RELAZIONE FINALE DEL PROGRAMMA DI RICERCA STM

Fruitore: Giovanna Sannino

Istituto di afferenza: Istituto di Calcolo e Reti ad Alte Prestazioni - ICAR

qualifica Ricercatore **livello** III

Istituzione ospitante: University of Warwick (UK) - School of Engineering, Coventy (CV47AL) – Applied Biomedical Signal Processing and Intelligent eHealth Lab.

Dipartimento di afferenza: Biomedical Engineering

Titolo del programma:

Sleep Quality study to estimate the risk of falling and predict accidental falls

Studio della qualità del sono per stimare il rischio di cadute e predire cadute accidentali.

Sintesi delle attività svolte

Lo studio avviato ha come obiettivo la modellazione della relazione tra qualità del sonno, centri di pressione posturale e fenomeni di cali di pressione dovuti alla Standing Hypotension con eventuali perdite di equilibrio per stimare i soggetti a rischio di cadute e predire eventi critici intervenendo tempestivamente.

Al fine di effettuare la modellazione, è stata necessaria una prima fase di raccolta dati, condotta a partire dalla definizione di un protocollo sperimentale, ovvero un documento che descrive, in maniera chiara ed esplicita, obiettivi, disegno, metodologia, considerazioni statistiche ed organizzazione dello studio.

Il protocollo redatto è stato approvato dal comitato etico dell'University of Warwick (UK). Ad ogni partecipante sono state illustrate le finalità dello studio e sono state fornite schede informative circa il progetto, e, prima dell'avvio della sperimentazione, ogni partecipante ha firmato il consenso al trattamento dati e compilato apposite schede anamnestiche.

Sono stati reclutati 10 soggetti sani volontari (70% donne, 30% uomini), di età compresa tra i 21 ed i 38 anni. Per il reclutamento dei soggetti sono stati previsti i seguenti criteri di inclusione:

- Nessuna presenza di: patologie cardiovascolari, patologie neurologiche, disturbi psichiatrici o altre malattie gravi
- Nessuna assunzione di farmaci al momento dello studio
- No atleti professionisti

- Nessuna assunzione di caffeina e/o alcool nelle 12h precedenti lo studio

Il protocollo viene brevemente riassunto nelle seguenti fasi:

- Giorno 1:
    - Al partecipante vengono illustrate le finalità dello studio e le modalità con cui verrà condotto. Viene fornito il materiale informativo ed il partecipante viene invitato alla firma del consenso informato (si allega copia del materiale informativo).
    - Il partecipante compila la scheda anamnestica ed il questionario "Pittsburgh sleep quality index".
    - Al partecipante viene illustrato l'uso del dispositivo wearable che dovrà indossare durante la notte per l'acquisizione in continua del segnale elettrocardiografico (ECG), lo Zephyr BioHarness BioPatch. Insieme al dispositivo, vengono consegnate istruzioni dettagliate su come apporre il sensore e su come utilizzarlo (si allega alla presente relazione copia delle istruzioni).
    - Al partecipante viene fornito un questionario di auto-valutazione della qualità del sonno che dovrà compilare l'indomani.
    - Viene fissato un appuntamento per il giorno successivo.

- Giorno 2:
    - Viene richiesto il questionario di auto-valutazione della qualità del sonno relativo alla notte 1 che il partecipante ha compilato.
    - Viene effettuato lo Standing Hypotension test (si allega copia del protocollo), durante il quale vengono acquisiti ECG (mediante l'uso del dispositivo Zephyt BioHarness BioPatch) e Pressione Arteriosa (mediante l'uso del dispositivo OMRON Digital – SEM 1).
    - Vengono raccolti i dati elettrocardiografici (ECG) acquisiti durante la notte 1 mediante lo Zephyt BioHarness BioPatch.
    - Al partecipante viene consegnato nuovamente lo Zephyt BioHarness BioPatch e un nuovo questionario di auto-valutazione della qualità del sonno che dovrà compilare l'indomani.
    - Viene fissato un appuntamento per il giorno successivo.

- Giorno 3:
    - Viene richiesto il questionario di auto-valutazione della qualità del sonno relativo alla notte 2 che il partecipante ha compilato.

- Viene effettuato nuovamente lo Standing Hypotension test, durante il quale vengono acquisiti ECG (mediante l'uso del dispositivo Zephyt BioHarness BioPatch) e Pressione Arteriosa (mediante l'uso del dispositivo OMRON Digital – SEM 1).
- Vengono raccolti i dati elettrocardiografici acquisiti durante la notte 2 mediante lo Zephyt BioHarness BioPatch.

Data la strumentazione hardware necessaria per le acquisizioni, è stato possibile raccogliere i dati fino ad un massimo di 4 soggetti alla settimana.

Tutti i dati raccolti sono stati processati mediante un software matlab-based, Kubios HRV, mediante il quale sono state estratte caratteristiche relative alla variabilità della frequenza cardiaca nel dominio del tempo, della frequenza, e nel dominio non lineare.

Considerate le mie esperienze pregresse, la complessità del presente progetto e le tempistiche avute a disposizione, le attività che mi hanno vista coinvolta in prima persona, a valle delle attività di acquisizione dati, hanno riguardato la modellazione dei cali di pressione, calcolati durante lo Standing Hypotension Test in funzione del segnale elettrocardiografico, al fine di studiare la possibilità di predire cali di pressione, e dunque possibili cadute accidentali del soggetto, a partire da segnali acquisiti in modalità wearable, ovvero l'ECG.

I risultati di questo studio, saranno poi combinati ai risultati ottenuti dallo sleep quality analysis e dall'analisi dei dati elettrocardiografici (ECG) acquisiti durante le due notti di monitoraggio.

Lo Standing Hypotension Test è suddiviso in tre fasi: Sitting, Lying e Standing.

Durante le fasi di Lying e Standing sono stati acquisiti quatto valori di pressione arteriosa, come illustrato in Fig. 1, mentre il segnale ECG viene costantemente acquisito.

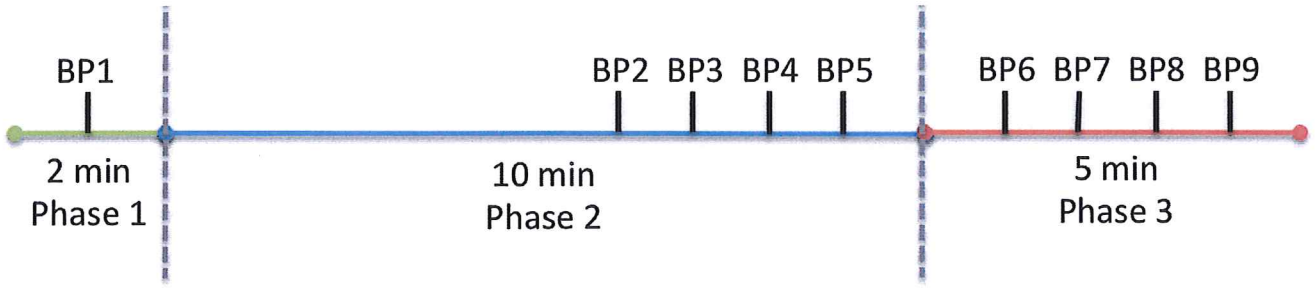


Figura 1 - Fasi dello Standing Hypotension Test.

Il calo di pressione è definito come:

$$\Delta BP = BP7\text{-}media(BP2{:}BP5)$$

Per quel che concerne l'ECG, sono stati estratti 22 parametri caratteristici, riassunti in Figura 2.

LINEAR AND NON-LINEAR HEART RATE VARIABILITY MEASUREMENTS SELECTED IN THE CURRENT STUDY

	Measure	UNIT	Description
			Time-Domain
1	MeanRR	ms	The mean of RR intervals
2	STDNN	ms	Standard deviation of RR (NN) intervals
3	RMSSD	ms	Square root of the mean squared differences between successive RR intervals
4	NN50	count	Number of successive RR interval pairs that differ more than 50 m
5	pNN50	%	NN50 divided by the total number of RR intervals
6	HRVtri		The integral of the RR interval histogram divided by the height of the histogram
7	TINN	Ms	Baseline width of the RR interval histogram
			Frequency-Domain
8	LF	ms^2	Absolute powers of LF band, calculated with AR
9	HF	ms^2	Absolute powers of HF band, calculated with AR
10	LF/HF		Ratio between LF and HF band powers
			Nonlinear
11	SD_1	ms	The standard deviation of the Poincar´e plot perpendicular to the line of identity
12	SD_2	ms	The standard deviation of the Poincar´e plot along to the line of identity
13	ApEn		Approximate entropy
14	SampEn		Sample entropy
15	D_2		Correlation Dimension
16	DFA_1		Short-term fluctuation slope in Detrended Fluctuation Analysis
17	DFA_2		Long-term fluctuation slope in Detrended Fluctuation Analysis
18	RPLmean	beats	Recurrent Plot (RP) mean line length
19	RPLmax	beats	RP maximum line length
20	RPREC	%	RP Recurrence Rate
21	RPDET	%	RP Determinism
22	RPShan		RP Shannon Entropy

Figura 2 - Parametri dell'HRV estratti dall'ECG.

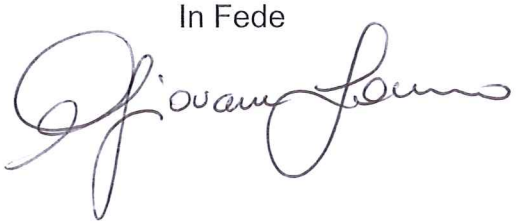
Ipotizzando una correlazione tra i dati dell'ECG ed il calo di pressione calcolato, è stato identificato un modello matematico utilizzando una interpolazione polinomiale.

Tale modello matematico estratto è ora in fase di validazione in termini di corretta classificazione dei cali di pressione identificati come gravi ($\Delta BP \geq 9mmHg$) e non gravi ($\Delta BP < 9mmHg$).

Per effettuare un confronto con altri classificatori si sta utilizzando Weka (Waikato Environment for Knowledge Analysis), un software per il Data Mining/Machine learning scritto in Java grazie al quale è possibile applicare diverse tipologie di classificatori ad una base di dati e confrontarne i risultati.

Napoli, 04/07/2016

In Fede



THE UNIVERSITY OF WARWICK

BIOMEDICAL & SCIENTIFIC RESEARCH ETHICS COMMITTEE (BSREC)

Protocol/Proposal Guidance

An ethics committee will expect to see evidence in the protocol that the applicant has submitted a well-designed study, with careful and logical thought having been given to its structure and proposed method.

Section/Chapter Headings

Normal section or chapter headings should include, but not be limited to:

Title:	**Standing Hypotension Test**
Lay Summary:	Orthostatic hypotension (also called postural hypotension or standing hypotension) is a form of low blood pressure that happens when a subject stand up from sitting or lying down. Orthostatic hypotension can cause dizziness and maybe faintness. This study will study how biomedical signals change before standing and if those changes may be used to predict standing hypotension using wearable devices. This may bring to the development of wearable system that help to predict falls in the elderly.
Background:	Healthcare systems are under stress due to the burden of an ageing population. Pervasive monitoring via e-health/m-health may reduce this burden and facilitate a paradigm shift in healthcare, facilitating early interventions that are likely to avoid the instauration of more severe conditions, which would reduce QoL and require more costly care. Falls are a major problem in later life reducing the well-being, mobility and quality of life, of the whole family. In the UK, 30% of elderly people fall once per year, with a mean cost for a fall of about £7k and falls in hospitals are even more costly (about £7.4k). There is evidence that: 1) 33% of falls in hospitals happen while rising from bed/chair; 2) 25% of falls are due to transient problems with the cardiovascular system (CVS), i.e. orthostatic hypotension, and equilibrium, which is controlled by Autonomous Nervous System (ANS); 3) Heart Rate Variability (HRV) is considered a good estimator of CVS and ANS activities.

Orthostatic hypotension is defined as a decrease in systolic blood pressure of 20 mm Hg or a decrease in diastolic blood pressure of 10 mm Hg within three minutes of standing when compared with blood pressure from the sitting or supine position. Only one study [1] investigated HRV before and after standing, enrolling 2 groups of healthy subjects: 10 younger (21-23 years old) and 9 older subjects (64-79 years old). This study demonstrated that HRV features changed significantly after standing in both groups. However, in this study no predictive models were proposed to predict standing hypotension, only few biomedical signals were observed (HRV, NIBP, HbT) and only a very basic HRV analysis was performed.

Aims/Objectives:

Primary goal:

1) determine the minimum number of subjects to be enrolled to acquire sufficient signals to develop a predictive model

Secondary goals:

2) describe the association between biomedical signals and standing hypotension events
3) assess the capability of this model to predict standing hypotension

Design/Methodology:

This is a prospective qualitative study. 2 groups of 10 subjects each will be enrolled: (1) health younger subject (age range 20-45), (2) healthy adult subjects (age range 46-60). These numbers were chosen according to the only available study using a similar design[1].

As suggested in [1], the voluntears will be trained to stand in a uniform manner consisting of initial forward flexion of the back and neck followed by extension of the body. Two tasks will be executed:

1) "active standing," with guidance from an assistant, and
2) "passive standing," in which the subjects remained passive while an assistant placed them in a standing position.

The active standing procedure will began with the assistant holding the subject by both hands. The subject will be asked to remain with their knees in flexion until a verbal cue will be given, after which the subject will assume a standing position with guidance from the assistant. The passive standing procedure will began with the assistant placing a knee between both legs of the subject, positioning the subject's arms at their side, and putting both hands of the subject around the neck of the assistant. While maintaining the centre of gravity downward, the assistant will position the subject in a standing position. To maximize the cooperation of the subjects during the study, a female researcher will assist female subjects and a male researcher will assist male subjects.

Both tasks will be repeated 5 times after 5 minutes of resting.

Biomedical signals which have proved to be good estimators of cardiovascular and Autonomous Nervous System (respectively CVS and ANS) activities (ECG, HRV, Galvanic Skin Conductance,

Temperature, Blood Volume Pulse, breathing rhythm) will be collected before, during and after the subjects performing the 2 tasks.
Additionally, nominal 24hours ECG will be recorded in the day before the experiment. This will be used to correlate the quality of sleep, estimated via HRV, and the standing hypotension.
The signals acquired will be processed to extract meaningful features. Pattern recognition methods will be applied to these features in order to investigate if there are correlation between the CVS/ ANS states at rest (i.e. 2 minutes before rising from bed/chair) and orthostatic hypotension, which is one of the causes of falls.
Since only healthy subjects will be enrolled in this pilot, it is likely that none will present a major case of standing hypotension (decrease in systolic blood pressure of 20 mm Hg or a decrease in diastolic blood pressure of 10 mm Hg). In this case, mild cases of standing hypotension will be observed (i.e. 5 or 10 mm Hg).
Associations between these decreases and HRV features in the different groups of healthy subjects will be modelled using polynomial models of different order where the independent variable will be the most significant HRV features and the dependent variable will be the BP values after monitored each 15 seconds for 3 minutes after standing.
HRV extracted during the night will be used as baseline measurement to identify subjects that did not have a regular sleep the night before the experiments.
Materials & Methods: The signals will be acquired using 2 wearable biomedical amplifiers:

1) Nexus 10 from Mindmedia, which acquire simultaneously ECG, EEG, EMG, EOM, SPo2, Temperature, Breathing, Galvanic Skin response.
2) Zephyr BioHarness , which acquire simultaneously ECG, temperature, breathing rate, £D trunk accellerations)

Blood pressure will be measured with a commercial sphygmomanometer to measure blood pressure variation after standing.
The signals will be pre-processed (i.e. exclusion of low-quality registration, filtering, data resampling, interpolation, data de-trending), processed (features detection), and post processed (statistical study of significant differences) according to the best available evidence, and using tools in Matlab developed ad hoc[2-5].

Ethical Considerations: *Informed Consent*: The participants will be freely giving fully informed consent to participate. Volunteers will be required the complete a consent form, where the methods, advantages and disadvantages in taking part to the experiment will be explained.

Participant Confidentiality and Data Security: the data registered will be biomedical signals (including ECG, EEG, EMG, EOM, SPo2, Temperature, Breathing, Galvanic Skin response), biomechanical variables (3D truck accelerations) and personal information (age, gender). The registrations will be done in the lab of the University of Warwick, Engineering building. The data will be stored for the duration of the project (and however no longer than 10 years, as required by University of Warwick regulations) on the Desktop PC of Dr Pecchia, which is in his office, locked by key closed door, protected by user name and password. The data will be saved as an encrypted zipped file with username and password. Only researchers involved in this study will accessed to them. The original data will be processed to extract meaningful features. From these features, it is not possible to reconstruct the original data. Original data will be cancelled with all the safe mode possible (HD cleaning) after the extraction of features. Extracted features and population information (e.g. mean age, % of gender) will be stored and eventually published on journal/conference scientific papers and of thesis. No relevant clinical information may be derived from the signals acquired.

Right of withdraw: If the volunteers agree to participate, they may withdraw from the study at any time without any collateral effect. They have the right to withdraw from the study completely and decline any further contact by study staff after they withdraw. In this case, none of their data will be used.

Benefits and risks: Taking part in this study, subjects can help to predict standing hypotension and therefore falls by a non-invasive technique. No side effects or possible disadvantages are foreseen. No specific risks emerged by previous studies using the same protocol. However, in case of excessive discomfort, the procedure will be interrupted, the subject will be given the time to recover and, in case needed, he will be released.

Recruitment: volunteers will be recruited as following:

- young healthy subjects will be enrolled as following: an email of invitation will be sent to PhD students and researchers of biomedical engineering (BME) of the School of Engineering (SoE); a leaflet will be printed and attached on the boards of the BME labs of the SoE inviting to contact Dr Pecchia if interested in participating in the study;
- senior healthy subjects will be enrolled as following: an email will be sent to Staff members of the SoE; a leaflet will be printed and attached on the boards of the BME labs or other staff

common spaces of the SoE inviting to contact Dr Pecchia if interested in participating in the study.

Financing: The project is supported by the University of Warwick via a Research Development Award.

Dissemination and implementation: Scientific papers will be submitted to scientific conferences and relevant journals, as appropriate.

References:

1. Kawaguchi T, Uyama O, Konishi M, Nishiyama T, Iida T. Orthostatic hypotension in elderly persons during passive standing: a comparison with young persons. The journals of gerontology Series A, Biological sciences and medical sciences. 2001;56(5):M273-80.
2. Melillo P, De Luca N, Bracale M, Pecchia L. Classification Tree for Risk Assessment in Patients Suffering From Congestive Heart Failure via Long-Term Heart Rate Variability. Biomedical and Health Informatics, IEEE Journal of. 2013;PP(99):727-33. doi:10.1109/jbhi.2013.2244902.
3. Melillo P, Izzo R, De Luca N, Pecchia L. Heart rate variability and target organ damage in hypertensive patients. BMC cardiovascular disorders. 2012;12(1):105.
4. Pecchia L, Melillo P, Sansone M, Bracale M. Discrimination Power of Short-Term Heart Rate Variability Measures for CHF Assessment. Ieee T Inf Technol B. 2011;15(1):40-6. doi:Doi 10.1109/Titb.2010.2091647.
5. Pecchia L, Melillo P, Bracale M. Remote Health Monitoring of Heart Failure With Data Mining via CART Method on HRV Features. Ieee T Bio-Med Eng. 2011;58(3):800-4. doi:Doi 10.1109/Tbme.2010.2092776.

Appendices: patient information leaflet, consent form.

Ethical Considerations

The section on Ethical Considerations can include any or all of the points described below, along with others. An ethics committee will expect to see evidence in the protocol that the applicant has given consideration to these issues, and designed the study so as to address these. These points should be addressed specifically in the '**Ethical Considerations'** section of the protocol, and in other relevant sections as appropriate, e.g. the Method section may also include a description of the informed consent process.

As a *minimum*, the section on Ethical Considerations should contain sub-sections examining **Informed Consent**, and **Participant Confidentiality and Data Security**.

Informed Consent

Describe the process you will use to ensure your participants are freely giving fully informed consent to participate. This will usually include the provision of an information sheet, and will normally require the completion of a consent form, unless it is a self-completion questionnaire based study, or there is justification for not doing (which must be clearly detailed).

Participant Confidentiality and Data Security
Provide details of the degree of anonymity of the data you will have access to. If the data you will access contains identifiable data, state what this data will be. If the data you will access has been anonymised, clarify how this has been done (bear in mind that combinations of demographic data can still identify individual participants from the original dataset, particularly for small sample sizes).

State how long study information (including research data, consent forms and administrative records) will be retained for. Also, state in what format(s) the information will be retained (for example, as physical and/or electronic copies), and state the specific physical location where the data will be stored (for example, where within the University of Warwick). Detail the security arrangements for the stored data, e.g. passwords on files and computers, and locked cabinets and offices for paper records.

Other Considerations:

Right of Withdrawal
Participants should be able to withdraw from the research process at any time. Participants also should be able to withdraw their data if it is identifiable as theirs, and should be told when this will no longer be possible (e.g. once it has been included in a final report or publication). Describe the exact arrangements for withdrawal from participation and withdrawal of data depending on your study design

Process for dealing with sensitive disclosures
If it is possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could be made during the study, the procedures that will be put in place to deal with these issues should be detailed. In certain circumstances there may be a need for disclosures to be communicated outside of the research team. The limits to confidentiality must be made clear to participants at the outset. The Participant Information Sheet should make it clear to potential participants under what circumstances action may be taken and what that may be.

Benefits and risks
Describe any expected benefits to the research participant, e.g. will participants receive a copy of the final report. Also, describe any possible risks to the research participant, e.g. what is the potential for adverse effects resulting from study participation. The potential for each of these should be identified and the protocol should state how you will minimise these risks and deal with any untoward incidents and adverse reactions.

Further Issues
Provide details of any other ethical issues or risks that may arise as a result of the dissemination of the research findings. For example, provide details if there are any anticipated limitations or restrictions on how the research findings might be disseminated or published (perhaps imposed by research funders, sponsors, or collaborating bodies). Outline the risks and how they will be minimised, if the dissemination of findings might present risks to the participants.

Additional reading:
British Psychological Association guidance. Accessible at:
http://www.bris.ac.uk/Depts/DeafStudiesTeaching/dissert/BPS%20Ethical%20Guidelines.htm

ESRC Framework for Research Ethics (2010): http://www.esrc.ac.uk/_images/Framework-for-Research-Ethics_tcm8-4586.pdf.

MRC Good research practice: Principles and guidelines (2012):
http://www.mrc.ac.uk/consumption/groups/public/documents/content/mrc002415.pdf

THE UNIVERSITY OF WARWICK

Study Number: REGO-2014-1039

Name of Researcher(s): Dr Leandro Pecchia (PI), Dr Saverio Stranges, MD, Ms Rossana Castaldo, Ms Giovanna Sannino

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated [ ] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical, social care, education, or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from The University of Warwick, from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

THE UNIVERSITY OF WARWICK

TEMPLATE PARTICIPANT INFORMATION LEAFLET

Investigator(s):

Dr Leandro Pecchia (PI)

Dr Saverio Stranges, MD

Ms Rossana Castaldo (PhD student)

Dr Giovanna Sannino (Visiting Researcher)

Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study)

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the study about?

This study aims to collect preliminary data to investigate if it is possible to predict standing hypotension, which is the phenomena that make you feel a bit dizzy when you stand-up too fast from a bed or chair.
This is important because standing hypotension, in frail subjects, may cause falls.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part.
You will be free to withdraw at any time, without giving a reason and this will not affect you or your circumstances in any way. In case of withdrawal, your data will be destroyed and never used for the study.

What will happen to me if I take part?

You will be asked to wear an ECG recorder for 24 hours. You will be invited to come in the School of Engineering where you will be given all the instructions and explanations about the device you will be asked to wear. The following morning you will be invited to come again in the school of Engineering where you will be asked to repeat 2 exercises up to 10 times: active standing and passive standing.
Active standing will consist in standing-up from a bed/chair. Passive standing will consist in one of us rising you from a bed/chair without your active collaboration.
Before, during and after these exercises, your biomedical signals will be registered and will

then be studied to investigate if there is any association between standing hypotension and biomedical signals.
The signals will be acquired using 2 wearable devices. These devices will be positioned under clothing and hold by a chest belt (see figure below, which shows one of the two). In respect to your privacy, you will be invited to go in a separate room to wear the device. To avoid any gender-related discomfort or embracement, you will be assisted by a staff member of your gender, if needed.
The experiment will last 24hours of which between 30 and 60 minutes to perform the tasks described above.

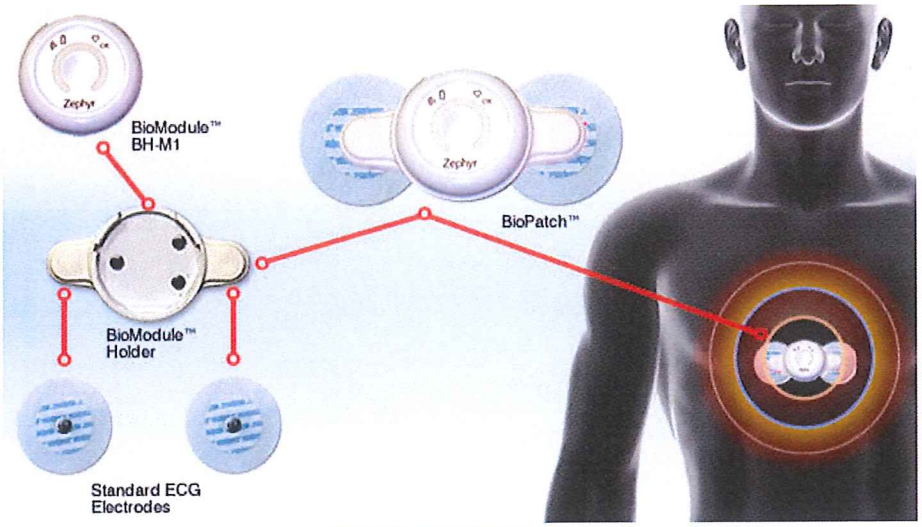


Figure 1: wearable monitor

What are the possible disadvantages, side effects, risks, and/or discomforts of taking part in this study?

No disadvantages, side effects, risks, and/or discomforts where registered during previous studies performing the similar protocols.

What are the possible benefits of taking part in this study?

Although there are no direct benefits for you, your participation is particularly useful to develop mathematical models that will in future help predicting falls in elderly.

Expenses and payments

The participation to this study is completely free and no reimbursements or payments are foreseen.

What will happen when the study ends?

The data collected during this study will be anonymised and analysed using scientific software tools. A mathematical model to predict standing hypotension will be developed and tested.

Will my taking part be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be

handled in confidence. Further details are included in Part 2.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm that you might suffer will be addressed. Detailed information is given in Part 2.

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

Who is organising and funding the study?

The project is organised and supported by the University of Warwick.

What will happen if I don't want to carry on being part of the study?

Participation in this study is voluntary. Refusal to participate will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have given your consent to participate.

If you agree to participate, you may nevertheless withdraw from the study at any time without affecting you in any way.

You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

In case of withdrawal, your data will be destroyed and never used for the study.

What if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact Jo Horsburgh (details below).

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick official entirely independent of this study:

Jo Horsburgh
Deputy Registrar
Deputy Registrar's Office
University of Warwick
Coventry, UK, CV4 8UW.
T: +00 44 (0) 2476 522 713 E: J.Horsburgh@warwick.ac.uk

T: +00 44 (0) 2476 522 713 E: J.Horsburgh@warwick.ac.uk

Will my taking part be kept confidential?

Yes. The data will be stored for the duration of the project (and however no longer than 10 years, as required by University of Warwick regulations) on a Desktop PC positioned in a room locked by key, and saved as an encrypted zipped file with username and password.

What will happen to the results of the study?

The data will be used to develop mathematical models to predict standing hypotension. Original data will be cancelled permanently after being used. Only relevant information (e.g. mean age, % of gender) will be stored and eventually published in journal/conference. No other clinical information may be extracted from the signals acquired.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): **REGO-2014-1039.**

What if I want more information about the study?

If you have any questions about any aspect of the study or your participation in it not answered by this participant information leaflet, please contact:

Leandro Pecchia, L.Pecchia@warwick.ac.uk

Thank you for taking the time to read this participant information leaflet.