Deliverable No. 9.2

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DECODER

"Deployment of Brain-Computer Interfaces for the Detection of Consciousness in Non-Responsive Patients"

Collaborative Project
Information and Communication Technology

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Lead Contractor:	**Université de Liège (ULG) and Association du locked-in syndrome (ALIS)**

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Dissemination Level
PU Public
PP Restricted to other programme participants (including the Commission Services)
RE Restricted to a group specified by the consortium (including the Commission Services)
CO Confidential, only for members of the consortium (including the Commission Services)

DETAILED PLAN ON HOW TO SELECT PARTICIPANTS (HEALTHY AND PATIENTS) AND HOW TO GET INFORMED CONSENT (SPECIFICALLY WITH REGARDS TO NON-RESPONSIVE PATIENTS)

ALIS, ULG, UW

Abstract

The work package 9 (WP9) is dedicated to the evaluation of both the diagnostic battery and the ssBCI. In this deliverable we establish the exclusion and inclusion criteria of both patients and control subjects, in order to have the most homogeneous groups possible.

Also we establish the procedure to obtain informed consent, particularly in case of patients unable to give themselves their agreement, this in order to comply strictly with the measures established by the various ethics committees regarding research on humans (see also D1.2).

Content

1 Introduction

1.1 Objectives

The aim of this working package is to evaluate the application of passive and active paradigms for diagnosis of non-responsive patients in an interactive process between developers and users.

Paradigms will have to be tested in the scientific realm and in the next step the resulting diagnostic battery has to be evaluated by clinicians at the patient's bedside.

Furthermore the transition from active paradigms to communication with the ssBCI will have to be evaluated by clinicians and patients.

Finally, the use of the ssBCI at the patients home has to be evaluated by the patients and their significant others.

2 Implementation

It will be presented the general criteria for exclusion and inclusion, to which will be added the specific requirements for some tasks, e.g., native language speakers for the hierarchy. Same for the mode of recruitment, which will vary according to the characteristics of the participating institutions (see details in milestone 4.1).

2.1 How to select participants

2.1.1 Patients

2.1.1.1 To test the diagnostic battery

INCLUSION CRITERIA

- Age above 18
- Informed consent from the patient him- or herself; in case of non-responsive patients from the legal representative
- Severe motor disability or disease, leading to motor restrictions and no verbal communication (locked-in patients) or non-responsive patients (minimally conscious patients; PVS patients)
- Good vision and/or hearing
- Any etiology of brain damage
- Any time of evolution but stable on the clinical plan

- Patients sedation free. If necessary, a washout period for drugs in use will be provided
- In good general conditions (no infection, optimal medical conditions).
- Reasonable expectation of life of patients
- Not too much involuntary movements (proper EEG recordings must be possible)

EXCLUSION CRITERIA

- EEG related: allergy gel electrode, skin contamination, wound on scalp, dermatitis, craniotomy and/or cranioplasty, uncontrolled gross muscular activity, electrically noisy environment
- fMRI related: presence of metal objects in the body that can interact with the magnetic field: pacemaker, metal prostheses or implants (heart valves, cochlear implant) , aneurysm clip, metal projectiles (shrapnel, bullets...) notably in the head and near the eyes, metallic contraceptive (diaphragm), uncontrolled gross muscular activity
- fNIRS related: uncontrolled gross muscular activity

2.1.1.2 To test the ssBCI

INCLUSION CRITERIA

- Age: above 18
- Informed consent available either from the patient him- or herself or of the legal representative
- Completely locked-in; locked-in, locked-in recovered (but still severely impaired such that only residual muscular movement possible)
- Non-responsive patients with positive results (= conscious awareness) from the diagnostic battery (see WP3 and WP4)
- Possible access to an appropriate test setting (clinic, nursing home, home)
- Presence of supportive person / environment
- Good vision and/ or hearing
- Patients sedation free. If necessary, a washout period for drugs in use will be provided
- Not too much involuntary movements

EXCLUSION CRITERIA

- EEG related: allergy gel electrode, skin contamination, wound on scalp, dermatitis, craniotomy and/or cranioplasty, uncontrolled gross muscular activity, electrically noisy environment

2.1.2 Healthy subjects

INCLUSION CRITERIA

- Age above 18
- Informed consent
- No history of neurological or psychiatric disease
- They will be recruited through advertisements at University, website, hospital,
- and they will receive a monetary compensation for time and travel costs or research credits.

2.2 How to get informed consent

2.2.1 Procedure with patients (see also D1.2)

- Patients who attend the clinics or research centers of the consortium members for diagnostic or therapeutic reasons will be included in the study. In case of inclusion of non-responsive patients, legal

representatives and the most significant other will be informed accordingly and will be asked to answer on behalf of the patient.

- Patients and – when non-responsive – significant others and the legal representative who usually accompany the patient will be fully informed about the background, objectives, and possible risks of DECODER in general and about the specific experiment he or she will participate. When no legal representative of a non-responsive patient is personally available, the legal representatives will be contacted via telephone and mail to inform about the study by the doctor or researcher who is in charge of the patient. The exact nature of the research procedures will be explained to the participants and legal representative/significant other verbally and they will be given sufficient opportunity to read an information sheet in the appropriate language, describing the procedure.

- The patient – when non-responsive – significant others and the legal representative will be informed about their right not to take part in the study and to withdraw from the study at any time without the need of justification. It will be specifically pointed out that any medical treatment/therapeutic intervention is completely independent from the participation in the study and no consequences will result from the decision to not participate. Sufficient time will be provided to let the person decide on participation. They will receive the written form of the participants' information with the telephone number of the person who is in charge of the experiment. If no voluntary response of the patient is available (probably in MCS and PVS patients), the family (significant other) or legal representative is requested to sign the informed consent. Before each session of EEG/fMRI the patient or legal representative will be asked if participation in the study is still wanted.

- If patients diagnosed as non-responsive responds to any of the active paradigms, we will be able to ask them directly whether they would like to continue with the procedure. It is our experience in the work with patients that those patients who proof to be able to communicate throughout experimental procedures, are eager and highly motivated to proceed with experiments.

- If a patient is released from the clinics/therapeutic centers of the consortium members before all measurements requested for the study are performed, patients and legal representatives are informed that measurements can be continued at the next visit. Otherwise, they will be offered to get an additional transport to the clinics/therapeutic center paid by the consortium member. Depending on the geographical distance of the patients' home from the research unit (max. 150 km single) it can be offered to complete EEG-based testing at the patients' home.

2.2.2 Procedure with healthy subjects

- Informed consent hast to be must be obtained from each subject after detailed explanation of experimental procedure.

- The exact nature of the research procedures will be explained to the subjects verbally and they will be given sufficient opportunity to read an information sheet in the appropriate language, describing the procedure.

- Participation in research will be entirely voluntary. Participants will be informed that whatever their choice, their present or future medical treatment will not be affected by their decision.

- Participants will be informed that they may withdraw from research at any time without giving a reason.

- Any risks will be explained. In practice, the present research is non-invasive and safe

2.3 Data confidentiality

- Background data of participants will have to be collected. These will include age and gender. Participants will be asked to indicate if they have any neurological or psychiatric disease or any other disease that could affect the brain.

- The participants will be informed that the signed informed consent will at no time be stored together with the collected data to ensure anonymity. Each participant will receive a code number. Only the person in charge of the study will have a list with names and codes to allow participants to withdraw the data at any point in time during the study. These lists will be stored in a locker. For all members of the Consortium these are routine procedures for privacy and data protection.

- Data stored on computer will be protected by password and encoding (SSL-technology), and any publication derived from personal data will be presented in a way that makes it impossible to identify individuals.

2.4 Ethical Approval

All experiments performed in DECODER with patients and healthy subjects will be approved by the local ethics committee prior to any testing.