 'quality' of brain recruitment rather than 'quantity'.

As a result of these studies a set of up to three innovative consoles has been developed. Each console, named MentalBio (Fig 1), has four screens, which can capture and transmit in telemetry some physiological parameters of the athlete while engaged in mental performances.

Fig. 1 The MentalBio console in Formula Medicine facilities

As in every biofeedback application one of the key of the whole process is represented by biomedical instrumentation able to acquire and visualize signals and parameters of the subject in a reliable manner. Since the aim of MentalBio console is to evaluate the mental effort in simulated conditions that must be as close as possible to the real environments in which the athletes are used to operate, the electronic equipments must be minimally invasive. The wearable platforms WWS, fully respond to this requirements giving the possibility to monitor many parameters, ECG (1 lead) with the extracted parameters Heart Rate and RR intervals, respiratory signals and activity (3D accelerometers). A Shirt or a Band and a miniaturized data-logger constitute the system (Fig 2), the data-logger can be housed in a pocket of the garment without any discomfort. Data are transmitted to the console via Bluetooth© wireless communication.

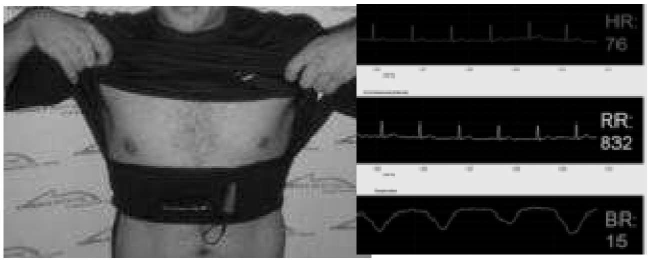

Fig. 2 a) on the top, the WWS system; b) in the insect the signals displayed on the console

In addition also GSR, the peripheral temperature and the level of the front muscle contraction is monitored in the MentalBio console with the use of conventional wired instruments. The specific test that are offered to the subjects aim to evaluate reaction time, concentration, visual-space capacity, memory and visual-coordination capacity, both in terms of mono-task and of dual task. The console also allows trainers to study the nervous activity of 3 drivers involved in a race simulation. The final aim of the console is to become a valid instrument in the loop Trainer-Driver to train psycho-functional characteristics of the driver, such as analysis of the personalized techniques of relaxation and concentration and mental gymnastics alternating phases of maximum activity with phases of relaxation, in order to control and optimize the resources in track. Moreover the console could be used to give also a quantitative assessment of the mental consumption of the driver. The idea is to collect a large cluster of different data that can be then correlated each other in order to extract a sort of Mental Index that can give an estimation of the mental energy expenditure, with the possibility to evaluate the trends among the seasonal training protocols.

V. Results and Discussion

A preliminary example of the correlation between physiological signals and changes inducted in the sympato-vagal balance by a virtual environment is shown in Fig 3 where the LF/HF ratio evaluated from the HRV signals acquired during the simulation of a speedy and a normal lap is reported, the LF/HF ratio characterizes the autonomic regulation of the heart period.

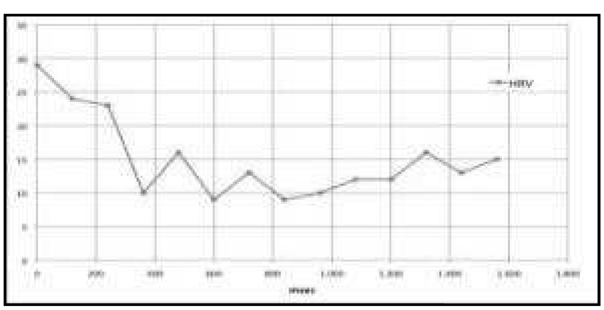

Fig. 3 LF/HF ratio during a training session on the simulator, sampling time 60 sec.

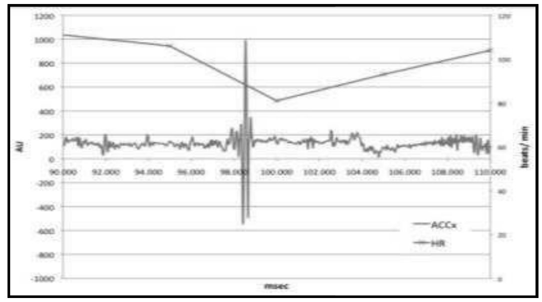

Fig. 4 Insect of HR and acceleration signals acquired during the simulated lap, a drop of the HR, on the top graph, in correlation with a drastic deceleration before the curve, on the lower graph

The signals have been acquired during a training session on the new Dallara SPA driver simulator [10]. Heart Rate Variability (HRV), that is the variance of the heart rate signal, has been obtained through parametric methods based on autoregressive AR models.

A variation in the sympatovagal balance can be observed during the lap in combination of change of acceleration as reported in Fig 4, where the reduction of velocity in proximity of a curve is correlated to the drop of HR value.

Differences in HR values can be observed by comparing the signals during a normal lap and a speed lap on the same circuit as showed in Fig 5.

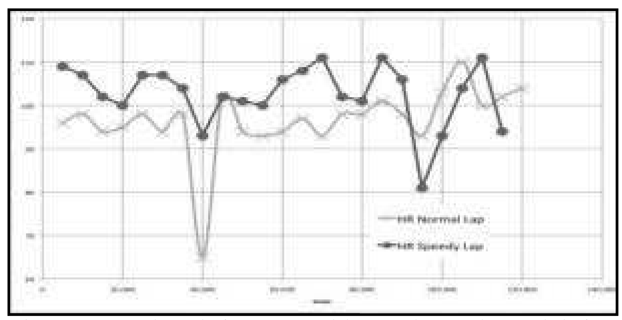

Fig. 5 Heart rate values during a normal lap on the graph 1 and during a speedy lap on the graph 2, sampling time 5 sec.

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